
# Diagnostic Accreditation Program
# Accreditation Standards 2015

## Laboratory Medicine

Version 1.3 (Effective February 1, 2017)

College of Physicians and Surgeons of British Columbia
Diagnostic Accreditation Program
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DIAGNOSTIC ACCREDITATION PROGRAM

# Accreditation Standards 2015

## Laboratory Medicine

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## Diagnostic Accreditation Program

Established in 1971, the Diagnostic Accreditation Program (DAP) has a mandate to assess the quality of diagnostic services in the province of British Columbia through accreditation activities. As a program of the College of Physicians and Surgeons of British Columbia, the mandate and authority of the DAP is derived from section 5 of the College Bylaws under the *Health Professions Act,* RSBC 1996, c.183.

The DAP is committed to promoting excellence in diagnostic health care through the following activities:

- establishing performance standards that are consistent with professional knowledge to ensure the delivery of safe, high quality diagnostic service
- evaluating a diagnostic service's level of actual performance to achieving the performance standards
- establishing a comparative database of health-care organizations, and their performance to selected structure, process, and outcome standards or criteria
- monitoring the performance of organizations through the establishment of external proficiency testing programs and other robust quality indicators of performance
- providing education and consultation to health-care organizations, managers, and health professionals on quality improvement strategies and best practices in diagnostic health care
- ensuring information learned from accreditation processes is used for system-wide improvement
- reporting to government, stakeholders and the public on the performance of the diagnostic health-care system as assessed through accreditation
- strengthening the public's confidence in the quality of diagnostic health care
- assisting organizations to reduce risks and increase safety for patients and personnel
- assisting organizations to reduce health-care costs by promoting quality practices that increase efficiency and effectiveness of services
- serving and safeguarding the public

The Diagnostic Accreditation Program currently has 23 accreditation programs covering the following diagnostic services:

**Diagnostic imaging**

- diagnostic radiology
- diagnostic mammography
- diagnostic ultrasound
- diagnostic echocardiography
- diagnostic computed tomography
- diagnostic magnetic resonance imaging
- diagnostic nuclear medicine
- diagnostic bone densitometry

**Laboratory medicine**

- anatomic pathology
- chemistry
- cytogenetics
- cytology
- hematology
- microbiology
- molecular genetics
- point-of-care testing
- transfusion medicine

**Neurodiagnostic services**

- electroencephalography
- evoked potentials
- electromyography and nerve conduction studies

**Pulmonary function**

- hospital-based services
- community-based services

**Polysomnography**

- adult and pediatric polysomnography

## ACCREDITATION STANDARDS

The foundation of the accreditation programs are the provincial standards and accompanying criteria set by the Diagnostic Accreditation Program. These are evidence-based, outcome-focused mandatory requirements and best practices that are aligned to the principles of quality. The standards and criteria are directive in nature yet allow the diagnostic service flexibility in how they approach and address each element. The accreditation standards are directive, deliverable statements. The accompanying criteria specify the activities that must be completed to achieve the standard.

**Standards**

- Outcome focused
- Directed at the operational level
- Directive not prescriptive

**Criteria**

- Specify activities to be completed
- Lead to standard attainment

The Diagnostic Accreditation Program's accreditation standards are developed through a collaborative, consultative and consensus building process that involves health professionals and organizations, academics, experts, consumers, health authorities, colleges and the Ministry of Health. The process for standards development and review allows for considerable input from the diagnostic services that will be using the standards.

The DAP accreditation standards consist of three components:

1. **Standards group** – A standards group is identified as a whole number with header (e.g. 1.0 Governance and Leadership).

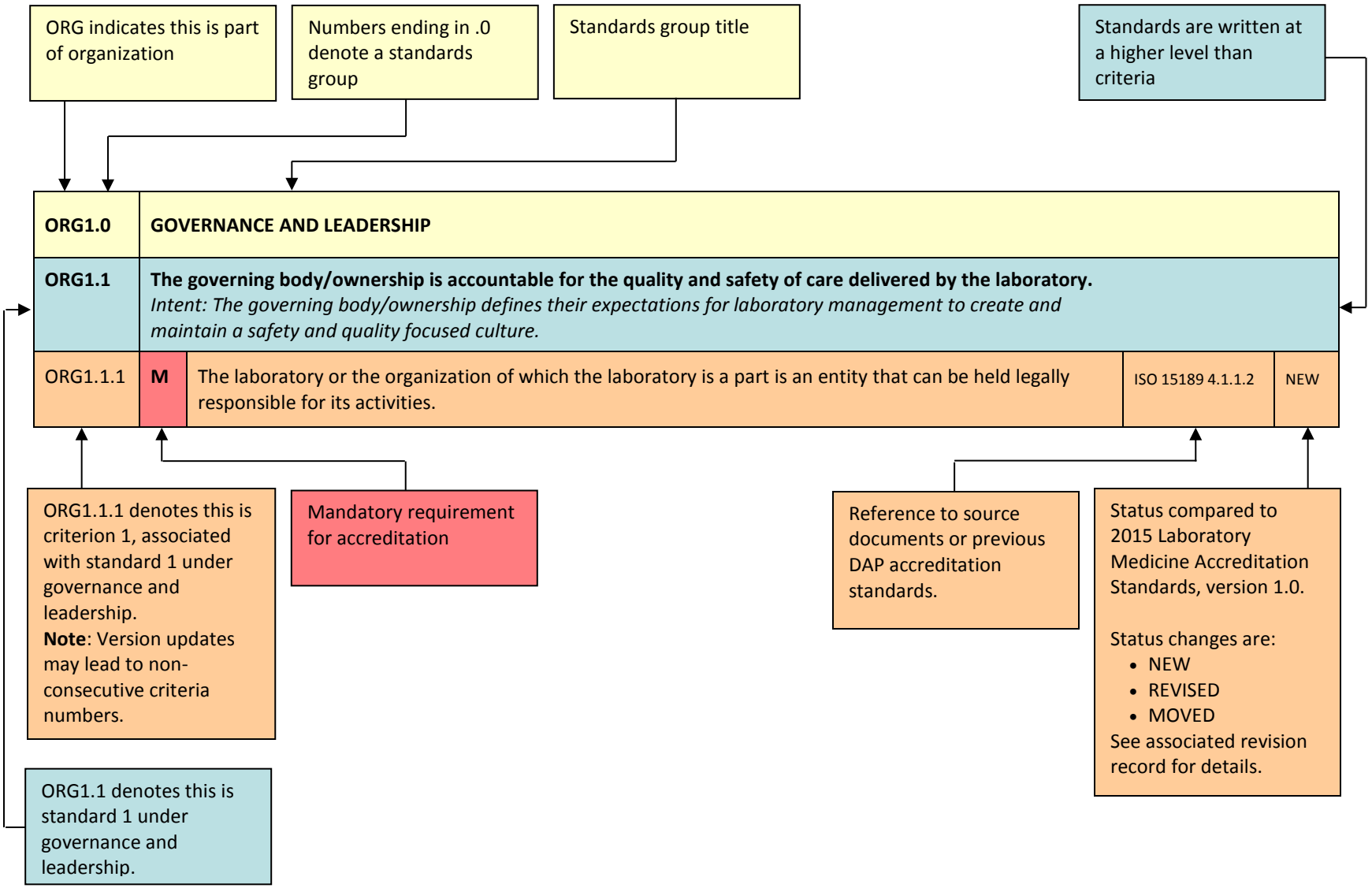
2. **Standard** – A statement that contains one or more related specific criteria. A standard is identified by a two digit number indicating the standards group that it is associated to, and a second level identifier (e.g. 1.1).

3. **Criteria** – Specific actions for each standard, criteria are identified by three digits (e.g. 1.1.1). A criterion is either a mandatory requirement for accreditation, or a best practice. Mandatory criteria are indicated by a bold type face **M**.

## CATEGORY CODES

| | | | |
|---|---|---|---|
| Organization | ORG | Anatomic Pathology | ANP |
| Quality Management System | QMS | Chemistry | CHE |
| Safety | SAF | Cytogenetics | CYG |
| Facilities | FAC | Cytology | CYT |
| Equipment, Reagents and Supplies | ERS | Hematology | HEM |
| Information Management and Informatics | IMI | Microbiology | MIC |
| Quality Assurance | QUA | Molecular Genetics | MOL |
| Pre-Examination | PRE | Point-of-Care Testing | POC |
| Examination | EXA | Transfusion Medicine | TRM |
| Post-Examination | POS | | |
| Sample Collection | SCT | | |

## EXAMPLE FROM THE ACCREDITATION STANDARDS



# GLOSSARY

**Note:** The definitions provided here are only applicable to the DAP 2015 Laboratory Medicine Accreditation Standards.

| | | |
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| **audit** | A systematic, independent, documented process for obtaining evidence and evaluating it objectively to determine the extent to which criteria are fulfilled. | ISO 9000 2015 |
| **calibration** | The process of examination and adjustment of an instrument, kit or system to provide a known relationship between the measurement response and the value of the substance measured by the examination | CLSI QMS13-A |
| **competence** | Demonstrated ability to apply knowledge and skills. | ISO 15189 |
| **competency assessment** | Evaluating a person's ability to perform all aspects of a task, process or procedure. | CLSI POCT08-A |
| **consultant** | An expert laboratory physician or clinical doctoral scientist who provides diagnostic advice or services. | MW<br>DAP |
| **corrective action** | Action taken to eliminate the cause(s) of nonconformities.<br>**Note:** Corrective action is usually taken in response to nonconformity or an identified problem noted in audits or during the accreditation process. | ISO 15189<br>DAP |
| **critical value** | A result for an examination that indicates an immediate risk of injury or death to the patient. | ISO 15189 |
| **defined interval** | A documented period of time between events. | MW, DAP |
| **director – administrative** | Person with the competence and delegated responsibility for direction of operational and technical activities of the laboratory. | ISO 15189<br>DAP |
| **director – laboratory** | Person(s) with the responsibility for, and authority over, a laboratory. For the purposes of accreditation, the person or persons referred to are designated collectively as laboratory director. | ISO 15189 |

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| **director – medical** | Person with the competence and delegated responsibility for the delivery and all matters pertaining to procedures and medical care in the laboratory. | College Bylaws |
| **efficacy** | The ability to produce a desired result or effect. | MW |
| **examination** | A set of operations having the object of determining the value or characteristics of a property.<br>**Synonyms:** analysis, assessment, investigation, measurement, study, test | ISO 15189 |
| **expedited** | An accelerated process.<br>**Note:** For the purpose of the accreditation, there are three categories of requests and examinations: routine; urgent; and stat. Expedited requests and examinations include those requested as urgent or stat. | DAP |
| **governance** | The way that an organization is controlled by the people who run it. | MW |
| **immediate action** | Action taken at the time of nonconformity to mitigate the immediate effects. | ISO 15189 |
| **interim report** | Laboratory report that are issued before final reports.<br>**Synonyms:** preliminary reports, provisional reports | DAP |
| **management review** | A comprehensive, systematic review of the quality management system at a defined interval to ensure continued suitability, adequacy, effectiveness and support of patient care. | ISO 15189 |
| **measurand** | Quantity intended to be measured.<br>**Synonym:** analyte | ISO/IEC Guide 99 |
| **measurement uncertainty** | A calculation using quantity values obtained by the measurement of QC materials under intermediate precision conditions that includes as many routine changes as routinely possible. | ISO 15189 |
| **measuring interval** | A set of values of quantities of the same kind that can be measured by a given measuring instrument or measuring system with specified instrumental uncertainty, under defined conditions. | ISO/IEC Guide 99 |

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| **medical leader** | The laboratory physician charged with the responsibility for the medical peer review program. | DAP |
| **metadata** | A set of data that describes and provides information about other data. | MW |
| **neonate** | For the purposes of transfusion medicine: an infant less than four months old.<br>For other purposes: an infant less than one month old. | CSTM v. 3 |
| **nonconformity** | Failure to fulfill a requirement.<br>**Synonym:** accident, adverse event, error, event, incident, critical incident, occurrence, nonconformance | ISO 15189 |
| **personnel** | People working or operating within a section, department, area or organization. Personnel include staff, volunteers, contractors, visitors and others. | MW DAP |
| **POCT equipment** | Any device or system used for point-of-care testing (POCT).<br>**Synonyms:** POCT testing device, POCT system | DAP |
| **post-examination** | Processes following the examination including review of results, retention and storage of clinical material, sample and waste disposal and the formatting, release, reporting and retention of examination results. | ISO 15189 |
| **pre-examination** | Processes that start, in chronological order including the examination request, preparation and identification of the patient, collection of sample(s), and transportation to and within the laboratory. Pre-examination processes end when examination processes begin. | ISO 15189 |
| **preventive action** | A proactive process for identifying opportunities for improvement rather than a reaction to identified problems. | ISO 15189 |
| **procedure** | A documented, specified way to carry out an activity of a process.<br>**Note:** For the purposes of accreditation, procedures must always be documented, implemented and maintained. | ISO 15189 |
| **process** | A set of interrelated or interacting activities which transform inputs into outputs. | ISO 15189 |

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| **quality indicator** | A measure of the degree to which a set of inherent characteristics fulfills requirements.<br>**Note:** Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.<br>**Synonyms:** performance indicator | ISO 15189 |
| **quality management system** | A coordinated system to direct and control an organization with regard to quality.<br>**Note:** This relates to general management activities, the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement. | ISO 15189 |
| **quality manager** | Appointed laboratory personnel with authority and responsibility for the processes of the quality management system. The title "quality manager" does not have to be used and the tasks of the quality manager may be dealt with by an existing position in the laboratory structure. | ISO 15189 |
| **quality objectives** | A quality-related result that you intend to achieve. | ISO 9000 |
| **quality policy** | Overall intentions and direction of a laboratory related to quality as formally expressed by the management of the laboratory.<br>**Note:** The quality policy is consistent with the overall policy of an organization and provides a framework for setting quality objectives. | ISO 15189 |
| **referral consultants** | See consultant. | |
| **referral laboratory (revised)** | An external laboratory where a sample is submitted for examination.<br>**Note:** Each external laboratory where a sample is submitted should be considered to be a referral laboratory. | ISO 15189 |
| **request** | A written, electronic or verbal order for an examination or product provided by the laboratory. | DAP |
| **risk management** | The identification, assessment and prioritization of risks followed by coordinated application of resources to minimize, monitor and control the probability of occurrence. | DAP |

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| **sample** | A discrete portion of a body fluid, breath, hair or tissue taken for examination of one or more quantities or properties assumed to apply for the whole. One or more parts taken from a primary sample.<br><br>**Synonyms:** specimen, primary sample, aliquot | ISO 15189 |
| **sanitation** | For transfusion medicine purposes: The promotion of hygiene and prevention of disease by maintenance of sanitary conditions. | MW |
| **source of truth** | In telepathology, the source of truth refers to the interpretation of the telepathology image and its report only. The Canadian Association of Pathologists has defined the captured image as the source of truth, as opposed to the transmitted image. The glass slide and tissue remain the source of diagnostic truth for patient care, similar to a frozen section diagnosis. | DAP |
| **streamlined QC** | A reduction in quality control (QC) for a commercial microbial identification system. | CLSI M50-A |
| **trueness (of measurement)** | The closeness of agreement between the average values obtained from a large series of examination results and an accepted reference value. The measure of trueness is usually expressed in terms of bias | CLSI EP15-A2 |
| **universal protocol** | A process incorporating verification, site marking and a time out to reduce the risk to patients undergoing invasive procedures. | DAP |
| **user (of laboratory services)** | Physicians and others who order diagnostic examinations and/or receive diagnostic information and reports from laboratories.<br><br>**Synonyms:** authorized requestor, ordering physician, clinical personnel | DAP<br>ISO 15189 |
| **validation** | Confirmation through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.<br><br>**Note:** The laboratory must validate non-standard methods, laboratory-designed or developed methods, standard methods used outside the intended scope and validated methods that have been modified. | ISO 15189 |

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| **verification** | Confirmation through provision of objective evidence that specified requirements have been fulfilled.<br><br>**Note:** The laboratory must verify validated examination procedures used without modification to confirm the performance characteristics of the procedure. | ISO 15189 |
| **version** | An issued original or revised document.<br><br>**Synonym:** edition | DAP |

# Accreditation Standards 2015

Laboratory Medicine

## General Standards

The general standards for laboratory medicine accreditation include the following standards categories:

- Organization
- Quality Management System
- Safety
- Facilities
- Equipment and Supplies
- Information Management and Informatics
- Quality Assurance
- Pre-Examination
- Examination
- Post-Examination
- Sample Collection

The general standards are used in conjunction with the appropriate discipline-specific standards for each laboratory.

**Note:** Version updates may contain non-consecutive numbering of criteria as a result of deleted, combined or revised criteria.

# ORGANIZATION

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **ORG1.0** | **GOVERNANCE AND LEADERSHIP** | | | |
| **ORG1.1** | **The governing body/ownership is accountable for the quality and safety of care delivered by the laboratory.** | | | |
| ORG1.1.1 | **M** | The laboratory, or the organization of which the laboratory is a part, is an entity that can be held legally responsible for its activities. | ISO 15189 4.1.1.2 | |
| ORG1.1.2 | **M** | The governing body/ownership ensures the availability of resources to enable the proper conduct of pre-examination, examination and post-examination activities. | ISO 15189 4.1.2.1i | REVISED |
| ORG1.1.3 | **M** | Reports on quality and safety within the laboratory are received by the governing body/ownership at least once per year.<br>*Intent: The governing body/ownership defines their expectations for laboratory management to create and maintain a safety and quality focused culture.* | DAP15 | |
| ORG1.1.4 | **M** | The governing body/ownership is committed to good professional practice examinations that are fit for intended use, compliant with the requirements of accreditation, consistent with national and international standards and encourage continual improvement of the quality of laboratory services. | ISO 15189 4.1.2.3b | |
| ORG1.1.5 | **M** | The governing body/ownership communicates to laboratory personnel the importance of meeting the needs and requirements of users, as well as regulatory and accreditation requirements. | ISO 15189 4.1.2.1 a<br>ISQua 4.7a | |
| ORG1.1.6 | | The laboratory is in alignment with the established mission, vision and values of the organization and has communicated these to all personnel.<br>*Guidance: The laboratory is not prohibited from establishing its own mission, vision and values as long as they are not in conflict with the mission, vision and values of the organization.* | ISQua 3.1 | |
| ORG1.1.7 | | The laboratory uses a risk management framework to proactively and reactively identify and manage significant risks to quality and safety.<br>*Guidance: The risk management framework includes the scope, objectives and criteria for assessing risk, the identification of risk management responsibilities and functions, training, plans to address significant risks and the communication of risk plans to stakeholders.* | ISQua 4.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|

## ORG2.0 ORGANIZATIONAL STRUCTURE

| | | | | |
|---|---|---|---|---|
| **ORG2.1** | **Responsibilities, authorities and interrelationships are defined and documented.** | | | |
| ORG2.1.1 | **M** | Responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory. This includes the appointment of personnel responsible for each laboratory function and the appointment of alternates for key managerial and technical personnel. | ISO 15189 4.1.2.5 | |
| ORG2.1.2 | **M** | There is a documented and dated organizational chart with clear lines of accountability, responsibility, interrelationship and authority.<br>*Guidance: The organizational chart delineates the management structure of the laboratory and identifies relationships within the organization (e.g. remotely located laboratories) and with other organizations.* | ISO 15189 4.2.2.2c<br>ISO 15189 4.1.2.1d | |
| | | Specific individuals are assigned accountability and responsibility for: | | |
| ORG2.1.3 | | • defining scope of service | DAP15 | |
| ORG2.1.4 | | • budget development | DAP15 | |
| ORG2.1.5 | | • medical personnel | DAP15 | |
| ORG2.1.6 | | • human resources | DAP LGL 2.1.5 | |
| ORG2.1.7 | **M** | • competency assessments | ISO 15189 4.1.2.1h | |
| ORG2.1.8 | | • satisfaction and complaint management | DAP15 | |
| ORG2.1.9 | | • prevention of laboratory acquired infections | DAP15 | |
| ORG2.1.10 | | • radiation safety, where applicable | DAP15 | |
| ORG2.1.11 | | • disaster planning | DAP15 | |
| ORG2.1.12 | **M** | • establishing the quality policy | ISO 15189 4.1.2.1b | |
| ORG2.1.13 | **M** | • establishing quality objectives and planning | ISO 15189 4.1.2.1c | |
| ORG2.1.14 | **M** | • conducting management reviews | ISO 15189 4.1.2.1g | |
| ORG2.1.15 | **M** | • appointing a quality manager, however named | ISO 15189 4.1.2.1f | |
| ORG2.1.16 | | • risk management | ISQua1.3.3b | |
| ORG2.1.17 | | • information management | DAP15 | |

| No. | Standard / Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG2.1.18 | **M** | • equipment and supplies | ISO 15189 4.1.2.1e | |
| ORG2.1.19 | **M** | • technical operations | ISO 15189 4.1.2.1e | |
| ORG2.1.20 | **M** | • establishing communication processes | ISO 15189 4.1.2.1e | |
| ORG2.1.21 | | • education and training | ISQua 3.3b | |
| ORG2.1.22 | | • research and development | ISQua 3.3b | |
| **ORG2.2** | **The responsibilities of laboratory directors are defined and documented.** | | | |
| ORG2.2.1 | **M** | The laboratory is directed by a person or persons with the competence and delegated responsibility for the services provided.<br>*Guidance: Under the Bylaws of the College of Physicians and Surgeons of British Columbia, every laboratory must have an appointed medical director. Recognizing that many organizations use a co-management model, the standards also recognize administrative directors who may perform those non-medical duties of a laboratory director. For the purpose of this document, the term "laboratory director(s)" refers to medical and/or operational directors who may direct activities within the criteria. The medical responsibilities of a medical director are addressed in ORG3.1.* | ISO 15189 4.1.1.4 | |
| ORG2.2.2 | **M** | The responsibilities of laboratory directors include professional, scientific, consultative or advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory. | ISO 15189 4.1.1.4a | |
| ORG2.2.3 | **M** | The duties and responsibilities of laboratory directors are documented. | ISO 15189 4.1.1.4 | |
| ORG2.2.4 | **M** | A medical director is appointed with responsibility for the quality and safety of the medical practice within the laboratory. | DAP15 | |
| ORG2.2.5 | | Administrative directors are appointed with responsibility for the quality and safety of operational processes and technical operations within the laboratory. | DAP15 | |
| ORG2.2.6 | **M** | There is a defined structure and process through which laboratory directors are held accountable. | DAP15 | |
| ORG2.2.7 | **M** | The organization provides laboratory directors with the necessary training and support to effectively oversee laboratory quality and safety. | DAP15 | |
| ORG2.2.8 | | Laboratory directors establish an operational plan that is consistent with the strategic direction of the organization. | ISQua 3.1 | |
| ORG2.2.9 | **M** | Laboratory directors provide effective leadership of the laboratory, including budget planning and financial management, in accordance with organizational assignment of such responsibilities. | ISO 15189 4.1.1.4 a | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG2.2.10 | **M** | Laboratory directors relate and function effectively with accrediting and regulatory agencies, administrative officials, the health-care community and the patient population served, and providers of formal agreements, when required.<br>*Guidance: Laboratory directors ensure access for the DAP to the laboratory for the assessment of records, manuals and equipment, including the availability of personnel for interviews, and to any other data and information that may be required for the assessment of the operation and the quality of work produced by the laboratory.* | ISO 15189 4.1.1.4b<br>ISQua 4.7a | REVISED |
| ORG2.2.11 | **M** | Laboratory directors ensure that there are personnel with the required education, training and competence to provide laboratory services that meet the needs and requirements of users. | ISO 15189 4.1.1.4c | REVISED |
| ORG2.2.12 | **M** | Laboratory directors ensure implementation of the quality policy. | ISO 15189 4.1.1.4d | |
| ORG2.2.13 | **M** | Laboratory directors implement a safe laboratory environment in compliance with good practice and applicable requirements. | ISO 15189 4.1.1.4e | |
| ORG2.2.14 | **M** | Laboratory directors select referral laboratories and monitor the quality of service provided.<br>*Guidance: For the purpose of these standards, referral laboratories within British Columbia that are accredited by the DAP are exempt.* | ISO 15189 4.1.1.4i | |
| ORG2.2.15 | **M** | Laboratory directors provide professional development programs for laboratory personnel which may include opportunities to participate in scientific and other activities of professional laboratory organizations. | ISO 15189 4.1.1.4j | |
| ORG2.2.16 | **M** | Laboratory directors address complaints, requests or suggestions from personnel and users of laboratory services. | ISO 15189 4.1.1.4m | |
| ORG2.2.17 | **M** | Laboratory directors design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.<br>*Guidance: Priorities within the contingency plan are based on a risk management framework.* | ISO 15189 4.1.1.4n<br>ISO 22367: 2008 Intro | |
| ORG2.2.18 | **M** | Laboratory directors plan and direct diagnostic research and development. | ISO 15189 4.1.1.4o | REVISED |

## ORG3.0 MEDICAL LEADERSHIP

| | |
|---|---|
| **ORG3.1** | **A medical director is appointed with assigned responsibilities for the laboratory.** |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG3.1.1 | **M** | A medical director and an alternate (both who are registrants of the College of Physicians and Surgeons of British Columbia and whose credentials are acceptable to the DAP Committee) are appointed for every laboratory with responsibility for the delivery and all matters pertaining to procedures and medical care in the laboratory. | College Bylaws<br>s.5-26 (1)-(2a) | |
| ORG3.1.2 | **M** | The medical director or alternate ensure that diagnostic procedures are performed only as permitted by the terms of accreditation, the Bylaws, and in accordance with the requirements of the standards of professional ethics and standards of practice of the College of Physicians and Surgeons of British Columbia. | College Bylaws<br>s.5-26(2)(b) | |
| ORG3.1.3 | **M** | The medical director or alternate have access to all records and documents relating to the operation of the laboratory and the procedures performed. | College Bylaws<br>s.5-26 (2)(c) | |
| ORG3.1.4 | **M** | The medical director or alternate promptly notifies the DAP Committee of any change in the ownership or directorship of the laboratory or any significant change in service or operation. | College Bylaws<br>s.5-26 (2)(d) | |
| ORG3.1.5 | **M** | The medical director or alternate ensures compliance with the Bylaws of the College of Physicians and Surgeons of British Columbia. | College Bylaws<br>s.5-26 (2)(d)-(e) | |
| ORG3.1.6 | **M** | The medical director works in collaboration with the governing body/ownership to grant physician privileges within the laboratory according to hospital or regional bylaws. | DAP15 | |
| ORG3.1.7 | **M** | The medical director participates in the development and monitoring of performance measures for the laboratory. | DAP15 | |
| ORG3.1.8 | **M** | The medical director provides direction for the production, development and review of examination availability and algorithms. | DAP15 | |
| ORG3.1.9 | | The medical director coordinates and integrates laboratory services with other departments and services. | DAP15 | |
| ORG3.1.10 | **M** | The medical director serves as a contributing member of medical personnel for those facilities served, if applicable and appropriate. | ISO 15189 4.1.1.4f | |
| ORG3.1.11 | **M** | The medical director defines, implements and monitors standards of performance and quality improvement of the laboratory. | ISO 15189 4.1.1.4k | |
| ORG3.1.12 | **M** | The medical director monitors all work performed in the laboratory to determine that clinically relevant information is being generated. | ISO 15189 4.1.1.4l | |
| ORG3.1.13 | **M** | The medical director approves all changes to the laboratory information system (LIS) that may affect patient care. | CAP GEN.43022 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG3.1.14 | **M** | LIS-generated patient report templates are reviewed for content and format and approved by the medical director or designate. | CAP GEN.41067 | |
| ORG3.1.15 | **M** | The medical director establishes standardized interpretive comments. | DAP15 | |
| ORG3.1.16 | **M** | The medical director or other authorized personnel reviews the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received (e.g. discontinuing outdated examinations) at a defined interval. | ISO 15189 4.1.4.2 | |
| **ORG3.2** | **Personnel and structures are established to provide guidance in facilities without an on-site laboratory medical director or pathologist.** | | | |
| ORG3.2.1 | **M** | A medical director is appointed with assigned responsibility and accountability for the laboratory service at sites without an on-site medical director or pathologist. | DAP15 | |
| ORG3.2.2 | **M** | Medical directors visit remotely supervised sites when medical leadership responsibility commences, and once per year thereafter.<br>*Guidance: The annual visit may be undertaken by another pathologist, or a technical delegate deemed qualified by the medical director.* | DAP15 | |
| ORG3.2.3 | **M** | The medical director assesses the complexity of services provided and undertakes more frequent visits, if warranted. | DAP15 | |
| ORG3.2.4 | **M** | A log is kept to record the visit of the medical director or delegate to the laboratory, recommendations for improvement or required follow-up are recorded in the log, and the log is signed by the person conducting the visit. | DAP15 | |
| ORG3.2.5 | **M** | The medical director or delegate maintains ongoing communication with technical personnel and users of laboratory services. | DAP15 | |
| ORG3.2.6 | **M** | Documented processes ensure the prompt availability of a laboratory physician for consultation, whenever required.<br>*Guidance: The degree of availability is appropriate to the medical requirement for consultation.* | DAP15 | |

## CREDENTIALING AND PRIVILEGING

Credentialing is a process that involves the collection, verification and assessment of information regarding the education, training, experience and ability of an individual physician to perform a requested privilege. In British Columbia physicians must have the requisite credentials as outlined in the Provincial Privileging Dictionaries (http://bcmqi.ca/privileging-dictionaries).

Credentialing for physicians who hold privileges at any health authority facility is performed by the health authority, and includes assessing eligibility for MSP billings for restricted services. Many medical offices are owner-operated solo practices and the physician may not hold privileges with a health authority; therefore, the physician would not have proceeded through a credentialing process. In these instances the physician is licensed to their scope of practice through the College of Physicians and Surgeons of BC. For MSP billing purposes for a restricted diagnostic service, the College will review the associated credentials required to be eligible to bill for these services and will notify MSP of the eligibility. For further information please contact credentialing@cpsbc.ca.

For community-based multi-physician facilities the medical director and ownership are responsible to ensure the physicians that practice in their facilities are appropriately credentialed, either through the health authority or by reviewing the credentials of the physician and ensuring that the physician has been deemed eligible to bill MSP for the services. There must be a formal process used for credentialing and privileging, and it is the expectation of these accreditation standards that the medical director and ownership can demonstrate these processes.

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **ORG3.3** | **Qualified and competent medical personnel practise within the laboratory.** | | | |
| ORG3.3.1 | **M** | An accurate list of all medical personnel practising within the laboratory is maintained.<br>*Guidance: The list should include permanent and temporary personnel.* | DAP15 | |
| ORG3.3.2 | | Information for each medical practitioner is collected, verified and assessed relative to the requested scope of practice. | DAP15 | |
| ORG3.3.3 | **M** | Laboratory physicians have current licensure from the College of Physicians and Surgeons of British Columbia in the relevant specialty. | DAP15 | |
| ORG3.3.4 | **M** | Laboratory physicians have relevant education and training. | DAP15 | |
| ORG3.3.5 | **M** | Physical impairment that may impede the scope of practice is identified. | DAP15 | |
| ORG3.3.6 | **M** | Laboratory physicians have the experience and competence to perform the scope of practice and procedures. | DAP15 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG3.3.7 | **M** | A record is maintained for each medical practitioner indicating the scope of service and procedures (including any MSP billing eligibility confirmation for restricted services) they are permitted to perform within the laboratory and this is communicated to the practitioner and the organization. | DAP15 | REVISED |
| ORG3.3.8 | **M** | Medical personnel only practise within the scope of their privileges. | DAP15 | |
| ORG3.3.9 | **M** | Physicians providing medical biochemistry services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries.<br>*Guidance: Medical biochemistry services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform medical biochemistry.* | DAP15 | REVISED |
| ORG3.3.10 | **M** | Physicians providing hematology services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries.<br>*Guidance: Hematology services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform hematology.* | DAP15 | REVISED |
| ORG3.3.11 | **M** | Physicians providing medical microbiology services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries.<br>*Guidance: Medical microbiology services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform medical microbiology.* | DAP15 | REVISED |
| ORG3.3.12 | **M** | Physicians providing transfusion medicine services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries.<br>*Guidance: Transfusion medicine services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform transfusion medicine.* | DAP15 | REVISED |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG3.3.13 | **M** | Physicians providing anatomic pathology services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries.<br>*Guidance: Anatomic pathology services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform anatomic pathology.* | DAP15 | REVISED |
| ORG3.3.14 | **M** | Physicians providing genetic and cytogenetic services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries.<br>*Guidance: Genetics and cytogentics services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform genetics and cytogenetics.* | DAP15 | REVISED |
| ORG3.3.15 | | There is an agreement, contract, or bylaws established for the medical practitioner/group and the organization. | DAP15 | |
| ORG3.3.16 | **M** | There are procedures for the establishment and review of agreements for providing medical laboratory services. | ISO 15189 4.4.1 | |

## ORG4.0 HUMAN RESOURCES MANAGEMENT

| **ORG4.1** | **There is a plan to manage human resources requirements.** | | | |
|---|---|---|---|---|
| ORG4.1.1 | | There is a human resources plan to identify personnel numbers and required competencies to meet the current and future needs of the laboratory. | ISO 15189 4.1.1.4 c<br>ISQua 3.5 | REVISED |
| ORG4.1.2 | | The human resources planning process involves key personnel who are knowledgeable about advances in laboratory service delivery and technology, and able to determine the required competencies of personnel. | DAP15 | |
| ORG4.1.3 | | The human resources plan is monitored and revised, as necessary. | DAP15 | |
| ORG4.1.4 | | Clinical teaching and training requirements are included in the human resources plan. | DAP15 | |
| ORG4.1.5 | **M** | Personnel undergoing training are supervised at all times by experienced and qualified personnel. | ISO 15189 5.1.5 | |
| ORG4.1.6 | | The laboratory has personnel to fulfill training obligations. | DAP:LHR 17.5 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG4.1.7 | **M** | Patient safety and service standards are not compromised during, or as a result of training.<br>*Intent: The laboratory has determined if, when, and under what conditions students can work alone or unsupervised, and what safeguards have been established.* | DAP15 | |
| ORG4.1.8 | | Workloads are monitored and managed. | DAP15 | |
| **ORG4.2** | **Qualified personnel work within the laboratory.** | | | |
| ORG4.2.1 | **M** | The laboratory selects and recruits personnel based on qualifications and experience (e.g. certification, academic preparation, knowledge, skills and reference checks). | ISO 15189 5.1.2 | |
| ORG4.2.2 | **M** | Personnel making judgments with reference to examinations have the education, training, theoretical and practical background, and qualifications relevant to the job. | ISO 15189 5.1.2 | REVISED |
| ORG4.2.3 | **M** | Scientific personnel providing laboratory services have a university-level education specific to the laboratory discipline and have a specific scope of practice defined by the medical director. | DAP15 | |
| ORG4.2.4 | **M** | Laboratory doctoral scientists providing clinical services have a doctorate degree specific to the laboratory discipline, and are fellows (certified, or eligible for certification) in good standing with one of the following:<br>• Canadian College of Medical Geneticists<br>• Canadian Academy of Clinical Biochemistry and the Canadian Society of Clinical Chemists<br>• Canadian College of Microbiologists | DAP15 | |
| ORG4.2.5 | **M** | Technologists are certified or eligible for certification with the Canadian Society for Medical Laboratory Science (CSMLS). | DAP15 | |
| ORG4.2.6 | **M** | Combined laboratory/X-ray technologists (CLXT) are certified and have a defined scope of practice in alignment with their certification.<br>*Guidance: Under their certification, CLXT personnel have a limited scope of laboratory testing. If CLXT personnel are required to practise outside of this limited scope, competency in the performance of the examination must be demonstrated prior to the technologist working independently.* | DAP15 | |
| ORG4.2.7 | | Laboratory assistants providing services have completed a British Columbia Society of Laboratory Science-approved medical laboratory assistant training program or recognized equivalent, or are certified with the Canadian Society for Medical Laboratory Sciences. | DAP15 | |
| ORG4.2.8 | **M** | Pathologist's assistants have graduated from a recognized university-based pathologist's assistant program or have equivalent documented training and expertise as assessed by the medical director of anatomic pathology. | DAP15 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **ORG4.3** | **There are job descriptions for all personnel.** | | | |
| ORG4.3.1 | **M** | There are job descriptions for all personnel that describe responsibilities, authorities and tasks. | ISO 15189 5.1.3 | |
| ORG4.3.2 | | Job descriptions are reviewed at a defined frequency to ensure they reflect current practice and changing performance requirements, duties or qualifications. | DAP15 | |
| ORG4.3.3 | | Personnel are aware of their responsibilities and understand reporting relationships relevant to their position. | DAP15 | |
| **ORG4.4** | **There are processes to address conflict of interest and ethical conduct.** | | | |
| ORG4.4.1 | **M** | There are processes to ensure there is no involvement in activities that would diminish confidence in the laboratory's competence, impartiality, judgment or operational integrity. | ISO 15189 4.1.1.3a | |
| ORG4.4.2 | **M** | There are processes to ensure that personnel are free from any undue commercial, financial or other pressures and influences that may adversely affect the quality of their work. | ISO 15189 4.1.1.3b | |
| ORG4.4.3 | **M** | There are processes to ensure that existing potential conflicts and competing interests are openly declared. | ISO 15189 4.1.1.3c | REVISED |
| ORG4.4.4 | **M** | There are procedures to ensure that personnel treat human samples, tissues or remains according to relevant legal requirements. | ISO 15189 4.1.1.3d | |
| ORG4.4.5 | **M** | There are procedures to ensure that the confidentiality of patient information is maintained at all times. | ISO 15189 4.1.1.3 e<br>ISO 15189 5.10.1<br>CLSI QMS01-A4 5.9.2 | REVISED |
| ORG4.4.6 | | There is a written code of ethics for professional behaviour. | ISQua 3.1 | |
| ORG4.4.7 | | There is a documented process for addressing unethical or unprofessional behaviour. | DAP15 | |
| **ORG4.5** | **Continuing education or professional development is available for all personnel.** | | | |
| ORG4.5.1 | **M** | Continuing education is encouraged, supported and made available for management and technical personnel. | ISO 15189 5.1.8<br>ISO 15189 4.1.1.4j | |
| ORG4.5.2 | **M** | The effectiveness of professional development and continuing education programs is reviewed at a defined interval. | ISO 15189 5.1.8 | |
| ORG4.5.3 | **M** | Personnel participate in regular professional development or other professional liaison activities. | ISO 15189 5.1.8 | |
| **ORG4.6** | **General orientation and training is provided.** | | | |
| ORG4.6.1 | **M** | The training process includes orientation for new personnel (e.g. terms and conditions of employment, facilities, and health and safety requirements). | ISO 15189 5.1.4 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG4.6.2 | **M** | Orientation and training is provided to existing personnel in response to changing roles, technology, competency demands, laws and regulations or after an extended absence. | ISO 15189 5.1.5 | |
| | | At a frequency determined by the organization, personnel receive orientation and training as relevant to their role on: | | REVISED |
| ORG4.6.3 | **M** | • the quality management system | ISO 15189 5.1.5a<br>CLSI QMS01-A4 5.4.3 | |
| ORG4.6.4 | **M** | • assigned work policies, processes and procedures | ISO 15189 5.1.5b | |
| ORG4.6.6 | **M** | • the confidentiality of patient information | ISO 15189 5.1.5f | |
| ORG4.6.7 | **M** | • ethics | ISO 15189 5.1.5e | |
| ORG4.6.8 | | • identifying, reporting and disclosing information regarding nonconformities | ISQua 4.4 | |
| ORG4.6.9 | **M** | • the prevention and containment of the effects of nonconformities—this training is documented | ISO 15189 5.1.5d | |
| ORG4.6.10 | | • risk management | ISQua 4.1 iv | |
| ORG4.6.11 | **M** | • patient identification | DAP15 | |
| ORG4.6.12 | **M** | • roles and responsibilities of the individual and key personnel | DAP15 | |
| ORG4.6.13 | | • patient rights and patient consent | ISQua 5.1, 5.4 | |
| ORG4.6.14 | | • the mission, vision, and values of the organization | ISQua 3.1 | |
| ORG4.6.15 | | • sensitivity to cultural and religious diversity | ISQua 5.5 | |
| ORG4.6.16 | **M** | • management of aggressive behaviour | DAP15 ORG4.7.5 | MOVED |
| ORG4.6.17 | **M** | • violence and harassment in the workplace | DAP15 ORG4.7.6 | MOVED |
| ORG4.6.18 | **M** | • emergency responses or codes | DAP15 ORG4.7.7 | MOVED |
| ORG4.6.19 | | • disaster response | DAP15 ORG4.7.8 | MOVED |
| ORG4.6.20 | **M** | The effectiveness of the training program is reviewed at a defined interval. | ISO 15189 5.1.5 | MOVED |
| **ORG4.8** | **The competency of personnel is assessed.** | | | |
| ORG4.8.1 | **M** | There is a documented process to assess the competence of all personnel to perform assigned tasks after training. | ISO 15189 5.1.6 | |
| ORG4.8.2 | **M** | Reassessment occurs annually and when the need to reassess is identified. | ISO 15189 5.1.6 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG4.8.3 | **M** | The laboratory has defined the knowledge and skills that are subject to competency assessment. | DAP MAC | |
| ORG4.8.4 | **M** | Competency assessment of new personnel is performed prior to the completion of a probationary or orientation period. | DAP15 | |
| ORG4.8.5 | **M** | Competency assessment of existing personnel is performed when new technology or new procedures are introduced. | DAP15 LHR 18.2.2 | |
| ORG4.8.7 | **M** | The education, experience and qualifications of individuals performing competency assessment are defined | DAP15 | REVISED |
| ORG4.8.8 | **M** | Competency assessment uses a combination of approaches under the same conditions as the general working environment (e.g. direct observation, monitoring, recording and reporting of results, review of work records). | ISO 15189 5.1.6 | |
| ORG4.8.9 | | The focus of personnel competency assessments is quality improvement. | DAP MAC | |
| ORG4.8.10 | **M** | Corrective action plans are developed for personnel following unacceptable competency assessments. | DAP15 | |
| **ORG4.9** | **Performance appraisals are conducted.** | | | |
| ORG4.9.1 | **M** | A performance appraisal based on job responsibilities is conducted at a defined frequency. | ISO 15189 5.1.7 | |
| ORG4.9.2 | | Development plans are generated, monitored and revised, as necessary. | DAP15 | |
| **ORG4.10** | **Individual human resource records are kept for all personnel.** | | | |
| ORG4.10.1 | **M** | Human resources records contain educational and professional qualifications, a copy of certification or licence if applicable, and previous work experience. | ISO 15189 5.1.9a,b,c | |
| ORG4.10.2 | **M** | Human resources records include records of orientation, training in current job tasks, competency assessments, continuing education and achievement, and performance reviews. | ISO 15189 5.1.9d-h | |
| ORG4.10.3 | **M** | Human resources records contain reports of accidents and exposure to occupational hazards and immunization status when relevant. | ISO 15189 5.1.9i, j | |
| ORG4.10.4 | **M** | Human resources records contain a criminal record check if personnel are in contact with children or vulnerable adults. | ISO 15189 5.1.9 k | |
| ORG4.10.5 | **M** | Only authorized individuals have access to human resources records. | DAP15 | |
| ORG4.10.6 | **M** | Consent is obtained from personnel prior to the release of information contained in their human resources record. | DAP15 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG4.10.7 | **M** | There is a documented process for human resource record disposal in that is accordance with regulations. | DAP15 | REVISED |

## ORG5.0 DELEGATED MEDICAL ACTS

| | | | | |
|---|---|---|---|---|
| **ORG5.1** | **Delegated medical acts are clearly defined** | | | |
| ORG5.1.1 | **M** | Each delegated medical act is clearly defined and circumscribed. | DAP10: LMS4.1.1 | NEW |
| ORG5.1.2 | **M** | The degree of medical supervision required is identified.<br>*Guidance: Medical supervision may be direct, with the physician in attendance, or through technology (video link, digital imaging, telephone), or according to a written protocol.* | DAP10: LMS4.1.2 | NEW |
| ORG5.1.3 | **M** | Competency requirements to perform the delegated medical act are clearly identified. | DAP10: LMS4.1.3 | NEW |
| **ORG5.2** | **The delegation of medical acts has been approved and accepted.** | | | |
| ORG5.2.1 | **M** | Approval from the governing body/ownership of the organization has been obtained prior to the delegated medical act being carried out in the organization. | DAP10: LMS4.2.4 | NEW |
| ORG5.2.2 | **M** | The delegation of the medical act has been accepted by the individual(s) who will perform the delegated medical act. | DAP10: LMA4.2.3 | NEW |
| ORG5.2.3 | **M** | The laboratory maintains a list of approved medical acts that may be delegated and the individuals authorized to conduct each delegated medical act. | DAP10: LMS4.4.1 | NEW |
| **ORG5.3** | **Delegated medical acts are performed by competent individuals.** | | | |
| ORG5.3.1 | **M** | Additional training is provided to individuals performing the delegated medical act. | DAP10: LMS4.3.1 | NEW |
| ORG5.3.2 | **M** | Competency assessment to perform a specific delegated medical act is conducted by a physician or technical delegate.<br>*Guidance: Competency assessment of the technical delegate is conducted by a physician with relevant expertise in the medical act.* | DAP10: LMS4.3.2 | NEW |
| | | There is a competency assessment record for each individual performing delegated medical acts. The competency assessment record includes: | DAP10: LMS4.3.9 | NEW |
| ORG5.3.3 | **M** | • the date of the assessment | DAP10: LMS4.3.4 | NEW |
| ORG5.3.4 | **M** | • the specific act(s) being assessed | DAP10: LMS4.3.5 | NEW |
| ORG5.3.5 | **M** | • the name of the physician or technical delegate conducting the assessment | DAP10: LMS4.3.6 | NEW |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ORG5.3.6 | **M** | • the signature of the physician or technical delegate attesting to the competence of the individual performing the specific act(s) | DAP10: LMS4.3.7 | NEW |
| ORG5.3.7 | **M** | The competency of the individual performing the specific delegated medical act is reassessed annually by a physician or technical delegate.<br>*Guidance: The record of assessment for each individual is updated annually following the reassessment.* | DAP10: LMS4.3.8 | NEW |

# QUALITY MANAGEMENT SYSTEM

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| **QMS1.0** | **QUALITY MANAGEMENT POLICY, SYSTEM MANAGER AND MANUAL** | | | |
| **QMS1.1** | **A quality policy has been defined for the quality management system (QMS).** | | | |
| QMS1.1.1 | **M** | The quality policy defines the intent of the QMS and is appropriate to the purpose of organization. | ISO 15189 4.1.2.3<br>ISO 15189 4.2.3a | |
| QMS1.1.2 | **M** | The quality policy includes a commitment to good professional practice, examinations that are fit for intended use and continual improvement of the quality of laboratory services. | ISO 15189 4.2.3b | |
| QMS1.1.3 | **M** | The quality policy provides a framework for establishing and reviewing quality objectives. | ISO 15189 4.2.3c | |
| QMS1.1.4 | **M** | The quality policy is communicated and understood within the laboratory. | ISO 15189 4.2.3d | |
| QMS1.1.5 | **M** | The quality policy is reviewed for continuing suitability and revised as required. | ISO 15189 4.2.3e | REVISED |
| QMS1.1.6 | **M** | The QMS provides for the integration of all processes required to fulfill its quality policy and objectives. | ISO 15189 4.2.1 | |
| **QMS1.2** | **There is a quality management system for the laboratory.** | | | |
| QMS1.2.1 | **M** | Planning of the QMS is carried out to meet the requirements and quality objectives of the QMS. | ISO 15189 4.1.2.4 | |
| QMS1.2.2 | **M** | A QMS is established, documented, implemented and maintained to ensure that medical laboratory services meet regulatory requirements and the needs of patients and all personnel responsible for patient care. | ISO 15189 4.2.1 | |
| QMS1.2.3 | **M** | The QMS supports continuous improvement. | ISO 15189 4.2.1<br>ISQua 6.2c | |
| QMS1.2.4 | **M** | Quality objectives are established and include those needed to meet the needs and requirements of users. | ISO 15189 4.1.2.4 | |
| QMS1.2.5 | **M** | Established quality objectives are measurable and consistent with the quality policy. | ISO 15189 4.1.2.4 | |
| QMS1.2.6 | **M** | There are documented processes to review the effectiveness of the QMS and to communicate that effectiveness to laboratory personnel. | ISO 15189 4.15.3<br>CLSI QMS01-A4 5.1.6<br>ISO 15189 4.1.2.6 | |
| QMS1.2.7 | **M** | The integrity of the QMS is maintained when changes to it are planned and implemented. | ISO 15189 4.1.2.4 | |
| **QMS1.3** | **There is a quality manager for the quality management system.** | | | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS1.3.1 | **M** | A quality manager (or otherwise titled) has been appointed or selected for the laboratory with delegated responsibility and authority to ensure compliance with the QMS.<br>*Guidance: The quality manager duties may be assigned to an existing position in the laboratory.* | ISO 15189 4.1.2.1f<br>ISO 15189 4.1.2.7<br>CLSI QMS01-A4<br>5.1.2.1 | |
| QMS1.3.2 | **M** | The quality manager ensures that processes needed for the QMS are established, implemented and maintained. | ISO 15189 4.1.2.7a | |
| QMS1.3.3 | **M** | The quality manager reports on the performance of the QMS and any need for improvement to the level of laboratory management where decisions are made on laboratory policy and resources. | ISO 15189 4.1.2.7b | |
| QMS1.3.4 | **M** | The quality manager promotes awareness of users' needs and requirements throughout the laboratory. | ISO 15189 4.1.2.7c | |
| **QMS1.4** | **There is a quality manual for the quality management system.** | | | |
| QMS1.4.1 | **M** | The laboratory has established and maintains a quality manual.<br>*Guidance: The quality manual describes the QMS using policies and management processes. Technical procedures are not included, but may be referenced when appropriate.* | ISO 15189 4.2.2.2<br>CLSI QMS01-A4<br>5.1.3.1 | |
| QMS1.4.2 | **M** | The quality manual includes the quality policy (or makes reference to it). | ISO 15189 4.2.2.2a | |
| QMS1.4.3 | **M** | The quality manual includes a description of the scope of the QMS. | ISO 15189 4.2.2.2b | |
| QMS1.4.4 | **M** | The quality manual includes a presentation of the organization and management structure of the laboratory and its place in any parent organization. | ISO 15189 4.2.2.2c | |
| QMS1.4.5 | **M** | The quality manual includes a description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with ISO 15189. | ISO 15189 4.2.2.2d | |
| QMS1.4.6 | **M** | The quality manual includes a description of the structure and relationships of the documentation used in the QMS. | ISO 15189 4.2.2.2e | |
| QMS1.4.7 | **M** | The quality manual includes documented policies for the QMS and reference to the managerial and technical activities that support them. | ISO 15189 4.2.2.2f | |
| QMS1.4.8 | **M** | All laboratory personnel have access to and instruction on the use and application of the quality manual and referenced documents. | ISO 15189 4.2.2.2 | |
| QMS1.4.9 | **M** | There is a documented review of the QMS manual at defined intervals. | ISO 15189 4.15.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|

## QMS2.0 DOCUMENTS AND RECORDS

| | | | | |
|---|---|---|---|---|
| **QMS2.1** | **There are processes for the maintenance of documents (document control).** | | | |
| QMS2.1.1 | **M** | There are defined authorities, procedures and processes for the maintenance and review of documents.<br>*Guidance: The laboratory controls documents required by the QMS and ensures that unintended use of any obsolete document is prevented.* | ISO 15189 4.3<br>CLSI QMS01-A4 5.8.1<br>CLSI QMS02-A6 | REVISED |
| QMS2.1.3 | **M** | All documents, including those maintained in a computerized system and issued as part of the QMS, are reviewed and approved by the laboratory director or designate prior to issue. | ISO 15189 4.3a,<br>CLSI QMS01-A4 5.8.1<br>CLSI QMS02-A6 11.1 | |
| QMS2.1.4 | **M** | Documents are reviewed and updated at a frequency that ensures that they remain fit for the intended purpose.<br>*Guidance: Procedures are reviewed every one to three years by qualified individuals.* | ISO 15189 4.3h<br>CLSI QMS01-A4 5.8.1<br>CLSI QMS02-A6 | |
| QMS2.1.5 | **M** | There is a list (e.g. document register, log or master index) of current authorized versions of documents and their distribution. | ISO 15189 4.3c<br>CLSI QMS01-A4 5.8.1<br>CLSI QMS02-A6 | |
| QMS2.1.6 | **M** | Only current, authorized versions of applicable documents are available at points of use. | ISO 15189 4.3d,i<br>ISO 15189 5.5.3<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.1.7 | **M** | Obsolete controlled documents are dated, marked as obsolete and promptly removed from all points of use and at least one copy is retained for a specified time period. | ISO 15189 4.3i, j<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.1.8 | **M** | Where the document control system allows for the amendment of documents by hand, procedures and authorities for such amendments are defined. | ISO 15189 4.3e, g<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.1.9 | **M** | Documents amended by hand remain legible, amendments are clearly indicated, initialed and dated and a revised document is issued within a specified time. | ISO 15189 4.3e, g<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.1.10 | **M** | There are procedures for changes to documents in computerized systems. | ISO 15189 4.3<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.1.11 | **M** | There is a documented process to manage printed copies of controlled documents when the official version is electronic. | ISO 15189 4.3<br>CLSI QMS01-A4 5.8.1<br>CLSI QMS02-A6 | |
| QMS2.1.12 | **M** | All documents that are associated with the performance of examinations, including procedures, summary documents, and product instructions for use, are subject to document control. | ISO 15189 5.5.3 | MOVED |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **QMS2.2** | **All documents contain standardized elements.** | | | |
| QMS2.2.1 | **M** | All laboratory documents include a title. | ISO 15189 4.3b<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.2.2 | **M** | All laboratory documents include a unique identifier on every page. | ISO 15189 4.3b<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.2.3 | **M** | All laboratory documents include version information. | ISO 15189 4.3b<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.2.4 | **M** | All laboratory documents include the page number to total number of pages (e.g. page 1 of 5). | ISO 15189 4.3b<br>CLSI QMS01-A4 5.8.1 | |
| QMS2.2.5 | **M** | All laboratory documents include the authority for issue (sign-off). | ISO 15189 4.3b<br>CLSI QMS01-A4 5.8.1 | |
| **QMS2.3** | **There are procedures for the management of quality and technical records.** | | | |
| QMS2.3.1 | **M** | The laboratory has a procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records. | ISO 15189 4.13<br>CLSI QMS01-A4 5.8.2 | |
| QMS2.3.2 | **M** | Records are created concurrently with the performance of each activity that affects the quality of the examination. | ISO 15189 4.13<br>CLSI QMS01-A4 5.8.2 | |
| QMS2.3.3 | **M** | The date and, where relevant, the time of amendments to records are captured along with the identity of personnel making amendments. | ISO 15189 4.13<br>CLSI QMS01-A4 5.8.2 | |
| QMS2.3.4 | **M** | Where there are non-computerized information systems, storage conditions safeguard the integrity of manual recording and transcription. | ISO 15189 5.10.3e | |
| QMS2.3.5 | **M** | Records are stored in a suitable environment to prevent damage, deterioration, loss and unauthorized access. | ISO 15189 5.10.3c,d | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS2.3.6 | **M** | The retention time for various records pertaining to the QMS has been defined.<br>*Guidance: These records include, at a minimum, the following:*<br>• *supplier selection and performance, and changes to the approved supplier list*<br>• *request for examination*<br>• *information on reagents and materials used for examinations (e.g. lot documentation)*<br>• *laboratory work books or work sheets*<br>• *instrument maintenance records*<br>• *QC records*<br>• *incident records and action taken*<br>• *preventive action taken*<br>• *records of internal and external audits*<br>• *nonconformities identified and immediate or corrective action taken*<br>• *records of quality improvement activities*<br>• *all qualifications, training and competency records*<br>• *records of receipt of samples in the laboratory*<br>• *instrument printouts and retained data and information*<br>• *examination results and reports*<br>• *calibration functions and conversion factors*<br>• *risk management records*<br>• *accident records and action taken*<br>• *complaints and action taken*<br>• *PT and alternative assessment results*<br>• *minutes of meetings that record decisions made about QMS activities*<br>• *records of management reviews* | ISO 15189 4.13<br>CLSI QMS01-A4 5.8.1 | |

## QMS3.0 EXTERNAL SERVICES

| QMS3.1 | There are procedures for referral laboratories and consultants. | | | |
|---|---|---|---|---|
| QMS3.1.1 | **M** | There is a procedure for the selection, evaluation and monitoring of the quality and competence of referral laboratories and consultants.<br>*Guidance: A procedure should be developed with users of laboratory services where appropriate. The referring laboratory is not expected to assess the quality of the referral laboratory or the referral consultant directly. The referring laboratory is required to maintain evidence from the referral laboratory or referral consultant that demonstrates competence, such as licensure, certification or accreditation status. For the purpose of these standards, referral laboratories and referral consultants working in laboratories that are accredited by the DAP are exempt.* | ISO 15189 4.5.1a<br>CLSI QMS01-A4 5.5.2.5<br>CLSI QMS05-A2 | |
| QMS3.1.2 | **M** | A register of all referral laboratories and referral consultants is maintained. | ISO 15189 4.5.1d | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| **QMS3.2** | **There are procedures for agreements to provide medical laboratory services.** | | | |
| QMS3.2.1 | **M** | There are procedures for the establishment and review of agreements for providing medical laboratory services.<br>*Guidance: These service agreements often involve contracts with outside groups or other parties (e.g. insurance companies, sports franchises).* | ISO 15189 4.4.1-2<br>CLSI QMS01-A4 5.5.2 | |
| QMS3.2.2 | **M** | The requirements of the patients, users, other parties and of the provider of the laboratory services, are defined, documented and understood. This includes the examination processes that are to be used. | ISO 15189 4.4.1a | |
| QMS3.2.3 | **M** | The laboratory has the capability and resources to meet the requirements of agreements including personnel with the skills and expertise necessary for the performance of the intended examinations. | ISO 15189 4.4.1b,c | REVISED |
| QMS3.2.5 | **M** | Examination procedures selected are appropriate and able to meet the user's needs. | ISO 15189 4.4.1d | |
| QMS3.2.6 | **M** | Reviews of agreements to provide medical laboratory services include all aspects of the agreement. Records of these reviews include any changes to the agreement and any pertinent discussions. Any amendments are communicated to all affected parties. | ISO 15189 4.4.2 | |
| QMS3.2.7 | **M** | Users and other parties are informed of deviations from the agreement that impact upon examination results. | ISO 15189 4.4.1e | |
| QMS3.2.8 | **M** | Reference is made to any work referred by the laboratory to a referral laboratory or consultant. | ISO 15189 4.4.1f | |

## QMS4.0 COMMUNICATION AND CONSULTATION

| QMS4.1 | There are provisions for communication with patients and users | | | |
|---|---|---|---|---|
| QMS4.1.1 | **M** | There are advisory and interpretative services that meet the needs of patients, users and other parties. | ISO 15189 4.1.2.2 | REVISED |
| QMS4.1.2 | **M** | The laboratory has established arrangements for communicating with users on advising on the choice of examinations and use of laboratory services (e.g. the required sample type, clinical indications, limitations of examination procedures, the frequency of requesting the examination). | ISO 15189 4.7a | |
| QMS4.1.3 | **M** | The laboratory has established arrangements for communicating with users on case specific inquiries, professional judgement on the interpretation of the results of examinations, promotion of the effective utilization of laboratory services and consulting on scientific and logistic matters (e.g. instances of failure of samples to meet acceptance criteria). | ISO 15189 4.7b-e | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS4.1.4 | **M** | The laboratory solicits information relating to user perception as to whether the service has met the needs and requirements of users. Records of information collected and actions taken are maintained.<br>*Guidance: The process should ensure confidentiality to users.* | ISO 15189 4.14.3<br>CLSI QMS01-A4 5.2.3 | |
| QMS4.1.5 | | The laboratory ensures that communication processes are established with its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and QMS. | ISO 15189 4.1.2.6<br>CLSI QMS01-A4 6.4 | REVISED |
| QMS4.1.6 | | Pathologists participate in interdepartmental working groups to assess new cases, review specific cases and discuss treatment and case management. | CAP ANP.30100<br>CAP ANP.30150<br>GOBC PHA | |
| **QMS4.2** | **There is a process for the management of feedback from patients, users and other parties.** | | | |
| QMS4.2.1 | **M** | There is a procedure for the management of complaints or other feedback received from patients, users and other parties. | ISO 15189 4.8<br>CLSI QMS01-A4 5.2.4 | |
| QMS4.2.2 | | Clinicians, patients, or other parties are informed of the process to register complaints and feedback. | CLSI QMS01-A4 5.2.4 | |
| QMS4.2.3 | | Clinician, patient and other party inquiries and complaints are addressed promptly and effectively. | CLSI QMS01-A4 5.2.4 | |
| QMS4.2.4 | **M** | Records of all complaints, their investigation and the action taken are maintained. | ISO 15189 4.8<br>CLSI QMS01-A4 5.2.4 | |
| **QMS4.3** | **There is a process for the management of feedback from personnel.** | | | |
| QMS4.3.1 | **M** | There are documented processes for personnel to bring forward concerns or complaints and to make suggestions for the improvement of any aspect of the laboratory service. | ISO 15189 4.14.4 | |
| QMS4.3.2 | **M** | Suggestions are evaluated, implemented as appropriate, and feedback is provided to personnel. | ISO 15189 4.14.4 | |
| QMS4.3.3 | **M** | Records of suggestions and action taken by laboratory management are maintained. | ISO 15189 4.14.4 | |

## QMS5.0 NONCONFORMITIES AND POTENTIAL NONCONFORMITIES

| | | | | |
|---|---|---|---|---|
| **QMS5.1** | **There are procedures to manage nonconformities.** | | | |
| QMS5.1.1 | | Definitions of nonconformity applicable to the laboratory are communicated to personnel.<br>*Guidance: Although ISO defines nonconformities as the non-fulfillment of a requirement, other terms for nonconformities include accident, adverse event, error, event, incident, critical incident and occurrence.* | ISO 22367 6<br>CLSI QMS01-A4 5.10 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS5.1.2 | **M** | There is a procedure to identify and manage nonconformities, including pre-examination, examination and post-examination processes. This procedure is available to all personnel. *Guidance: This may include, but is not exclusive to the use of the patient safety learning system (PSLS) reporting.* | ISO 15189 4.9<br>ISO 22367 4<br>CLSI QMS01-A4 5.10 | |
| QMS5.1.3 | **M** | The responsibilities and authorities for handling nonconformities are designated. | ISO 15189 4.9a | |
| QMS5.1.4 | **M** | Immediate actions to be taken are defined and the extent of the nonconformity is determined. | ISO 15189 4.9b, c | |
| QMS5.1.5 | **M** | Examinations are halted and reports withheld as necessary, and the responsibility for authorization of the resumption of examinations is defined. | ISO 15189 4.9d, g | |
| QMS5.1.6 | **M** | The medical significance of any nonconforming examination is considered and where appropriate, users of laboratory services are informed. | ISO 15189 4.9e | |
| QMS5.1.7 | **M** | There are procedures for disclosing information to patients in concordance with the patient's physician following an adverse event or critical incident. | CLSI QMS01-A4 5.10.2 | |
| QMS5.1.8 | **M** | The results of any nonconforming examinations already released are amended where necessary. | ISO 15189 4.9f | REVISED |
| QMS5.1.9 | **M** | When reviews by external organizations indicate the laboratory has nonconformities the laboratory takes immediate, corrective action to ensure continuing compliance with the requirements of ISO 15189. | ISO 15189 4.14.8 | REVISED |
| QMS5.1.10 | **M** | All nonconformity is documented and recorded. | ISO 15189 4.9h | |
| QMS5.1.11 | **M** | There are procedures for the review of nonconformities, their cause, and an evaluation of the need for corrective action to ensure that nonconformities do not recur. | ISO 15189 4.10a-c<br>CLSI QMS01-A4 5.10 | |
| QMS5.1.12 | **M** | If needed, corrective action is determined, and implemented. The results of corrective action taken is recorded and reviewed for effectiveness. | ISO 15189 4.10d-f<br>CLSI QMS01-A4 5.10 | |
| QMS5.1.13 | **M** | When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur, or that there is doubt about the laboratory's compliance with its own procedures, the laboratory identifies, documents and eliminates the cause(s). | ISO 15189 4.9 | |
| **QMS5.2** | **There are procedures to manage potential nonconformities.** | | | |
| QMS5.2.1 | **M** | There are procedures for reviewing laboratory information and data to determine where potential nonconformities exist, identifying the cause(s) of potential nonconformities, and evaluating the need for preventive action. | ISO 15189 4.11a-c | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS5.2.2 | **M** | If needed, preventive action is determined and implemented. The results of preventive action taken is recorded and reviewed for effectiveness. | ISO 15189 4.11d-f | |
| QMS5.2.3 | **M** | The results of any potentially nonconforming examinations already released are recalled or identified, as necessary. | ISO 15189 4.9f | REVISED |
| QMS5.2.4 | **M** | When reviews by external organizations indicate the laboratory has potential nonconformities, the laboratory takes preventive action to ensure continuing compliance with the requirements of ISO 15189. | ISO 15189 4.14.8 | REVISED |

## QMS6.0 QUALITY MANAGEMENT SYSTEM IMPROVEMENT

| | | | | |
|---|---|---|---|---|
| **QMS6.1** | **There are processes to improve the quality management system.** | | | |
| QMS6.1.1 | **M** | The laboratory's actual performance in its evaluation activities, corrective actions and preventive actions is compared with its intentions, as stated in the quality policy and quality objectives. | ISO 15189 4.12 | |
| QMS6.1.2 | **M** | The laboratory addresses identified opportunities for improvement, regardless of where they occur and communicates improvement plans and related goals to personnel. | ISO 15189 4.12 | |
| QMS6.1.3 | **M** | Quality indicators have been established to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes, including the laboratory's contribution to patient care and quality improvement of the services offered. | ISO 15189 4.14.7<br>CLSI QMS01-A4 5.11.2.2 | |
| QMS6.1.4 | **M** | The process of monitoring quality indicators is planned, and includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement. | ISO 15189 4.14.7 | |
| QMS6.1.5 | | Indicators are rate based (contain a numerator and denominator), and have defined reporting periods. | DAP15 | |
| QMS6.1.6 | **M** | Quality indicators are reviewed at a defined interval. | ISO 15189 4.14.7 | REVISED |
| **QMS6.2** | **There are procedures to evaluate work processes and eliminate identified risk.** | | | |
| QMS6.2.1 | **M** | The laboratory has evaluated the impact of work processes and potential failure on examination results as they affect patient safety, and modifies processes to reduce or eliminate the identified risks. Decisions made and actions taken are documented. | ISO 15189 4.14.6 | |
| QMS6.2.2 | **M** | There are documented processes to report and review personnel and patient risk. A risk register of all identified risks is maintained. | ISQua 4.2 | |
| QMS6.2.3 | **M** | Action plans for improvement of identified risk are developed, documented and implemented. | ISO 15189 4.12 | REVISED |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS6.2.4 | **M** | Improvement activities are directed at areas of high priority based on risk assessments. A risk matrix is used to determine risk. | ISO 15189 4.12 | |
| QMS6.2.5 | **M** | The effectiveness of actions taken is determined through an audit of the area concerned. | ISO 15189 4.12 | |
| QMS6.2.6 | **M** | The laboratory participates in continual improvement activities that encompass relevant areas and outcomes to patient care. | ISO 15189 4.12 | |
| **QMS6.3** | **There are procedures for conducting internal audits.** | | | |
| QMS6.3.1 | **M** | There are procedures to define the responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records. | ISO 15189 4.14.5 | |
| QMS6.3.2 | **M** | Internal audits demonstrate that the pre-examination, examination, post-examination and supporting processes meet the needs and requirements of users. | ISO 15189 4.14.1a<br>CLSI QMS01-A4 5.11.2<br>ISQua 4.2 | |
| QMS6.3.3 | **M** | Internal audits ensure conformity to the QMS and are used to continually improve its effectiveness. | ISO 15189 4.14.1b, c | |
| QMS6.3.4 | **M** | Internal audits are conducted at planned intervals to verify that operations continue to comply with the QMS, for both technical and management functions.<br>*Guidance: Annual audits are recommended.* | ISO 15189 4.14.5 | |
| QMS6.3.5 | **M** | The selection, training and conduct of auditors ensure objectivity and impartiality of the audit process.<br>*Guidance: Auditors are independent of the activity to be audited, wherever resources permit.* | ISO 15189 4.14.5 | |
| QMS6.3.6 | **M** | Internal audits take into account the status and importance of the processes, the technical and management areas to be audited, as well as the results of previous audits. | ISO 15189 4.14.5 | |
| QMS6.3.7 | **M** | Audit criteria, scope, frequency and methods are defined and documented. | ISO 15189 4.14.5 | |
| QMS6.3.8 | **M** | Personnel responsible for the area being audited ensure that action is promptly undertaken to eliminate the causes of identified nonconformities. | ISO 15189 4.14.5 | REVISED |
| **QMS6.4** | **There are procedures for conducting periodic management review.** | | | |
| QMS6.4.1 | **M** | There is a periodic management review of the documents and records of the QMS.<br>*Guidance: Time frames for periodic review are defined in the QMS.* | ISO 15189 4.15.1<br>CLSI QMS01-A4 5.1.6 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS6.4.2 | **M** | The QMS data examined in the management review is defined.<br>*Guidance: The management review includes:*<br>• *evaluations of assessment of user feedback*<br>• *internal audits*<br>• *use of quality indicators*<br>• *results of participation in proficiency testing and alternative assessment*<br>• *performance of suppliers*<br>• *monitoring and resolution of complaints*<br>• *follow-up actions from previous management reviews*<br>• *personnel and premises that affect the QMS*<br>• *personnel suggestions*<br>• *risk management*<br>• *reviews by external organizations*<br>• *results of continual improvement including corrective actions and preventive actions*<br>• *identification and control of nonconformities*<br>• *changes in the volume and scope of work*<br>• *recommendations for improvement, including technical requirements* | ISO 15189 4.15.2b-o | |
| QMS6.4.3 | **M** | The results of QMS evaluation and improvement activities are included in the management review. | ISO 15189 4.14.1 | |
| QMS6.4.4 | **M** | Management review analyzes the input information of the causes of nonconformities, trends and patterns that indicate process problems. | ISO 15189 4.15.3<br>CLSI QMS01-A4 5.1.6 | |
| QMS6.4.5 | | The management review and associated output is focused on improvement of the effectiveness of the QMS and its processes, and improvement of services to users. | ISO 15189 4.15.4<br>CLSI QMS01-A4 5.1.6 | |
| QMS6.4.6 | | The review includes assessing these opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. | ISO 15189 4.15.3<br>CLSI QMS01-A4 5.1.6 | |
| QMS6.4.7 | **M** | The laboratory's contribution to patient care is objectively evaluated (to the extent possible). | ISO 15189 4.15.3<br>CLSI QMS01-A4 5.1.6 | REVISED |
| QMS6.4.8 | **M** | Findings and actions arising from management reviews are recorded and reported to laboratory personnel, and reported within the organization. | ISO 15189 4.15.4<br>CLSI QMS01-A4 5.1.6 | REVISED |
| QMS6.4.9 | **M** | Actions arising from management review are completed within a defined timeframe. | ISO 15189 4.15.4<br>CLSI QMS01-A4 5.1.6 | |

## QMS7.0 MEDICAL PEER REVIEW

| | |
|---|---|
| **QMS7.1** | **There is an established medical peer review program.** |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QMS7.1.1 | **M** | Medical leadership for the medical peer review program is assigned. | DAP15 | |
| | | The medical leader is responsible to ensure: | DAP15 | |
| QMS7.1.2 | **M** | • the medical peer review program is developed, implemented, actively monitored and documented | DAP15 | |
| QMS7.1.3 | **M** | • the focus of the peer review program is quality improvement, patient safety and harm reduction | DAP15 | |
| QMS7.1.4 | **M** | • the peer review program is integrated with other clinical audit and quality improvement activities of the laboratory and the organization | DAP15 | |
| QMS7.1.5 | **M** | • errors and/or discrepancies identified through medical peer review program are conveyed to the responsible pathologist(s) in a timely manner | DAP15 | |
| QMS7.1.6 | **M** | • aggregate results of medical peer review are communicated to the laboratory medical practitioners | DAP15 | |
| QMS7.1.7 | **M** | • changes in practice are implemented, as necessary | DAP15 | |
| QMS7.1.8 | | • where possible, there is participation in larger peer review databases to enable comparisons, benchmarking and statistical relevance | DAP15 | |
| | | Procedures for conducting medical peer review are documented and include: | DAP15 | |
| QMS7.1.9 | | • type of medical peer review to be conducted | DAP15 | |
| QMS7.1.10 | | • types of cases to be reviewed | DAP15 | |
| QMS7.1.11 | | • frequency of review | DAP15 | |
| QMS7.1.12 | | • individual(s) with relevant scope of practice to conduct the peer review<br>*Guidance: Ideally, the individual conducting the peer review should have similar training, work in similar environments, and have similar proficiency and demonstrated competency in the medical specialty.* | DAP15 | |
| QMS7.1.13 | | • methodology to conduct the peer review process and related documentation | DAP15 | |
| QMS7.1.14 | **M** | • individual/committee that results of the peer review are to be submitted to | DAP15 | |
| QMS7.1.15 | **M** | Participation is mandatory for all medical practitioners. | DAP15 | |
| **QMS7.2** | **The medical peer review program includes defined elements.** | | | |
| | | The medical peer review program includes the following minimum elements: | DAP15 | |

| No. | Standard | Criterion | Reference | Change |
|---|---|---|---|---|
| QMS7.2.1 | **M** | • each laboratory physician participates in the medical peer review process commensurate with the average rate of participation in the service | DAP15 | |
| QMS7.2.2 | **M** | • completeness and accuracy of reporting is assessed | DAP15 | |
| QMS7.2.3 | | • correlation of interpretation with other diagnostic examinations, pathology/surgical results and/or patient outcomes where applicable | DAP15 | |
| QMS7.2.4 | **M** | • the number of cases reviewed is recorded and reported | DAP15 | |
| QMS7.2.5 | **M** | • significant discrepancies between the primary report and the review are recorded and reported | DAP15 | |
| QMS7.2.6 | | • strategies are employed to reduce inter-observer variability | DAP15 | |

# SAFETY

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **SAF1.0** | | **GENERAL SAFETY** | | |
| **SAF1.1** | | **There is a safety program.** | | |
| SAF1.1.1 | **M** | The safety program includes a safety committee or health and safety representative.<br>*Guidance:*<br>*Greater than 20 personnel* — *Joint occupational health and safety committee with a member of committee representing laboratory*<br>*Between 10 and 19 personnel* — *Workers select person as health and safety representative*<br>*Less than 10 personnel* — *Employer holds meetings with personnel to discuss health and safety in the workplace* | GOBC WCA sec 125-40 | |
| SAF1.1.2 | **M** | Records of the last three safety meetings are available. | GOBC WCA | |
| SAF1.1.3 | | A qualified laboratory safety officer has been designated with the authority to stop unsafe work activities. | ISO 15190 7.1 | REVISED |
| SAF1.1.4 | **M** | The safety program includes reviewing health and safety activities and incident trends. | | |
| SAF1.1.5 | **M** | The safety program includes identifying and implementing courses of action to resolve health and safety concerns. | | |
| SAF1.1.7 | **M** | The safety program includes the retention of records and statistics, including reports of safety inspections and investigations. | ISO 15190 7.2 | |
| SAF1.1.9 | **M** | The safety program includes offering hepatitis B vaccination to personnel having potential exposure to blood and body fluids. Personnel are encouraged to be vaccinated. | ISO 15190 5.2<br>CLSI GP17-A3 10.1 | |
| SAF1.1.10 | | The safety program includes offering other vaccination to personnel based on potential exposure to pathogens. Personnel are encouraged to be vaccinated. | ISO 15190 11.3<br>CLSI GP17-A3 10.2 | |
| SAF1.1.11 | **M** | The safety program includes reducing the risk of musculoskeletal injury.<br>*Guidance: The laboratory must identify factors in the workplace that expose workers to a risk of musculoskeletal injury, and assess the risk to personnel. Those risk factors are then eliminated or reduced by redesign or repositioning activity, workspace or equipment.* | WSBC 4.47-8, 4.50<br>CLSI QMS04-A2 7.11 | |
| SAF1.1.13 | **M** | The safety program includes procedures to protect personnel working alone or in isolation. | GOBC OHSR 4.20-4.23 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF1.1.14 | **M** | The safety program includes procedures to manage violent and aggressive behaviour. | GOBC OHSR 4.27-4.31 | |
| SAF1.1.15 | | The safety program includes strategies to encourage health and wellness, enhance workforce engagement, motivation and morale. | DAP15 | |
| **SAF1.2** | **Safety procedures are available for personnel.** | | | |
| SAF1.2.1 | **M** | Safety procedures and references are available in all work areas.<br>*Guidance: Safety procedures and references may be in the form of online documents or a hard copy manual.* | ISO 15190 7.4<br>CLSI GP17-A3 5.4 | REVISED |
| SAF1.2.7 | **M** | Safety procedures are reviewed at defined intervals by the laboratory director or designate (e.g. the laboratory safety representative, safety committee). | ISO 15190 7.2, 7.4 | REVISED |
| SAF1.2.8 | **M** | Personnel review the safety procedures when there are changes relevant to their scope of practice and at a defined frequency. | ISO 15190 7.4 | REVISED |

## SAF2.0 IDENTIFICATION OF HAZARDS

| SAF2.1 | There are procedures for safety inspections and audits. | | | |
|---|---|---|---|---|
| SAF2.1.1 | **M** | Safety inspections are conducted monthly.<br>*Guidance: Safety inspections are conducted at an interval that allows for timely reporting to the monthly joint occupational health and safety committee or health and safety representative. In addition, supervisory personnel are expected to continually inspect and correct any hazards immediately.* | WSBC LHSH | |
| SAF2.1.2 | **M** | Safety inspections assess firefighting equipment and alarms. Alarm systems are tested at a defined frequency. | ISO 15190 7.3.2, 9.3, 9.7 | |
| SAF2.1.3 | **M** | Safety inspections assess emergency showers, eyewash stations and the availability of procedures and materials for hazardous spills. | ISO 15190 7.3.2b | |
| SAF2.1.4 | **M** | Safety inspections assess storage and control of flammable, infectious, radioactive and toxic materials. | ISO 15190 7.3.2c | |
| SAF2.1.5 | **M** | Safety inspections assess decontamination and disposal procedures. | ISO 15190 7.3.2d | |
| SAF2.1.6 | **M** | The laboratory has defined safety audits of work methods or practices to identify and resolve safety hazards (e.g. hand hygiene, use of PPE, decontamination processes). | ISO 15190 – 7.5.3<br>CLSI GP17-A3 – 13.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF2.1.7 | The safety program includes an overall audit conducted at least annually.<br>*Guidance: The audit includes the following:*<br>• *health and safety policy*<br>• *safety education and training*<br>• *inspections*<br>• *health surveillance*<br>• *accident and illness investigation*<br>• *procedures containing safe work practices*<br>• *health and safety committee review*<br>• *hazardous materials*<br>• *first aid services and equipment*<br>• *records and statistics* | | ISO 15190 7.3.1 | REVISED<br>MOVED |
| **SAF2.2** | **There are procedures to report, investigate and follow up on safety related incidents.** | | | **REVISED** |
| SAF2.2.1 | **M** | There is a documented process to promptly investigate and report safety incidents, injury, accidents and occupational illness. Investigating personnel have received specific orientation and training. | ISO 15190 8, 9, 10<br>ISQua 4.4 | REVISED |
| SAF2.2.2 | **M** | Safety investigation processes maintain the confidentiality of individuals involved. | GOBC WCA Div 7 | |
| SAF2.2.3 | **M** | Safety investigation processes define required documentation including a detailed description of the incident, potential causes and assessment. | ISO 15190 9<br>ISQua 4.4 | |
| SAF2.2.4 | **M** | Safety investigation processes include a review or analysis (including root cause analysis) by laboratory management, the safety committee, or safety representative and recommendations for prevention of future incidents and actions taken. | ISO 15190 9<br>ISQua 4.4 | |
| SAF2.2.5 | **M** | Recommendations resulting from investigations are implemented and documented. | ISO 15190 9<br>ISQua 4.4 | |
| SAF2.2.6 | **M** | Incidents are reported to the proper authorities (e.g. WorkSafeBC, Health Canada) when required. | GOBC WCA Div 10 | |
| SAF2.2.7 | **M** | There is a defined process to report and respond to potential safety hazards. This is documented. | ISO 15190 8, 9<br>ISQua 4.4 | |
| SAF2.2.8 | **M** | Potential hazards to pregnant women are identified and a risk assessment is conducted. | ISO 15190 8<br>CLSI GP17-A3 4.1 | |

## SAF3.0 PROTECTION OF PERSONNEL

| | | | | |
|---|---|---|---|---|
| **SAF3.1** | **Specific safety orientation and training is provided for personnel.** | | | |
| SAF3.1.1 | **M** | Personnel have received orientation and training in injury prevention and the identification and reporting of safety incidents, injury, accidents and occupational illness at a frequency determined by the organization. | ISO 15190 8, 10<br>ISQua 4.4<br>CLSI GP17-A3 11 | REVISED |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF3.1.2 | **M** | The laboratory has defined the specific training required for new and current personnel to address potential workplace hazards. | ISO 15190 – 8<br>CLSI GP17-A3 11 | |
| SAF3.1.3 | **M** | There is a documented process to ensure that personnel understand safety information relevant to their role. | ISO 15190 – 10<br>CLSI GP17-A3 11 | |
| SAF3.1.4 | **M** | The Workplace Hazardous Materials Information System (WHMIS) training program is reviewed at least annually or more frequently if required by a change in work conditions or available hazard information. | GOBC OHSRR 5.5 | |
| SAF3.1.6 | **M** | Personnel safety training records are retained according to organizational retention requirements. | ISO 15190 7.5.2<br>CLSIS GP17-A3 12.2 | |
| SAF3.1.7 | **M** | Laboratory personnel are provided with instruction and training on the recognition and evaluation of fire hazards, reducing the risk of fire and actions to take when fires occur at a frequency determined by the organization. | ISO 15190 19.6 | REVISED |
| SAF3.1.8 | **M** | Laboratory personnel understand their primary responsibility is to ensure safety by orderly evacuation, rather than attempting to extinguish fires. | ISO 15190 19.7 | |
| SAF3.1.9 | **M** | Personnel are aware of the location of firefighting equipment in the area and understand its use. | ISO 15190 19.7 | |
| SAF3.1.10 | **M** | Personnel have received orientation and training on infection prevention, control, and reporting (e.g. routine precautions, sharps handling, needle stick injury protocol, personal protective equipment) at a frequency determined by the organization. | ISO 15189 5.1.5d | REVISED<br>MOVED |
| SAF3.1.11 | | Laboratory personnel receive health and safety orientation and training for workplace hazardous materials information system (WHMIS) and other safety requirements at a frequency determined by the organization. | DAP15 ver1.0<br>ORG4.7.1 | REVISED<br>MOVED |
| **SAF3.2** | **The use of personal protective equipment (PPE) and other safety devices is defined.** | | | |
| SAF3.2.1 | **M** | PPE appropriate to the level of risk for the tasks performed is available | ISO 15190 12.1-12.6<br>CLSI GP17-A3 5.2 | REVISED |
| SAF3.2.2 | **M** | There are guidelines for the use of PPE and other safety equipment, appropriate to the level of risk for the tasks performed. | ISO 15190 10<br>CLSI GP17-A3 5.2 | |
| SAF3.2.3 | **M** | PPE is removed prior to leaving the laboratory and changed immediately when contaminated with hazardous or biohazardous materials. | ISO 15190 12.1 | |
| SAF3.2.4 | **M** | Long-sleeved fluid-resistant gowns that are closed at the front and neck are worn when working with biological and chemical hazardous materials. | ISO 15190 12.1<br>CLSI GP17-A3 5.2.2 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF3.2.5 | **M** | Protective gowns and coats worn in the laboratory are not used outside of the laboratory (e.g. for collecting samples). | ISO 15190 12.2<br>CLSI GP17-A3 5.2.2 | |
| SAF3.2.6 | **M** | Clean, in use, and soiled laboratory garments are kept separate. | ISO 15190 12.1<br>CLSI GP17-A3 5.2.2 | |
| SAF3.2.7 | **M** | Goggles, face shields, splashguards or other containment devices are used when there is potential for contact with blood and body fluids (e.g. uncapping sample tubes, aliquoting). | ISO 15190 12.3, 15<br>CLSI GP17-A3 5.1.2, 5.2.3, | |
| SAF3.2.8 | **M** | Gloves are worn during routine collection of blood samples, and when there is the potential for exposure to blood or body fluids. | ISO 15190 12.4<br>CLSI GP17-A3 5.2.4 | |
| SAF3.2.9 | **M** | Gloves are changed between patients. | ISO 15190 12.4<br>CLSI GP17-A3 5.2.4 | |
| SAF3.2.10 | **M** | Gloves are removed prior to handling non-contaminated items. | ISO 15190 12.4<br>CLSI GP17-A3 5.2.4 | |
| SAF3.2.11 | **M** | Gloves (other than heavy-duty gloves used for tasks such as wash-up) are not re-used. | ISO 15190 12.4<br>CLSI GP17-A3 5.2.4 | |
| SAF3.2.12 | **M** | Laboratory personnel wear non-slip footwear with closed toes and heels. | ISO 15190 12.5<br>CLSI GP17-A3 5.2.5 | |
| **SAF3.3** | **There are guidelines for the use of respiratory protection devices and reducing exposure to infectious aerosols.** | | | |
| SAF3.3.1 | **M** | There is a documented process for risk assessment and subsequent use of respirators or masks. | ISO 15190 12.6<br>CLSI GP17-A3 5.2.6 | |
| SAF3.3.2 | **M** | N95 masks are available and additional precautions are implemented (e.g. expedited procedures, separate waiting area) when there is a known or suspected patient with a communicable disease spread by airborne transmission (e.g. measles, varicella, influenza). | ISO 15190 12.6<br>WSBC PFID | |
| SAF3.3.3 | | Additional precautions (e.g. expedited procedures, separate waiting area, protective masks) are implemented when patients have a known or suspected communicable disease. | WSBC PFID | |
| SAF3.3.4 | **M** | Appropriate respirators are available when required (e.g. spill control). | ISO 15190 12.6<br>CLSI GP17-A3 5.2.6 | |
| SAF3.3.5 | **M** | Fit testing of respirators and masks is performed annually and documented. | ISO 15190 12.6<br>CLSI GP17-A3 5.2.6 | |
| **SAF3.4** | **There are guidelines for hand washing.** | | | |
| | | *Guidance: Alcohol-based hand-cleansing products are an acceptable alternative to traditional hand washing except when hands are visibly dirty or contaminated with potentially infectious material.* | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF3.4.1 | **M** | The laboratory ensures that personnel and visitors (e.g. vendors, service personnel) wash their hands prior to leaving the laboratory. | ISO 15190 12.7<br>CLSI GP17-A3 5.3.1 | |
| SAF3.4.2 | **M** | The laboratory ensures that personnel wash their hands prior to and after contact with each patient. | ISO 15190 12.7<br>CLSI GP17-A3 5.3.1 | REVISED |
| SAF3.4.3 | **M** | The laboratory ensures that personnel wash their hands after contact or potential contact with blood, body fluids or other contaminated material. | ISO 15190 12.7<br>CLSI GP17-A3 5.3.1 | REVISED |
| SAF3.4.4 | **M** | The laboratory ensures that personnel wash their hands immediately after removing gloves or prior to putting on gloves. | ISO 15190 12.7<br>CLSI GP17-A3 5.3.1 | REVISED |
| **SAF3.5** | **First aid services are available.** | | | |
| SAF3.5.1 | **M** | First aid services and resources available onsite are in compliance with British Columbia Occupational Health and Safety Regulations.<br>*Guidance: Detailed tables specifying the first aid requirements are found in the Occupational Health and Safety Regulation at the end of Part 3 (Schedule 3.A, Minimum Levels of First Aid). It must be noted that medical facilities are NOT exempt from these requirements. Medical facilities may have personnel take the appropriate occupational first aid course but some leeway is provided to allow for existing qualification to be considered equivalent.* | ISO 15190 12.9<br>CLSI GP17-A3 5.4.3<br>GOBC OHSR OFA1<br>GOBC OHSR Part 3 | |
| SAF3.5.2 | **M** | First aid attendants have access to material safety data sheets (MSDS) information for controlled substances used within the facility. | GOBC WCB-WCM Ch 5 | |
| SAF3.5.3 | **M** | Personnel know how to access first aid in the workplace. All injuries are reported to first aid. | ISO 15190 12.8<br>CLSI GP17-A3 5.4.3 | REVISED |
| SAF3.5.5 | **M** | After blood and body fluid exposure, personnel have local first aid administered if required, followed by referral for medical assessment within two hours. | ISO 15190 12.8<br>CLSI GP17-A3 5.4.3 | |
| SAF3.5.6 | **M** | An incident investigation is completed for all personnel who have a potential or actual blood or body fluid exposure. | ISO 15190 –9<br>ISQua 4.4 | |
| **SAF3.6** | **Eyewash stations and emergency showers are available.** | | | |
| SAF3.6.1 | **M** | Eyewash stations are conveniently located. Eyewash stations are tested and flushed monthly. This is documented.<br>*Guidance: Emergency eyewash stations must provide a minimum of 15-minute supply of tempered water. Consult with WorkSafeBC to determine the type of eyewash station required based upon the corrosives and irritants used.* | GOBC OHSR 5.93<br>ISO 15190 12.10<br>CLSI GP17-A3 5.4.1<br>ISO 15189 5.2.2.e | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF3.6.2 | **M** | Emergency showers are available and conveniently located. Emergency showers are tested and flushed monthly. This is documented.<br>*Guidance: Facilities should perform a risk assessment to determine if emergency showers are required. An emergency shower will normally be located in each section of the laboratory in which corrosive chemicals are used.* | GOBC OHSR 5.93<br>ISO 15190 12.11<br>CLSI GP17-A3 5.4.2<br>ISO 15189 5.2.2.e | |
| **SAF3.7** | **There are procedures for cleaning and disinfecting laboratory surfaces.** | | | |
| SAF3.7.1 | **M** | Laboratory areas are clean, well maintained and free of obstructions and potential tripping hazards. | ISO 15189 5.2.6<br>ISO 15190 13<br>CSA Z316.7 7.7<br>CLSI GP17-A3 5.3.2 | REVISED |
| SAF3.7.2 | **M** | Changes in housekeeping practices are assessed to ensure that risks or hazards do not result from the change (e.g. a change in disinfectants, a change in the frequency of cleaning). | ISO 15190 13<br>CLSI GP17-A3 5.3.2 | |
| SAF3.7.3 | **M** | Changes in laboratory practices or materials are assessed for required changes to housekeeping or maintenance requirements with subsequent notification to housekeeping and maintenance personnel. | ISO 15190 13<br>CLSI GP17-A3 5.3.2 | |
| SAF3.7.4 | **M** | There are procedures indicating the frequency and method of environmental cleaning and disinfection. This is documented. | ISO 15190 13<br>CLSI GP17-A3 5.3.2 | |
| SAF3.7.5 | **M** | Work surfaces are decontaminated immediately after a spill or other contamination. | ISO 15190 13<br>CLSI GP17-A3 5.3.2 | |
| SAF3.7.7 | | Laboratory surfaces (e.g. bench tops, chairs) are chemical resistant, impermeable, durable and readily cleanable. | ISO 15190 6.2<br>CSA Z316.7 – 8.3.4 | |
| SAF3.7.8 | | Floor surfaces are slip resistant and easily cleanable. | ISO 15190 6.2<br>CSA Z316.7 – 8.3.4 | |
| **SAF3.8** | **There is an emergency evacuation plan.** | | | |
| SAF3.8.1 | **M** | Primary exit routes are designated and secondary exits (where applicable) are provided. | ISO 15190 9.1, 9.2 | |
| SAF3.8.2 | **M** | Emergency exits are well marked and provide unimpeded exit. | ISO 15190 6.3.7<br>CLSI GP17-A3 4.2 | |
| SAF3.8.3 | **M** | An action plan for emergency evacuation has been developed. | ISO 15190 20 | |
| SAF3.8.4 | **M** | All laboratory personnel participate in an emergency evacuation drill (e.g. fire drill) at least once per year.<br>*Guidance: Emergency evacuation drills include each area, each shift and all personnel of the laboratory.* | ISO 15190 20 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|

## SAF4.0 BIOHAZARD CONTAINMENT

| | | | | |
|---|---|---|---|---|
| **SAF4.1** | **There are procedures to reduce the risk of biohazard exposure.** | | | |
| SAF4.1.1 | **M** | Safety-engineered sharps are used. | WSBC PWFID | |
| SAF4.1.2 | **M** | Used sharps are disposed of immediately in designated puncture-resistant containers located in the immediate area. | ISO 15190 14<br>CLSI GP17-A3 5 | |
| SAF4.1.3 | **M** | Sharps containers are sealed and replaced when filled to the fill line and disposed of in accordance with current guidelines for waste management. | ISO 15190 14<br>CLSI GP17-A3 5 | REVISED |
| SAF4.1.4 | **M** | The laboratory has developed guidelines for the reuse or disposal of tourniquets (e.g. disposal after contact with non-intact skin, cleaning). | WHO BPP Sect 2.1.4 | |
| **SAF4.2** | **Biological safety cabinets (BSC) and other measures are used to protect personnel from aerosols.** | | | |
| SAF4.2.1 | **M** | The laboratory has performed a risk assessment and determined which procedures require the use of a BSC. | ISO 15190 16<br>CLSI GP17-A3 5.1.1 | |
| SAF4.2.2 | **M** | BSCs meet Health Canada guidelines for the tasks performed and the location, design, type and venting of the BSC is appropriate to the level of risk containment. | GOC LBG Chap 9<br>ISO 15190 16<br>CLSI GP17-A3 5.1.1 | |
| SAF4.2.3 | **M** | BSCs are certified on installation, after changing the HEPA filter, after movement of the unit, after any repair or maintenance that could affect the seal of the HEPA filter, and recertified annually. These certification records are retained. | ISO 15190 16<br>CLSI GP17-A3 5.1.1 | REVISED |
| SAF4.2.4 | **M** | BSCs are operated in a manner that ensures optimal conditions are maintained (e.g. proper sash height, clutter-free, free of grill obstructions). | ISO 15190 16<br>CLSI GP17-A3 5.1.1 | |
| SAF4.2.5 | **M** | BSCs are used for handling organisms considered highly contagious by airborne routes and for setting up samples that may potentially contain these organisms. | ISO 15190 16<br>CLSI GP17-A3 5.1.1 | |
| SAF4.2.6 | **M** | The airflow at the face of the BSC is monitored and recorded on each day of use.<br>*Guidance: Refer to the WorkSafeBC Laboratory Health and Safety Handbook for acceptable face velocities for different designs of BSC.* | ISO 15190 16<br>CLSI GP17-A3 5.1.1<br>WSBC LHSH | |
| SAF4.2.7 | **M** | BSC surfaces are decontaminated daily or immediately after use when the BSC is used less than daily. This is documented. | ISO 15190 16<br>CLSI GP17-A3 5.1.1 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF4.2.8 | **M** | Centrifuges have safety-capped cup or rotor enclosures that provide aerosol containment. | ISO 15190 15<br>CLSI GP17-A3 5.1.3<br>GOBC OHSR 30:13 (2) | |
| SAF4.2.9 | **M** | Samples are vortex-agitated in closed containers with secure lids. | ISO 15190 15<br>CLSI GP17-A3 5.1.3 | |
| SAF4.2.10 | **M** | Centrifuge lids or doors are locked when the motor is energized and remain locked until the centrifuge stops. | ISO 15190 15<br>CLSI GP17-A3 5.1.3 | |

## SAF5.0 CHEMICAL SAFETY

| SAF5.1 | There are procedures for the safe handling, use, storage and discard of chemicals. | | | |
|---|---|---|---|---|
| SAF5.1.1 | **M** | There are procedures for the handling, use and storage of chemicals in accordance with good laboratory practice. | ISO 15190 17.1<br>CLSI GP17-A3 6.3 | |
| SAF5.1.2 | **M** | Fume hood operation ensures optimal conditions are maintained (e.g. proper sash height, free of obstructions). | GOBC OHSR 30.8<br>CLSI GP17-A3 5.1.3 | |
| SAF5.1.3 | **M** | Fume hood face velocity is checked at least annually, after installation, after movement of the unit, and after any repair or maintenance that could affect the airflow of the hood. | GOBC OHSR 30.8 | |
| SAF5.1.4 | **M** | There is a review at a defined frequency, of reagents and chemicals used in the laboratory to ensure that any controlled substances stored in the laboratory are required. | ISO 15190 17.1<br>CLSI GP17-A3 6.3 | |
| SAF5.1.5 | **M** | Current MSDS are available for all controlled substances. | WSBC WHMIS Core Material – Chapter 5 | |
| SAF5.1.6 | **M** | All controlled substances are labeled in accordance with WHMIS information.<br>*Guidance: This applies to both the original supplier issued container and any secondary containers that have a workplace label.* | CLSI GP17-A3 6.3.2 | REVISED |
| SAF5.1.7 | **M** | Controlled substances are stored in accordance with MSDS information and any applicable requirements. | ISO 15189 5.2.3 | |
| SAF5.1.8 | **M** | Hazardous liquids such as acids or alkalis are stored below eye level. | ISO 15190 17.1<br>CLSI GP17-A3 6.3 | |
| SAF5.1.9 | **M** | Acids are stored in cabinets approved for acid storage and separate from alcohols. | CLSI GP17-A3 6.3 | |
| SAF5.1.10 | **M** | Bottle carriers are used for transporting glass bottles containing hazardous chemicals in excess of 500 mL. | CLSI GP17-A3 6.3 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF5.1.11 | | There are procedures for the safe disposal of chemical products used in the laboratory according to MSDS information and current guidelines for waste management. | ISO 15190 – 17.3<br>WSBC LHSH p11 | |
| **SAF5.2** | **Flammable liquids and gases are used and stored safely.** | | | |
| SAF5.2.1 | **M** | Containers for flammable liquids are kept as small as possible and closed when not in use. | ISO 15190 19.5 | |
| SAF5.2.2 | **M** | Flammable liquids and gases are stored only in approved cabinets. | ISO 15190 19.5<br>GOBC WCA 5.1 | |
| SAF5.2.3 | **M** | Flammable liquids and gases are kept away from heat and sources of ignition and used only in well ventilated areas. | ISO 15190 19.5 | REVISED |
| SAF5.2.4 | **M** | Refrigerated flammable liquids are stored only in explosion-proof refrigerators. | ISO 15190 19.5 | |
| SAF5.2.6 | **M** | Piped-in gas has an emergency shut-off valve and pipework in accordance with any regulations. | ISO 15190 19.5 | |
| SAF5.2.10 | **M** | Work involving the release of flammable vapor is conducted only in a fume hood. | ISO 15190 19.5 | |
| SAF5.2.11 | | Smoke or heat detectors and alarm systems are where flammable gases or liquids are used or stored. | ISO 15190 9.3 | |
| **SAF5.3** | **Compressed gases and cryogenic material are handled and stored safely.** | | | |
| SAF5.3.1 | **M** | Instructions are available for the use, ventilation, storage and transportation of compressed gases and cryogenic material (e.g. liquid nitrogen, dry ice). | ISO 15190 17.1<br>CLSI GP17-A3 8.3-8.4<br>WSBC LHSH p. 20 | |
| SAF5.3.2 | **M** | Gas cylinders are clearly labeled with contents and the content of the cylinder is the correct product for use in the system. | ISO 15190 17.1<br>CLSI GP17-A3 8.3 | |
| SAF5.3.3 | **M** | Cylinders are stored in an upright position, secured by a holder or device and protected from overhead hazards, high temperatures and other sources of damage. Cylinders not in use are shut off and capped. | ISO 15190 17.1<br>CLSI GP17-A3 8.3 | |
| SAF5.3.4 | **M** | Cylinder carts are used to move large cylinders and specifically designed cylinder holders are used to carry small cylinders. | ISO 15190 17.1<br>CLSI GP17-A3 8.3 | |
| SAF5.3.5 | **M** | A pressure-reducing regulator or device is used for all compressed gas cylinders. | ISO 15190 17.1<br>CLSI GP17-A3 8.3 | |
| **SAF5.4** | **There are procedures for the management of spills.** | | | |
| SAF5.4.1 | **M** | The laboratory has performed a risk assessment to determine the number and type of spill kits required and to determine if a spill control team is necessary. | CLSI GP17-A3 6.3.4<br>WSBC LHSH p32, p64 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF5.4.2 | **M** | Spill kit material, procedures and PPE, all appropriate for the type of the spill are available in clearly marked locations. | ISO 15190 – 17.2<br>CLSI GP17-A3 6.3.4<br>WSBC LHSH p32 | |
| SAF5.4.3 | **M** | MSDS information on specific spill clean-up procedures and PPE required is available. | CLSI GP17-A3 6.3.4 | |

## SAF6.0 RADIATION AND MICROWAVE SAFETY

| | | | | |
|---|---|---|---|---|
| **SAF6.1** | **Radioisotope examination complies with regulations and resources are defined.** | | | |
| SAF6.1.1 | **M** | The laboratory director has assessed the justification for, extent of, and location of proposed use of radioisotopes prior to use. | ISO 15190 18.1<br>CLSI GP17-A3 6.4 | |
| SAF6.1.2 | **M** | Laboratories meet the Canadian Nuclear Safety Commission (CNSC) requirements for the possession and use of radioisotopes. | ISO 15190 18.1 | |
| SAF6.1.3 | **M** | Laboratories possessing nuclear substances exceeding the exemption quantities have a licence granted by the CNSC. | ISO 15190 18.1 | |
| SAF6.1.4 | **M** | The laboratory has consulted with an authorized radiation safety officer or equivalent on radiation protection practices and relevant regulations. | ISO 15190 18.2 | |
| SAF6.1.5 | **M** | The laboratory has assigned responsibility for the design, implementation and maintenance of a radiation protection program including day-to-day radiation practices. | ISO 15190 18.2 | |
| **SAF6.2** | **There are procedures to ensure radiation safety.** | | | |
| SAF6.2.1 | **M** | There are procedures for the safe use and handling of radioisotopes. | CLSI GP17-A3 6.4 | |
| SAF6.2.2 | **M** | Laboratory personnel working with or having exposure to radioisotopes have been trained and comply with safety policies and procedures. | ISO 15190 18.1 | |
| SAF6.2.3 | **M** | Signage is posted on doors (dependent on the amount of radioisotope present). | CLSI GP17-A3 6.4 | |
| SAF6.2.4 | **M** | There are documented processes for monitoring radioactivity in the workplace (e.g. wipe tests, trigger levels). | ISO 15190 18.3<br>CLSI GP17-A3 6.4 | |
| SAF6.2.5 | **M** | Routine cleaning and decontamination of areas where radioactive materials are used is defined and documented. | ISO 15190 18.3 | |
| SAF6.2.6 | **M** | The laboratory reviews the use of radioisotopes, monitors radioisotope work practices at a defined interval and implements remedial or permanent changes as required. This review is documented. | ISO 15190 18.3 | |
| SAF6.2.7 | **M** | There are records of radioisotope receipt, use and disposal. | ISO 15190 18.1 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF6.2.8 | **M** | There are documented emergency procedures (e.g. spill clean-up, requirements to report accidents and exposure to the CNSC). | CLSI GP17-A3 6.4 | |
| **SAF6.3** | **There are procedures for storage and disposal of radioactive waste.** | | | |
| SAF6.3.1 | **M** | There are procedures for the safe disposal of unused radioactive materials and materials that have been mixed with or contaminated by radioactive materials. | CLSI GP17-A3 6.4 | |
| SAF6.3.2 | **M** | Procedures for storage and disposal of radioactive waste comply with legislation, local requirements, and good practice. | ISO 15190 18.3<br>CLSI GP17-A3 6.4 | |
| SAF6.3.3 | **M** | Radioactive waste is labeled with the isotope(s) and the amount of radioactivity. | ISO 15190 18.3<br>CLSI GP17-A3 6.4 | |
| SAF6.3.4 | **M** | Labels are present on all containers of radioisotopes, radiopharmaceuticals and waste containers. | CLSI GP17-A3 6.4 | |
| SAF6.3.5 | **M** | Radioactive material storage and decay areas are locked when not under the supervision of laboratory personnel designated to handle radioisotopes. | ISO 15190 18.1 | |
| SAF6.3.6 | **M** | Radioactive material is stored in a secure and dedicated, shielded area. | ISO 15190 18.3<br>CLSI GP17-A3 6.4 | |
| SAF6.3.7 | **M** | The disposal of radioactive waste is documented. | ISO 15190 18.3<br>CLSI GP17-A3 6.4 | |
| **SAF6.5** | **There are procedures for the safe use of microwave equipment.** | | | |
| SAF6.5.1 | **M** | All containers used in microwave devices are vented. | ISO 15190 18.5 | |
| SAF6.5.2 | **M** | Microwave devices are checked for radiation leakage if there has been damage to the door or internal mechanism. | ISO 15190 18.5 | |
| SAF6.5.3 | | If high-powered microwave and radio-wave devices merit additional precautions, extra shields and protective covers are provided. | ISO 15190 18.5 | |
| SAF6.5.4 | | The possibility of interference with other pieces of equipment is considered when locating microwave devices. | ISO 15190 18.5 | |

## SAF7.0 ELECTRICAL SAFETY

| | | | | |
|---|---|---|---|---|
| **SAF7.1** | **Electrical equipment complies with safety regulations.** | | | |
| SAF7.1.1 | **M** | Electrical equipment complies with electrical safety regulations (e.g. Canadian Standards Association). | ISO 15190 21<br>CLSI GP17-A3 8.2 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SAF7.1.2 | **M** | New, modified or repaired equipment is not placed into service until electrical safety has been verified by qualified personnel. | ISO 15190 21 | |
| SAF7.1.3 | **M** | Electrical equipment is maintained in safe working condition. | ISO 15189 5.3.1.5<br>CLSI GP17-A3 8.2 | |
| SAF7.1.4 | **M** | Electrical outlets are grounded. | CLSI GP17-A3 8.2.1 | |
| SAF7.1.5 | | Breaker panels have a directory index identifying the receptacles, general area or equipment serviced by each breaker. | DAP15v1.0 | |

## SAF9.0 WASTE DISPOSAL

| **SAF9.1** | **There are procedures for waste disposal.** | | | |
|---|---|---|---|---|
| SAF9.1.1 | **M** | Waste disposal practices are consistent with current recommendations for waste management and minimize hazards to personnel and harmful effects to the environment. | ISO 15190 23<br>CLSI GP05-A3 | REVISED |
| SAF9.1.3 | **M** | Hazardous waste is handled by trained personnel using appropriate PPE. | ISO 15190 23 | |
| SAF9.1.4 | **M** | Waste containers are not over-filled. | ISO 15190 23 | |
| SAF9.1.5 | **M** | All biological material is discarded in specific containers for disposal of hazardous waste. | ISO 15190 23 | |
| SAF9.1.8 | **M** | Autoclave function is monitored at least weekly using a biological indicator (or a chemical equivalent). | CLSI GP05-A3 10.6.2.2 | |
| SAF9.1.9 | **M** | Waste for incineration is sent to an approved facility. | ISO 15190 23 | |

## SAF10.0 PATIENT SAFETY AND RIGHTS

| **SAF10.1** | **There are procedures to addresses patient safety issues.** | | | |
|---|---|---|---|---|
| SAF10.1.1 | **M** | Documented processes are available for personnel to identify, provide feedback and communicate openly about patient safety issues and concerns. | ISQua 4.4 | |
| SAF10.1.2 | **M** | There is a documented process for patients and their advocates to report patient safety concerns. | ISQua 4.4 | |
| SAF10.1.3 | **M** | Patient safety notices, alerts and other information is communicated. | ISQua 4.4 | |
| SAF10.1.4 | **M** | Documented processes address patient sensitivities and allergies. | | |
| SAF10.1.5 | **M** | All patient safety issues are documented and investigated. | ISQua 4.4 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **SAF10.2** | **A risk analysis has been performed to determine if any laboratory activities require application of a universal protocol.** | | | |
| SAF10.2.1 | **M** | If the laboratory has determined that there are activities that require application of the universal protocol, there is a documented policy and procedure for verification of patient identification, marking the procedure site and a time out (final verification) as appropriate.<br>*Guidance: The policy should clearly specify the activities that are subject to the universal protocol.* | ISQua 4.8 4 | |
| SAF10.2.2 | **M** | Personnel are provided with orientation and training on how and when to conduct the universal protocol if appropriate. | ISQua 4.8 4 | |
| **SAF10.3** | **There are procedures to ensure safe and effective administration of medications to patients.** | | | |
| SAF10.3.1 | **M** | The laboratory has identified any laboratory procedures that use medications.<br>*Guidance: There are rare occurrences of medication use in the laboratory, most commonly the use of local anesthetic when collecting samples such as bone marrow aspirates and fine needle aspirates.* | ISQua 4.3i<br>ISQua 4.8 1 | |
| SAF10.3.2 | **M** | All medications are labeled with the medication name, strength and expiration date. | DAP15 | |
| SAF10.3.3 | **M** | Only medical practitioners and authorized personnel obtain and administer medication. | DAP15 | |
| SAF10.3.4 | **M** | Patient identity is verified prior to medication administration. | DAP15 | |
| SAF10.3.5 | **M** | There is a documented process to ensure that the individual administering the medication verifies that no contraindications exist prior to administration. | DAP15 | |
| SAF10.3.6 | **M** | Patients are monitored for any potential side effects and adverse reactions resulting from medication administration. | DAP15 | |
| SAF10.3.7 | **M** | Personnel know how to respond to significant drug reactions and medication errors. | DAP15 | |
| SAF10.3.8 | **M** | Policies and procedures ensure the safety of patients prior to release after the administration of medications. | DAP15 | |
| **SAF10.4** | **Patient rights are communicated to patients and personnel.** | | | |
| SAF10.4.1 | | Personnel have been provided with training on and are aware of the rights of patients.<br>*Guidance: Patient rights include privacy, dignity and respect, personal safety and security, consent and the right to refuse laboratory services.* | ISQua 5.1 | REVISED |
| SAF10.4.2 | | Patients are informed of their rights. | ISQua 5.1 | |

# FACILITIES

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **FAC1.0** | | **SPACE DESIGN AND ALLOCATION** | | |
| **FAC1.1** | | **Facilities meet the needs of personnel.** | | |
| FAC1.1.1 | **M** | There is access to washrooms, a supply of drinking water and secure storage of personal belongings and clothing. | ISO 15189 5.2.4 | |
| FAC1.1.2 | | Personnel washrooms are conveniently located and separate from patient washrooms.<br>*Guidance: Separate male and female washrooms are provided when there are more than nine personnel.* | WSBC Guideline G4.85(1)-1 | |
| FAC1.1.3 | | A separate and comfortable location to rest is available for personnel during break times. | ISO 15189 5.2.4 | |
| FAC1.1.4 | **M** | Ambient temperature and humidity is controlled. | ISO 15190 6.3.2-3 | |
| FAC1.1.5 | **M** | Equipment with the potential to generate exhaust fumes or emit or generate excessive heat, steam or odor is isolated from the general workspace, or arrangements are provided for personnel comfort. | ISO 15190 6.3.3<br>CLSI GP17-A3 4.2.4 | |
| FAC1.1.6 | | Ventilation is provided where unpleasant or noxious odors could arise. | ISO 15190 6.3.3<br>CLSI GP17-A3 4.2.4 | |
| FAC1.1.8 | | There are processes to address excessive noise levels in the laboratory. | ISO 15190 6.3.4<br>CLSI GP17-A3 5.8.1 | |
| FAC1.1.9 | | The selection and location of equipment takes cumulative noise levels into consideration. | CLSI QMS01-A4 5.6.2 | |
| **FAC1.2** | | **The design and layout of the laboratory supports efficient service delivery.** | | |
| FAC1.2.1 | **M** | All laboratory work is performed in areas that are designed to ensure the health and safety of laboratory personnel, patients and visitors as well as ensuring the quality, safety and efficacy of the laboratory services provided. This includes primary sample collection areas and locations other than the main laboratory premises. | ISO 15189 5.2.1 | REVISED |
| FAC1.2.3 | **M** | Utilities are located to optimize the workload including electrical outlets, designated emergency outlets, gas, water and sinks. | ISO 15189 5.2.2.c | |
| FAC1.2.4 | **M** | The laboratory has identified equipment that requires an uninterrupted power supply (UPS) or other mechanism (e.g. emergency power). | CLSI QMS13-A 6.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| FAC1.2.5 | **M** | The UPS or other mechanism has been tested as specified by the manufacturer or by another approved process. | CLSI QMS13-A 6.1 | |
| FAC1.2.6 | | In the event of laboratory redesign, renovation or reorganization, operational efficiency and optimization is not compromised. | DAP15 | |
| FAC1.2.7 | **M** | There is space to allow unobstructed movement, safe working conditions, and access for maintenance and service personnel. | ISO 15189 5.3.1.5<br>ISO 15190 6.2<br>CLSI QMS01-A4 5.3.1.1 | REVISED |
| FAC1.2.9 | **M** | Laboratory communication systems allow for the efficient transfer of information.<br>*Guidance: This includes telephones, email, paging and intercom.* | ISO 15189 5.2.2d<br>CAP GEN.61750<br>CAP GEN.61800 | REVISED |
| FAC1.2.10 | | Monitors are protected from glare and reflections. | ISO 15189 5.2.6<br>ISO 15190 6.3.1 | |
| FAC1.2.11 | **M** | There is effective separation between laboratory sections in which there are incompatible activities (e.g. clear delineation between clean and dirty areas). | ISO 15189 5.2.6<br>CLSI QMS01-A4 5.3.1.1 | |
| FAC1.2.12 | **M** | There are procedures to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated (e.g. tissue culture, molecular testing). | ISO 15189 5.2.6<br>CLSI QMS01-A4 5.3.1.1 | |
| FAC1.2.13 | **M** | The laboratory monitors, records, and controls (as required by relevant specifications) environmental conditions that may influence the quality of the sample or examinations, including:<br>• temperature<br>• humidity<br>• sterility<br>• ventilation, hazardous fumes<br>• dust<br>• vibration<br>• electromagnetic interference<br>• electrical supply<br>• radiation<br>• any other factor(s) that may invalidate examination results or adversely affect the required quality of any examination | ISO 15189 5.2.6 | MOVED |
| FAC1.2.14 | **M** | A quiet work environment is provided where needed (e.g. cytopathology screening, data analysis of sequencing reactions). | ISO 15189 5.2.6 | MOVED |
| **FAC1.3** | **The design and layout of the laboratory ensures safe delivery of services.** | | | |
| FAC1.3.1 | **M** | The design and layout of the physical space in new construction meets laws, regulations and codes. | ISO 15190 6.1<br>CLSI QMS01-A4 5.3.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| FAC1.3.2 | | A professional engineer has attested that new construction or structural changes meet the minimum CSA Standards. | CLSI GP17-A3 4.2 | |
| FAC1.3.3 | **M** | Facilitation and cooperation with external inspection authorities occurs (e.g. fire marshal, WorkSafeBC, building inspectors). | GOBC BPFC | |
| FAC1.3.4 | **M** | Records of inspections and any issued orders are maintained.<br>*Guidance: Facilities maintain copies of permits, licences and records of inspection.* | GOBC BPFC | |
| FAC1.3.5 | **M** | Laboratory design ensures containment of physical, microbiological, chemical, and radiological hazards relative to the level of assessed risk. | ISO 15190 6.2<br>CLSI GP17-A3 4.3.2 | |
| FAC1.3.10 | **M** | There are safety features (e.g. emergency release or intercom and alarm systems for cold rooms, walk-in freezers) and their function is verified at a defined interval. This is documented. | ISO 15189 5.2.2.e | |
| FAC1.3.11 | **M** | Illumination provides for safe working conditions. Emergency lighting is available in the event of power failure. | WSBC 4.65-1, 69-1<br>CLSI GP17-A2 4.2.2 | |
| **FAC1.4** | **Dedicated hand washing sinks are identified.** | | | |
| FAC1.4.1 | **M** | There are dedicated and clearly designated hand washing sinks in all areas where there is potential for contact with biological or hazardous materials. | ISO 15190 6.2<br>CLSI GP17-A3 4.2.1 | |
| FAC1.4.2 | **M** | There is unimpeded access to hand washing sinks. Sinks have unimpeded drainage. | ISO 15190 6.2 | |

## FAC2.0 SAMPLE COLLECTION AREAS

| **FAC2.1** | **Patient sample collection facilities meet patient needs.** | | | |
|---|---|---|---|---|
| FAC2.1.1 | **M** | Clear signage is used to direct patients to the laboratory. | DAP15 | |
| FAC2.1.2 | **M** | Facilities allow that sample collection is performed in a manner that does not invalidate the results or adversely affect the quality of the examination. | ISO 15189 5.2.5<br>CLSI QMS01-A4 5.3.1.1 | |
| FAC2.1.3 | **M** | Consideration is given to patient comfort, needs (e.g. disabled access, toilet facility) and privacy.<br>*Guidance: Patient privacy is not compromised during the diagnostic procedure. Confidential or sensitive information is collected from and communicated to patients in an area that does not compromise their privacy. Telephone consultations involving the exchange of patient information are conducted in a private location.* | ISO 15189 5.2.5<br>CSA Z316.7 6.3.2, 6.4, 7.7.11<br>ISQua 5.6b | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| FAC2.1.4 | | Consideration is given to the accommodation of accompanying persons (e.g. guardian or interpreter) during sample collection. | ISO 15189 5.2.5 | |
| FAC2.1.5 | | Multi-lingual personnel are identified and available when required. | CSA Z316.7 6.2.2 | REVISED |
| FAC2.1.6 | | Cultural sensitivities of patients and clients are acknowledged and respected without compromising quality or safety. | CSA Z316.7 6.3.2<br>ISQua 5.5 | |
| FAC2.1.7 | **M** | Patient areas are safe, clean and private. | CSA Z316.7 7.1 | |
| FAC2.1.8 | | Patient washrooms are clean, conveniently located and accessible. | CSA Z316.7 7.3 | |
| FAC2.1.9 | | Temperature, humidity, lighting, noise level and air quality are controlled for patient comfort. | CSA Z316.7 7.9 | |
| FAC2.1.10 | **M** | There is clear separation of sample collection areas from the sample reception, reception/waiting areas and the administrative/analytic areas of the laboratory. | ISO 15189 5.2.5 | |
| FAC2.1.11 | **M** | Sample collection facilities maintain first aid materials for both patient and personnel needs.<br>*Guidance: See SAF3.5.1.* | ISO 15189 5.2.5<br>CSA Z316.7 6.5.1 | REVISED |

## FAC4.0 ACCESS CONTROL AND STORAGE

| FAC4.1 | | Laboratory areas, resources and data are protected from unauthorized access. | | |
|---|---|---|---|---|
| FAC4.1.1 | **M** | Areas of the laboratory that are restricted are clearly identified with signage indicating restricted access (e.g. authorized personnel only). | ISO 15190 6.3.7<br>CLSI GP17-A3 4.3 | |
| FAC4.1.2 | **M** | Signage is posted indicating areas of hazard (e.g. biohazard, radioactivity).<br>*Guidance: Signage may be subject to regulation (e.g. radioactive material). Internationally approved signage is preferred if available.* | ISO 15190 6.3.7<br>CLSI GP17-A3 4.3 | |
| FAC4.1.3 | **M** | Access to areas affecting the quality of examinations is controlled. | ISO 15189 5.2.2a | |
| FAC4.1.4 | | Lockable doors are provided, where it is necessary to further restrict entry.<br>*Guidance: Lockable doors must not prevent exit in an emergency.* | ISO 15190 6.3.8<br>CLSI GP17-A3 4.4 | |
| FAC4.1.5 | **M** | Medical information and laboratory resources are safeguarded from unauthorized access. | ISO 15189 5.2.2b | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| FAC4.1.6 | **M** | Security measures relative to the threat of theft and tampering with biological agents, samples, drugs, chemicals and confidential information have been established. | ISO 15190 6.3.8<br>CLSI GP17-A3 4.4 | |
| FAC4.1.7 | **M** | Samples are stored in a secured location.<br>*Guidance: Samples stored within the confines of the laboratory are considered secure. Samples stored in unlocked conditions outside the laboratory (e.g. in an unlocked freezer in a public hallway) are not considered secure.* | ISO 15190 6.3.8<br>CLSI GP17-A3 4.4 | |
| FAC4.1.8 | **M** | Associated office facilities safeguard information. | ISO 15189 5.2.2 | |
| **FAC4.2** | **There is controlled storage space.** | | | **REVISED** |
| FAC4.2.1 | **M** | Storage space and conditions ensure the continuing integrity of sample materials documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results. | ISO 15189 5.2.3<br>CLSI QMS01-A4 5.3.1.2 | |
| FAC4.2.2 | **M** | Stored samples can be easily retrieved. | CLSI QMS01-A4 5.3.1.2 | |
| FAC4.2.3 | **M** | Samples and materials used in examination processes are stored to prevent cross contamination. | ISO 15189 5.2.3<br>CLSI QMS01-A4 5.3.1.2 | |
| FAC4.2.4 | | The laboratory has determined the requirements for sample and reagent storage space and conditions, and ensures that the criteria are met. | CLSI QMS01-A4 5.3.1.2 | |

# EQUIPMENT AND SUPPLIES

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| **ERS1.0** | **ACQUISITION AND MANAGEMENT** | | | |
| **ERS1.1** | **There are procedures for acquisition and management of laboratory materials.** | | | |
| ERS1.1.1 | **M** | There are procedures for the selection, purchasing and management of supplies and equipment. | ISO 15189 5.3.1.1<br>ISO 15189 5.3.2.1<br>CLSI QMS13-A 5.1 | |
| ERS1.1.2 | **M** | The laboratory selects and approves suppliers using established criteria based on the suppliers' ability to provide external services, equipment, reagents and consumables in accordance with the laboratory's requirements. | ISO 15189 4.6<br>CLSI QMS01-A4 5.5.1 | REVISED |
| ERS1.1.3 | **M** | A list of selected and approved suppliers is maintained. | ISO 15189 4.6<br>CLSI QMS01-A4 5.5.2.4 | REVISED |
| ERS1.1.4 | **M** | The performance of suppliers is monitored to ensure that purchased services or items meet stated criteria. | ISO 15189 4.6<br>CLSI QMS01-A4 5.5.3 | |
| ERS1.1.5 | **M** | In those cases where the laboratory needs to use equipment outside its permanent control, the laboratory ensures that all requirements to fulfill the quality and safety of the service are met. | ISO 15189 5.3.1.1 | |
| ERS1.1.6 | **M** | Equipment is replaced as needed to ensure the quality of examinations. | ISO 15189 5.3.1.1 | |

## ERS2.0 REAGENTS AND CONSUMABLES

| | | | | |
|---|---|---|---|---|
| **ERS2.1** | **The quality of water is suitable for examinations.** | | | |
| ERS2.1.1 | **M** | Water quality is defined for each examination, when required. | CLSI GP40-A4-AMD 4.4 | |
| ERS2.1.2 | **M** | Water quality is tested at defined intervals.<br>*Guidance: A manufacturer's certificate of quality is acceptable for purchased water.* | CLSI GP40-A4-AMD 5.1, 5.2<br>CAP GEN.41500 | REVISED |
| **ERS2.2** | **There are procedures for the management of consumables.** | | | |
| ERS2.2.1 | **M** | There is a procedure for the receipt, storage, acceptance testing and inventory management of reagents and consumables. | ISO 15189 5.3.2.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ERS2.2.2 | **M** | Where the laboratory is not the receiving facility, it has verified that the receiving location has storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration. | ISO 15189 5.3.2.2 | REVISED |
| ERS2.2.3 | **M** | Consumables are inspected upon receipt in the laboratory and assessed according to established acceptance criteria. | CLSI QMS 01-A4 5.5.4 | |
| ERS2.2.4 | **M** | The laboratory has established an inventory control system for reagents and consumables. | ISO 15189 5.3.2.4<br>CLSI QMS 01-A4 5.5.6 | |
| ERS2.2.5 | **M** | Uninspected and unacceptable reagents and consumables are individually segregated from those that have been accepted for use. | ISO 15189 5.3.2.4<br>CLSI QMS 01-A4 5.5.6 | |
| ERS2.2.6 | **M** | Consumables are stored in accordance with manufacturer's specifications. | ISO 15189 5.3.2.2 | |
| ERS2.2.7 | **M** | Expiry dates are monitored. | CLSI QMS 01-A4 5.5.6 | |
| ERS2.2.8 | **M** | Rejected or expired materials are clearly marked. There is a documented process to deal with rejected or expired materials. | | |
| ERS2.2.9 | **M** | Consumables that can affect the quality of examinations are verified for performance prior to use. | ISO 15189 5.3.2.3 | |
| ERS2.2.10 | **M** | Procedures define alternate storage when storage equipment is defective or malfunctioning. | CSTM 3.1.9 | |
| ERS2.2.11 | **M** | The temperature is monitored where reagents are stored at room temperature.<br>*Guidance: Temperature monitoring need not be performed in situations where an assessment has determined there is a low risk of the ambient temperature falling outside the manufacturer's suggested storage temperature range.* | CLSI QMS 01-A4 5.5.5 | REVISED |
| ERS2.2.12 | **M** | Adverse incidents and accidents that can be attributed directly to specific reagents or consumables are investigated and reported to the manufacturer and appropriate authorities, as required. | ISO 15189 5.3.2.6 | |
| ERS2.2.13 | | There is a documented process for the management of vendor notifications of defects or issues with supplies that have the potential to affect examination results or laboratory services. | CLSI QMS01-A4 5.5.1<br>CLSI QMS13-A | |
| ERS2.2.14 | | The laboratory has evaluated its sample containers prior to purchase to ensure that they do not contribute to examination interference. | CLSI GP34-A 5.3 | |
| **ERS2.3** | **There are records of reagents and consumables.** | | | |
| | | There are records for each reagent and consumable that contributes to the performance of examinations including: | | |
| ERS2.3.1 | **M** | • identity and lot or batch number | ISO 15189 5.3.2.7a, b | |

| No. | Standard / Criterion | | Reference | Change |
|---|---|---|---|---|
| ERS2.3.2 | **M** | • manufacturer or supplier with contact information | ISO 15189 5.3.2.7b,c | |
| ERS2.3.3 | **M** | • date of receipt, the condition when received and date put into service | ISO 15189 5.3.2.7d,e | |
| ERS2.3.4 | **M** | • expiry date and where applicable, date material taken out of service | ISO 15189 5.3.2.7d | |
| ERS2.3.5 | **M** | • confirmation of acceptance for use and associated performance records | ISO 15189 5.3.2.7g, h | |
| ERS2.3.6 | **M** | • date of preparation and identification of personnel who prepared reagents | ISO 15189 5.3.2.7 | |
| ERS2.3.7 | **M** | Records of reagents and consumables are retained and are available. | CLSI QMS 01-A4 5.6.6 | |
| ERS2.3.8 | **M** | Instructions for the use of reagents and consumables, including those provided by the manufacturer, are readily available. | ISO 15189 5.3.2.7f<br>ISO 15189 5.3.2.5 | |
| **ERS2.4** | **All reagents are labeled.** | | | |
| ERS2.4.1 | **M** | All reagents are labeled with date of preparation or reconstitution where applicable. | CAP COM.30300 | |
| ERS2.4.2 | **M** | All reagents are labeled with content. | CAP COM.30300 | |
| ERS2.4.3 | **M** | All reagents are labeled with expiry date. | CAP COM.30300 | |
| ERS2.4.4 | **M** | An expiration date is assigned to any reagents that do not have a manufacturer provided expiration date.<br>*Guidance: Assigned expiration dates are based on known stability, frequency of use, storage conditions and risk of contamination.* | CAP ANP.21382 | |
| ERS2.4.5 | **M** | All reagents are labeled with quantity, concentration or titre where applicable. | CAP COM.30300 | |
| ERS2.4.6 | **M** | All reagents are labeled with storage requirements where applicable. | CAP COM.30300 | |
| ERS2.4.7 | **M** | All reagents are labeled with WHMIS information where applicable. | GOBC OHSR Sect 5 | |

## ERS3.0 CALIBRATION AND VERIFICATION

| | | | | |
|---|---|---|---|---|
| **ERS3.1** | **There are procedures for the calibration of equipment.** | | | |
| ERS3.1.1 | **M** | There are procedures for the calibration of equipment. | ISO 15189 5.3.1.4<br>CLSI QMS13-A 7.1 | |
| ERS3.1.2 | **M** | Calibration is performed in compliance with the manufacturer's instructions, including minimum frequency, unless documented otherwise. | ISO 15189 5.3.1.4a<br>CLSI QMS13-A 7.1.1 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ERS3.1.3 | **M** | Calibration procedures are performed when a new reagent lot number is introduced, when major preventive maintenance is performed, or when a critical part that may influence examination performance is replaced. | CLSI QMS13-A 7.1.1 | |
| ERS3.1.4 | **M** | Calibration is done when other corrective action does not rectify trends, shifts or out-of-limit QC. | CLSI QMS13-A 7.1.3 | |
| ERS3.1.5 | **M** | Calibration procedures define the number, type and concentration of materials to be used. | CLSI QMS13-A 7.1.3 | |
| ERS3.1.6 | **M** | Calibration procedures record the metrological traceability of the calibration standard and the traceable calibration of the item of equipment. | ISO 15189 5.3.1.4b | |
| ERS3.1.7 | **M** | Calibration procedures verify the required measurement accuracy and the functioning of the measuring system at defined intervals. | ISO 15189 5.3.1.4c | |
| ERS3.1.8 | **M** | Calibration records include the status of calibration, the date of calibration and the lot numbers of calibrators. | ISO 15189 5.3.1.4d<br>ISO 15189 5.6.2 | |
| ERS3.1.9 | **M** | Calibration records are retained. | CLSI QMS13-A 7.1.5 | |
| ERS3.1.10 | **M** | All corrective actions taken when calibration results are not within established limits are recorded. | CLSI QMS13-A 7.1.5 | |
| ERS3.1.11 | **M** | Where calibrations give rise to a change in correction factors, the laboratory has procedures to ensure that previous and new correction factors are recorded. | ISO 15189 5.3.1.4e | |
| ERS3.1.12 | **M** | When calibration results deviate from acceptable limits, there are defined criteria for corrective action. | CLSI QMS13-A 7.1.3 | |
| ERS3.1.13 | **M** | There are safeguards to prevent adjustments or tampering of calibration data that might invalidate examination results. | ISO 15189 5.3.1.4f | |
| ERS3.1.14 | **M** | QC is run after calibration to ensure that the intended level of quality has been achieved. | CLSI QMS13-A 7.1 | |
| **ERS3.2** | **There are procedures for the verification of examination kit and equipment performance.** | | | |
| ERS3.2.1 | **M** | New lots or shipments of examination kits, and examination kits with changes in reagents or procedures are verified prior to use. | ISO 15189 5.3.2.3 | |
| ERS3.2.2 | **M** | Where there are multiple components of a reagent kit, the laboratory uses only components of those kits within the same lot number, unless otherwise specified by the manufacturer. | CAP COM.30500 | |
| ERS3.2.3 | **M** | Allowable exceptions for mixing kit components from different lots are defined and documented. | CAP COM.30500 | |
| ERS3.2.4 | **M** | Manufacturer performance claims for all equipment are verified prior to use. | ISO 15189 5.3.1.2<br>CLSI QMS13-A 6 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ERS3.2.5 | **M** | Performance criteria for each verification process are established. | CLSI QMS13-A 6 | |
| ERS3.2.6 | **M** | Equipment performance is verified according to any equipment verification plan or when indicated by performance. | CLSI QMS13-A 6 | |
| ERS3.2.7 | **M** | When equipment undergoes a significant move, service or modification, operational parameters are verified according to a documented process before reentry into service. | CLSI QMS13-A 6 | |
| ERS3.2.8 | **M** | There is a documented process to verify the operation of replacement instruments (temporary or otherwise). | CLSI QMS13-A 6 | |
| **ERS3.3** | **There are procedures for temperature monitoring of equipment and corrective activity.** | | | |
| ERS3.3.1 | **M** | There are procedures for monitoring and documenting temperature data.<br>*Guidance: This excludes blood product and component storage equipment. See TRM5.2.* | CAP GEN.41042 | |
| ERS3.3.2 | **M** | Acceptable temperature ranges are defined for instruments and equipment. | CAP COM.30775 | REVISED |
| ERS3.3.3 | **M** | There are procedures for performing and recording corrective action when temperatures deviate from the acceptable range. | CAP COM.30800 | |
| ERS3.3.4 | **M** | The temperature of heating and refrigeration equipment is monitored daily or on day of use.<br>*Guidance: Where daily monitoring is not practical there is a documented process to provide for retroactive monitoring (e.g. min/max thermometers).* | CAP COM.30750 | |
| ERS3.3.5 | **M** | The laboratory has assessed that the temperature does not fluctuate beyond allowable, defined limits in areas of refrigerators and freezers where temperatures are prone to fluctuation (e.g. self-defrosting freezers, refrigerator doors). | DAP15 | |
| ERS3.3.6 | **M** | The laboratory has identified where recording devices and alarm systems are used. | DAP15 | |
| ERS3.3.7 | **M** | Thermometers and other temperature detection devices are verified against a certified reference thermometer at least annually. | CLSI GP31-A 6.12.1.2<br>CAP COM.30700 | |
| **ERS3.4** | **Ancillary equipment is verified for accuracy.** | | | |
| ERS3.4.1 | **M** | There are documented processes for verification of pipettes used for quantitative dispensing (e.g. single volume, multi-volume) at least annually. | CLSI QMS13-A 7.2.3<br>CAP CHM.24300<br>CAP CHM.24200 | |
| ERS3.4.2 | **M** | Stand-alone automated pipetting systems are evaluated for carry-over, for each applicable examination. | CAP CHM.24400 | |
| ERS3.4.3 | **M** | Balances are cleaned, serviced and checked at least annually by qualified service personnel. | CLSI QMS13-A 7.2.3<br>CAP CHM.25300 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ERS3.4.4 | **M** | Well-maintained, certified calibration weights are used to verify the accuracy of balances if performed by the laboratory. | CAP CHM.25500 | |
| ERS3.4.5 | **M** | The operating speed of centrifuges is verified and documented at defined intervals. | CAP GEN.41017 | |
| ERS3.4.6 | **M** | The cleaning and annual servicing of microscopes is documented. | CLSI QMS13-A 7.2.3 | |
| ERS3.4.7 | **M** | Functional checks of microscopes (e.g. Kohler illumination, phase alignment) are performed and documented at defined intervals. | CLSI QMS13-A 7.2.3 | |
| ERS3.4.8 | **M** | The configuration of fluorescent microscopes uses the correct filters for the examination. | CAP MIC.16275 | |
| ERS3.4.9 | **M** | Glass volumetric flasks and pipettes are of certified accuracy or if noncertified, are checked for accuracy prior to use. This is documented. | CAP CHM.23800<br>CAP CHM.23900 | |
| ERS3.4.10 | **M** | There are procedures for handling and cleaning glassware. Glassware is tested for detergent residue where appropriate. | CAP GEN.41770 | |
| **ERS3.5** | **Devices used to calibrate ancillary equipment are verified.** | | | |
| ERS3.5.1 | **M** | The laboratory has defined the frequency of verification of calibrating equipment (e.g. tachometers). | CLSI QMS13-A 7.2.3 | |
| ERS3.5.2 | **M** | Initial and subsequent verification of calibrating equipment is documented. | CLSI QMS13-A 7.2.3 | |

## ERS4.0 EQUIPMENT RECORDS, MAINTENANCE AND OPERATION

| | | | | |
|---|---|---|---|---|
| **ERS4.1** | **Equipment records are maintained.** | | | |
| ERS4.1.1 | **M** | Each item of equipment is uniquely labelled, marked or otherwise identified. | ISO 15189 5.3.1.2 | |
| ERS4.1.2 | **M** | Equipment records include identification and current location. | ISO 15189 5.3.1.7a, e | |
| ERS4.1.3 | **M** | Equipment records include manufacturer's name, model, serial number or other identification, and manufacturer's instructions. | ISO 15189 5.3.1.7b, g | |
| ERS4.1.4 | **M** | Equipment records include manufacturer or supplier contact information. | ISO 15189 5.3.1.7c | |
| ERS4.1.5 | **M** | Equipment records include date of receipt, condition when received and date put into service. | ISO 15189 5.3.1.7d, f | |
| ERS4.1.6 | **M** | Equipment records include initial verification studies. | ISO 15189 5.3.1.7h | |
| ERS4.1.7 | **M** | Equipment records include preventive maintenance and repair records. | ISO 15189 5.3.1.7i, k | |
| ERS4.1.8 | **M** | Equipment records include ongoing performance acceptance records. | ISO 15189 5.3.1.7j | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ERS4.1.9 | **M** | Equipment records include testing emergency stop devices according to the manufacturer's recommendations. | ISO 15189 5.3.1.5<br>CSA Z316.7 8.3.16 | |
| ERS4.1.10 | **M** | Equipment records are maintained and are readily available for the lifespan of the equipment. | CSA Z316.7 8.3.8 | |
| **ERS4.2** | **Equipment is operated and maintained by trained and authorized personnel.** | | | |
| ERS4.2.1 | **M** | Maintenance is performed in accordance with documented schedules. | ISO 15189 5.3.1.5<br>CLSI QMS 01-A4 5.6.4 | |
| ERS4.2.2 | **M** | There are instructions on the use, safety and maintenance of equipment. Equipment is operated following manufacturer's recommendations.<br>*Guidance: Manufacturer's documentation is only used as a supplement to a procedure.* | ISO 15189 5.3.1.3, 5<br>CLSI QMS 01-A4 5.6.4, 5.6.2.5 | |
| ERS4.2.3 | **M** | Equipment is operated by trained and authorized personnel at all times. Specialized equipment and instrumentation is operated by personnel with the necessary education, knowledge, and skills. | ISO 15189 5.3.1.3<br>CSA Z316.7 8.3.9 | |
| ERS4.2.4 | **M** | An orientation and training program is provided to those who use equipment to ensure safe, consistent, and accurate operation. | CLSI QMS 01-A4 5.6.2.5<br>CSA Z316.7 8.3.9 | |
| ERS4.2.5 | **M** | There are measures to protect all equipment from adjustments or tampering that may invalidate examination results. | CLSI QMS01-A4 5.6.2.5<br>CSA Z316.7 8.3.16 | |
| ERS4.2.6 | **M** | An examination result can be traced back to the instrument and the personnel performing or completing the examination. | CAP GEN.43920<br>CAP GEN.41306 | |
| **ERS4.3** | **There are procedures for defective equipment.** | | | |
| ERS4.3.1 | **M** | Roles and responsibilities for reporting, investigating and resolving equipment problems are clearly communicated and understood. Responsible personnel are trained in resolving equipment problems. | ISO 15189 5.3.1.5 | |
| ERS4.3.2 | **M** | There is a list of service personnel and their contact information. | CLSI QMS13-A 10.2 | |
| ERS4.3.3 | **M** | Information about problems is collected, documented, monitored and analyzed. Actions to prevent recurrence are identified. | CLSI QMS13-A 10.1 | |
| ERS4.3.4 | **M** | Manufacturer-issued defects, recalls and safety advisories are acted upon immediately. | CAP GEN.20340 | |
| ERS4.3.5 | **M** | There is a documented process for resolving non-compliance or quality issues with a vendor in a timely manner. | DAP15 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ERS4.3.6 | **M** | Equipment problems that impact examination quality or personnel safety are reported and repaired. | ISO 15189 5.3.1.5 | |
| ERS4.3.7 | **M** | The laboratory assesses the effect of any defects on previous examinations and institutes immediate action or corrective action. | ISO 15189 5.3.1.5 | |
| ERS4.3.8 | **M** | Defective equipment is promptly removed from service and clearly labelled. | ISO 15189 5.3.1.5<br>CSA Z316.7 8.3.11 | |
| ERS4.3.9 | **M** | There are procedures for the routine cleaning and disinfection of equipment, as well as immediate cleaning and decontamination of equipment after accidents or spills that result in biological, chemical or radioactive contamination. Equipment is decontaminated prior to service or repair (as appropriate) and prior to decommissioning. | ISO 15189 5.3.1.5<br>CSA Z316.7 8.3.11<br>CLSI GP17-A3 5.3.2 | |
| ERS4.3.10 | **M** | A list of decontamination measures performed is provided to service personnel, if required. | CSA Z316.7 8.3.12 | |
| ERS4.3.11 | **M** | Defective equipment is not used until it has been repaired and verified that it meets specified acceptance criteria. | CSA Z316.7 8.3.11 | |
| ERS4.3.12 | **M** | There are procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration. | ISO 15189 5.3.1.3<br>CSA Z316.7 8.3.15 | |
| **ERS4.4** | **There are procedures to ensure data integrity in instruments.** | | | |
| ERS4.4.1 | **M** | Instrument software is verified prior to installation and after major upgrades. | CLISQMS01-A4 5.6.2.4<br>CSA Z316.7 8.3.14 | |
| ERS4.4.2 | **M** | Optimal environmental and operating conditions for the maintenance of data integrity are maintained. | CSA Z316.7 8.3.14 | |
| ERS4.4.3 | **M** | Data integrity is protected at all times. | CSA Z316.7 8.3.14<br>CLSI AUTO11-A 4.2 | |
| ERS4.4.4 | **M** | Access, alteration or destruction of software by unauthorized individuals is prevented. | CSA Z316.7 8.3.14<br>CLSI AUTO11-A 4.1 | |

# INFORMATION MANAGEMENT AND INFORMATICS

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **IMI1.0** | | **INFORMATION MANAGEMENT** | | |
| **IMI1.1** | | **There is an information management plan for the laboratory.** | | |
| IMI1.1.1 | **M** | There is a documented information management plan that addresses the handling of both electronic and manually recorded data. | ISO 15189 5.10.1<br>CLSI QMS01-A4 5.9 | |
| IMI1.1.2 | | The information management planning process considers data organization, collection, storage, communication, display, security and information system performance. | CLSI QMS01-A4 5.9.1 | |
| IMI1.1.3 | | The information management plan engages key stakeholders and includes identification of information requirements. | DAP15 | |
| IMI1.1.4 | | The information management plan is aligned with organization wide plans and establishes the priority of current and future information needs within the laboratory. | DAP15 | |
| IMI1.1.5 | | The information management plan includes communication of priorities and identifies the resources required for the implementation and sustainability of the plan. | DAP15 | |
| **IMI1.2** | | **The information and data requirements for the laboratory are defined.** | | |
| IMI1.2.1 | **M** | The laboratory has access to the data and information needed to provide a service which meets the needs and requirements of users. | ISO 15189 5.10.1 | |
| IMI1.2.2 | **M** | Data can be accessed in a timely fashion. | CLSI QMS01-A4 5.9.1 | |
| IMI1.2.3 | | Data and information can be collected, linked and combined from multiple sources. | DAP15 | |
| IMI1.2.4 | | Historical and current data can be accessed and compared. | DAP15 | |
| IMI1.2.5 | | Costs associated with service delivery can be determined. | DAP15 | |
| IMI1.2.6 | | Resource utilization can be determined and managed. | DAP15 | |
| IMI1.2.7 | | Information can be exchanged with other organizations. | DAP15 | REVISED |
| IMI1.2.8 | | Management reports can be routinely obtained. | DAP15 | |
| **IMI1.3** | | **Information management training and procedures are available for users.** | | |
| IMI1.3.1 | **M** | Training is provided for users prior to use of information systems (IS). | ISO 15189 5.1.5c<br>CLSI AUTO13-A2 14.4<br>CAP GEN.43055 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| IMI1.3.2 | **M** | There are provisions for ongoing user training as new system features are deployed. | ISO 15189 5.1.5c<br>CLSI AUTO13-A2 14.4<br>CAP GEN.43055 | |
| IMI1.3.3 | **M** | IS documentation at an understandable level and language is readily available to authorized users. | ISO 15189 5.10.3.b<br>ISO 15189 5.5.3<br>CLSI AUTO13-A2 14.2 | REVISED |
| IMI1.3.5 | **M** | IS documentation contains maintenance, vendor support and emergency contact information. | DAP15 | |
| IMI1.3.6 | | IS documentation contains processes for system management including troubleshooting, modification, programming and changing user defined tables. | DAP15 | |
| IMI1.3.7 | **M** | IS procedures are reviewed at a defined frequency. | DAP15 | |
| **IMI1.4** | **There are procedures to protect the confidentiality of patient data.** | | | |
| IMI1.4.1 | **M** | There are procedures to ensure that the confidentiality of patient information is maintained at all times. | DAP15 | |
| IMI1.4.2 | **M** | Confidential data is destroyed in accordance with accepted guidelines. | DAP15 | REVISED |

## IMI2.0 LABORATORY INFORMATION SYSTEM (LIS) SECURITY

| **IMI2.1** | **There are procedures to maintain and protect the laboratory information system (LIS).** | | | |
|---|---|---|---|---|
| IMI2.1.1 | **M** | Access to data storage areas is controlled and secured. | DAP15 | |
| IMI2.1.2 | **M** | Unauthorized access to the LIS is prevented. Unauthorized user access is monitored and there is a policy that addresses unauthorized users. | DAP15 | |
| IMI2.1.3 | **M** | Security incidents are reported, documented, investigated and resolved. Actions taken to prevent recurrence are documented. | DAP15 | |
| IMI2.1.4 | **M** | There are procedures for vendors and others accessing the LIS and laboratory instruments. | DAP15 | |
| IMI2.1.5 | **M** | When using the Internet to allow public access to examination results, measures are taken to ensure data confidentiality and prevent access to the LIS by unauthorized sources.<br>*Guidance: Access to the Internet is limited to equipment not connected to the LIS.* | DAP15 | |
| IMI2.1.6 | **M** | Computer programs are protected against unauthorized alteration or destruction. | DAP15 | |
| IMI2.1.7 | **M** | Newly discovered or uncorrected computer software errors reported to the laboratory by the vendor are documented in detail. Actions taken are documented. | DAP15 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **IMI2.2** | **The authorities and responsibilities for management and use of the LIS are defined.** | | | |
| IMI2.2.1 | **M** | The laboratory defines the authorities and responsibilities of all personnel who use the LIS including those who access, enter or change patient data and examination results, authorize the release of examination results and reports, access statistical reporting or alter computer programs. | ISO 15189 5.10.2a-d<br>CAP GEN.43150 | |
| IMI2.2.2 | **M** | Authorized personnel maintain user access and restriction controls. | CLSI QMS01-A4 5.9.3<br>CAP GEN.43200 | |
| IMI2.2.3 | **M** | Each user is assigned an access security level appropriate to their role. | CLSI QMS01-A4 5.9.3<br>CAP GEN.43200 | |
| IMI2.2.4 | **M** | For computer-based systems there is a policy for password management. | CLSI QMS01-A4 5.9.3<br>CAP GEN.43200 | |
| IMI2.2.5 | **M** | There is an audit trail allowing the laboratory to identify all individuals that enter or modify patient data. | CLSI QMS01-A4 5.9.3<br>CAP GEN.43800 | |
| IMI2.2.6 | **M** | There are measures to prevent unauthorized access to data in other computer systems (e.g. pharmacy) that can be accessed through the LIS. | CLSI QMS01-A4 5.9.3<br>CLSI AUTO13-A2 14<br>CAP GEN.43150 | |
| **IMI2.3** | **There are processes to ensure data integrity in the LIS.** | | | |
| IMI2.3.1 | **M** | The LIS is maintained in a manner that ensures the integrity of the data and information and includes recording system failures and any immediate corrective actions. | ISO 15189 5.10.3f | REVISED |
| IMI2.3.3 | **M** | The LIS meets applicable data protection requirements. | ISO 15189 5.10.3g | |
| IMI2.3.4 | **M** | There is a policy that addresses unauthorized installation of software by users. | CAP GEN.43262 | |
| **IMI2.4** | **Computer facilities are operated in a suitable environment.** | | | |
| IMI2.4.1 | **M** | Computer facilities are clean, well-maintained and operated in an environment that complies with vendor specifications. | ISO 15189 5.10.3e<br>CAP GEN.42750 | REVISED |
| IMI2.4.2 | **M** | The laboratory ensures that information systems managed and maintained off-site (or subcontracted) comply with all applicable requirements. | ISO 15189 5.10.3 | |
| IMI2.4.4 | **M** | There are fire prevention and special fire extinguishing systems or other emergency equipment in or near the computer components and storage areas. | ISO 15189 5.10.3d<br>CAP GEN.42800 | |
| IMI2.4.5 | **M** | There is a UPS for LIS equipment that is able to facilitate a power down without the loss of information. | CAP GEN.42900 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **IMI3.0** | | **LABORATORY INFORMATION SYSTEM (LIS) VALIDATION AND MAINTENANCE** | | REVISED |
| **IMI3.1** | | **There are processes for verification of hardware, software and databases.** | | |
| IMI3.1.1 | **M** | Information systems are validated by the supplier and verified for functioning by the laboratory prior to implementation. Any modifications to the system are authorized, documented and validated prior to implementation. | ISO 15189 5.10.3a | |
| IMI3.1.2 | **M** | A documented plan for LIS verification is available and includes the testing of functional capabilities and other features of the system. | CLSI AUTO13-A2 14.2.2 | |
| IMI3.1.3 | **M** | A test environment exists to ensure that upgrades, maintenance, education, repairs and validation or verification can occur without interfering with the production environment. | CLSI AUTO13-A2 13 | |
| IMI3.1.4 | | A risk analysis is conducted when a new or modified database, new hardware, or new software is introduced. | CLSI AUTO13-A2 13 | |
| IMI3.1.5 | **M** | Software is verified for proper performance when first installed, after changes or modifications have been made and at a defined interval. | CLSI AUTO13-A2 13 | |
| **IMI3.2** | | **There are procedures for LIS hardware maintenance.** | | REVISED |
| IMI3.2.1 | **M** | There are procedures for the maintenance of computer hardware.<br>*Guidance: If maintenance is performed by vendors only, there is no need for the laboratory to have procedures.* | ISO 15189 5.10.3f | |
| IMI3.2.2 | **M** | There is a hardware maintenance record that includes hardware identifiers, the specific maintenance performed and the personnel performing the task. | ISO 15189 5.3.1.7 | |
| IMI3.2.3 | **M** | There is an LIS maintenance record that identifies the maintenance performed and the personnel performing the task. | ISO 15189 5.10.2 | |

| | | | | |
|---|---|---|---|---|
| **IMI4.0** | | **DATA VERIFICATION, REPORTING, STORAGE AND RETRIEVAL** | | |
| **IMI4.1** | | **There are procedures for verification of data entered into and reported by the LIS.** | | |
| IMI4.1.1 | **M** | Manual result entries are verified prior to final acceptance and reporting.<br>*Guidance: Results entered into the LIS manually are reviewed by authorized personnel prior to reporting.* | CAP GEN.43825 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| IMI4.1.2 | **M** | Autoverification procedures are established for each examination and approved by the medical director or designate. | CLSI QMS01-A4 5.9.4<br>CAP GEN.43850 | |
| IMI4.1.3 | **M** | Criteria for automated reporting are defined, approved, readily available and understood by personnel. | ISO 15189 5.9.2a | |
| IMI4.1.4 | **M** | Criteria for automated reporting are validated for proper functioning prior to use and verified after changes to the system that might affect their functioning. | ISO 15189 5.9.2b<br>CAP GEN.43875 | |
| IMI4.1.5 | **M** | There is a documented process for indicating the presence of sample interferences (e.g. hemolysis, icterus, lipemia) prior to autoverification of results. | ISO 15189 5.9.2c | |
| IMI4.1.6 | **M** | There is a documented process for incorporating warning messages from the instruments into the automated selection and reporting criteria. | ISO 15189 5.9.2d<br>CAP GEN.43884 | REVISED |
| IMI4.1.7 | **M** | An audit trail of the autoverification process identifies all results that were autoverified including the date and time of autoverification. | ISO 15189 5.9.2e<br>CAP GEN.43887 | |
| IMI4.1.8 | **M** | There is a procedure for rapid autoverification suspension. | ISO 15189 5.9.2f<br>CAP GEN.43893 | |
| IMI4.1.9 | **M** | A review of calculations performed on patient data by the LIS is performed at defined intervals to ensure that results and associated information are accurate. | ISO 15189 5.10<br>CLSI QMS01-A4 5.9.4<br>CAP GEN.43450 | |
| IMI4.1.10 | **M** | The reporting system allows for comments related to sample quality (e.g. hemolysis, icterus, lipemia) which may influence the interpretation of results. | ISO 15189 5.9.2 c<br>CAP GEN.43750 | |
| IMI4.1.11 | **M** | There is a documented process to randomly check final reports against original input (e.g. worksheets, instrument tapes, audiotapes) at a defined interval. | ISO 15189 5.10.3 | |
| **IMI4.2** | **There are procedures to verify the accuracy of transmitted data.** | | | |
| IMI4.2.1 | **M** | Results from instruments transmitted to the LIS via an interface are verified when the interface is set up, when there are changes to the interface, and at a defined interval. | CLSI AUTO13-A2 13<br>CAP GEN.48500 | |
| IMI4.2.2 | **M** | The laboratory verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (end-to-end validation).<br>*Guidance: The sending facility is responsible for ensuring successful and accurate transmission. The receiver is responsible to ensure the correct data was received.* | ISO 15189 5.10.3<br>CLSI QMS01-A4 5.9.4 | |
| IMI4.2.3 | **M** | When new examinations or new comments are implemented, the laboratory verifies that reports are accurately reproduced by the information systems external to the laboratory. | ISO 15189 5.10.3<br>CLSI AUTO13-A2 13 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **IMI4.3** | **Stored patient data is available.** | | | |
| IMI4.3.1 | **M** | Patient data is retrievable for as long as medically relevant or as required by regulation. | CLSI QMS01-A4 5.9.5<br>CAP GEN.43900 | |
| IMI4.3.2 | **M** | Previously reported results including reference intervals and any flags, footnotes and interpretative comments, originally provided with that result can be reproduced. Any uncertainty of measurement at the time the measurement was made is available. | ISO 15189 4.13<br>CAP GEN.43900 | |
| IMI4.3.3 | | Time frames for data retrieval are established. | CAP GEN.43900 | |
| IMI4.3.4 | | Online storage capacity is reviewed to ensure the storage needs are met. | ISO 15189 4.13 | |
| IMI4.3.5 | **M** | Reports are available when the patient moves from one facility to another. | ISO 15189 4.13 | |
| IMI4.3.6 | **M** | Data stored on-site and off-site is accessible, but protected from unauthorized access and safeguarded against tampering and loss. | ISO 15189 5.10.3c,d | |
| **IMI4.4** | **There are backup and recovery procedures to prevent the loss of patient data.** | | | |
| IMI4.4.1 | **M** | There are procedures for data backup and recovery. | CLSI QMS01-A4 5.9.5 | |
| IMI4.4.2 | **M** | For information systems, data backup is performed daily and the backup is securely located in a separate physical location. | CLSO AUTO08-A 7.2.1 | |
| IMI4.4.3 | **M** | The LIS is reviewed to ensure data integrity after backup or restoration of data files. | ISO 15189 5.10.3f | |
| IMI4.4.4 | **M** | Errors detected during backup are documented and reported to designated personnel. Any corrective action is documented. | DAP INAC | |

## IMI5.0 SYSTEM FAILURE, DOWNTIME AND RECOVERY

| | | | | |
|---|---|---|---|---|
| **IMI5.1** | **There are procedures to address information system malfunction, failure or downtime.** | | | |
| IMI5.1.1 | **M** | There are procedures to contact support personnel in the event of system and or hardware malfunction. | CAP GEN.43066 | |
| IMI5.1.2 | **M** | IS service specialists are available in case of system malfunctions. | CAP GEN.43066 | |
| IMI5.1.3 | **M** | All significant computer malfunctions are reported to designated personnel. | CAP GEN.43066 | |
| IMI5.1.4 | **M** | There are documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide services. | CLSI QMS01-A4 5.9.5<br>CAP GEN.43837<br>CAP GEN.48750 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| IMI5.1.5 | **M** | The documented contingency plans specify the actions necessary to protect data and hardware in case of an unexpected event, hardware or software failure. | CAP GEN.43946 | |
| IMI5.1.6 | **M** | The contingency plans define the individual responsible for determining when the system is powered down, when downtime procedures are implemented, notification of users of service interruption and restoration, provisions for moving back to the LIS, evaluation and monitoring of the system after restart, and guidelines for data reconciliation and accuracy verification. | CLSI QMS01-A4 5.9.5<br>CAP GEN.43837<br>CAP GEN.48750 | |
| IMI5.1.7 | **M** | The contingency plans are reviewed with personnel and tested at a defined interval. | CLSI QMS01-A4 5.9.5 | |
| IMI5.1.8 | **M** | Maintenance downtime is communicated to laboratory personnel and scheduled to minimize interruption. | CLSI QMS01-A4 5.9.5 | |
| IMI5.1.9 | **M** | Unscheduled downtime, system degradation, other problems and corrective actions taken are documented. | CLSI QMS01-A4 5.9.5 | |
| IMI5.1.10 | **M** | There are procedures to deal with downtime of other information systems (e.g. patient care information system, hospital information system) and provisions for data reconciliation.<br>*Guidance: At a minimum, there are procedures to ensure notification of critical results.* | CLSI QMS01-A4 5.9.5 | |
| IMI5.1.11 | **M** | There is a documented disaster recovery plan and associated risk assessment. The disaster recovery plan has been tested. | CLSI QMS01-A4 5.9.5<br>CAP GEN.43946 | |

## IMI6.0 TELEPATHOLOGY

| **IMI6.1** | | **The organization defines the uses and roles for telepathology.** | | |
|---|---|---|---|---|
| IMI6.1.1 | | The governing body of the facility or region is ultimately responsible for ensuring there are measures to monitor the quality of telepathology within the facility. | ISO 22870 4.1.1<br>ISO 15189 4.1.1 | REVISED |
| IMI6.1.2 | | A health professional group such as the medical advisory committee (in consultation with administration and the laboratory medical director or designate) is responsible to the governing body for defining the scope of telepathology. | ISO 22870 4.1.2.1 | |
| IMI6.1.3 | **M** | The clinical applications of telepathology for the facility have been defined and approved (e.g. primary diagnosis, intraoperative diagnosis). | ATA CGT | |
| IMI6.1.4 | | The medical advisory committee reviews and approves new telepathology procedures. | ISO 22870 4.1.2.5 | |
| IMI6.1.5 | **M** | The medical director of the laboratory determines which individuals will have privileges to practise specific clinical applications of telepathology at any applicable practice setting. | ATA CGT<br>GOBC MOH TP 5.1.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **IMI6.2** | **There are processes for training and competency assessment for telepathology.** | | | |
| IMI6.2.1 | | The laboratory has identified and documented the training and competencies necessary to use telepathology. | ATA CGT<br>GOBC MOH TP 5.1.1<br>CAP GEN.51728 | |
| IMI6.2.2 | **M** | For every user there is initial training on each telepathology system prior to use. | ATA CGT<br>GOBC MOH TP 5.1.10 | |
| IMI6.2.3 | **M** | There are training updates when software or hardware changes that impact the end user are implemented. | ATA CGT<br>GOBC MOH TP 5.1.10 | |
| IMI6.2.4 | **M** | There is an initial assessment of competency following training and provisions for ongoing competency assessment. | ATA CGT<br>GOBC MOH TP 5.1.9 | |
| IMI6.2.5 | **M** | Telepathology support personnel have equipment-specific training consistent with the manufacturer's recommendations. | ATA CGT<br>GOBC MOH TP 5.1.1 | |
| **IMI6.3** | **There are processes for the selection of telepathology materials.** | | | |
| IMI6.3.1 | **M** | The laboratory has defined and is able to meet the storage needs for telepathology. | GOBC MOH TP 5.1.3 | |
| IMI6.3.2 | **M** | There are selection criteria for telepathology equipment and materials. | GOBC MOH TP 5.1.3 | |
| IMI6.3.3 | **M** | Telepathology software meets all encryption regulation. | GOBC MOH TP 5.1.12 | |
| IMI6.3.4 | **M** | Digitization equipment is capable of achieving an acceptable digital resolution for the required application. | GOBC MOH TP 5.1.8 | |
| IMI6.3.5 | **M** | Physical facilities and equipment provided for telepathology allow safe and efficient operation including environmental controls, network infrastructure, physical space and utilities. | GOBC MOH TP 5.1.11 | REVISED |
| IMI6.3.6 | **M** | User workstations conform to applicable requirements. | GOBC MOH TP 5.1.11 | |
| **IMI6.4** | **The telepathology system is validated.** | | | |
| IMI6.4.1 | **M** | All laboratories implementing a telepathology service for diagnostic purposes perform their own validation studies. | ATA CGT<br>GOBC MOH TP 5.1.8 | |
| IMI6.4.2 | **M** | The validation process includes a number and mix of cases that reflects the spectrum and complexity of sample types and diagnoses likely to be encountered.<br>*Guidance: Validation for specific tissues, diseases, microscopic changes or diagnoses is not required.* | ATA CGT | REVISED |
| IMI6.4.3 | | All components of the telepathology workflow are validated as a single system. | ATA CGT | |
| IMI6.4.4 | | Pathologists involved in validation have been trained to use the telepathology system. | ATA CGT | REVISED |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| IMI6.4.5 | **M** | Validation processes include all personnel that will use the telepathology system. | ATA CGT | |
| IMI6.4.6 | | The validation process confirms that all of the material present or purposely selected areas of the glass slide are included in the digital image or video. | ATA CGT | |
| IMI6.4.7 | **M** | Validation confirms that the received image or video is identical to the sent image or video.<br>*Guidance: The received image is effectively identical with respect to diagnostic information, details and features.* | ATA CGT | |
| IMI6.4.8 | **M** | Validation documentation is retained. | ATA CGT | |
| **IMI6.5** | **Identification requirements for telepathology images are defined.** | | | |
| IMI6.5.1 | **M** | Telepathology images are uniquely identified and traceable to the source material or case. | GOBC MOH TP 5.1.4.1 | |
| IMI6.5.2 | **M** | The identity of images is maintained by unique identifiers at all times including image capture, diagnostic interpretation, reporting, storage and retrieval. | GOBC MOH TP 5.1.4.1 | REVISED |
| **IMI6.6** | **Relevant clinical information is available for telepathology users.** | | | |
| IMI6.6.1 | **M** | The minimal acceptable data accompanying digital material has been defined. | ATA CGT | |
| IMI6.6.2 | **M** | The sender includes all relevant clinical information for the receiving facility or consultant, including at a minimum, the information on the surgical pathology request. | ATA CGT | |
| IMI6.6.3 | **M** | The sender ensures that the receiving facility or consultant has access to any necessary and/or relevant material and prior diagnostic material. | ATA CGT | |
| IMI6.6.4 | **M** | The sender ensures that the correct image and metadata are sent. | ATA CGT | REVISED |
| **IMI6.7** | **The confidentiality of patient data is maintained during telepathology processes.** | | | |
| IMI6.7.1 | **M** | There are policies to ensure the confidentiality of patient data, including when mobile devices are used.<br>*Guidance: Access to patient data stored on any device is restricted, including a password or multi-factor authentication and a time-out function.* | CAP GEN.52842<br>ATA CGT<br>GOBC MOH TP 5.1.12 | REVISED |
| IMI6.7.2 | **M** | All data transmission is secured through the use of encryption that meets recognized standards. | ATA CGT<br>GOBC MOH TP 5.1.12 | |
| IMI6.7.3 | **M** | If video conferencing is used, privacy features including audio muting, video muting and the ability to change from public to private audio mode are available. | ATA CGT<br>GOBC MOH TP 5.1.12 | |
| **IMI6.8** | **There are procedures for the maintenance of telepathology equipment and services.** | | | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| IMI6.8.1 | **M** | Maintenance and service procedures are aligned with vendor service agreements and documented. | GOBC MOH TP 5.1.8 | |
| IMI6.8.2 | **M** | A test environment is maintained to ensure that all software upgrades, maintenance and repairs made to the telepathology infrastructure do not interfere with the production module. | GOBC MOH TP 5.1.7 | |
| IMI6.8.3 | | Documentation for daily operation includes all specialized settings to obtain the best image quality. | GOBC MOH TP 5.1.9 | |
| IMI6.8.4 | **M** | There are procedures for monitoring the quality of captured and transmitted images. | GOBC MOH TP 5.1.11 | |
| IMI6.8.5 | **M** | There are procedures for reporting and troubleshooting image quality issues. | GOBC MOH TP 5.1.8 | |
| **IMI6.9** | **There are procedures for reporting results using telepathology.** | | | |
| IMI6.9.1 | **M** | Telepathology consultations are recorded and tracked.<br>*Guidance: A diagnostic consultation by telepathology will generate a formal report for the medical record. The report that identifies the use of telepathology, and the report contents are in accordance with the laboratory's requirements for pathology reporting.* | ATA CGT<br>GOBC MOH TP 5.1.6<br>CAP GEN.52850 | |
| IMI6.9.2 | | The LIS is considered the single source of truth for all telepathology reports and images. | ATA CGT<br>GOBC MOH TP 5.1.6 | |
| IMI6.9.3 | **M** | There is a documented process for reconciliation of discrepancies between a telepathology interpretation and the microscopic glass slide. | ATA CGT<br>GOBC MOH TP 5.1.9 | |
| IMI6.9.4 | **M** | There is a policy to address data deletion and correction in telepathology.<br>*Guidance: This may require agreement between the sender and receiving facility/consultant regarding retention and/or deletion of images and patient data.* | ATA CGT | |
| **IMI6.10** | **Telepathology images are retained in accordance with the facility retention requirements for diagnostic materials.** | | | |
| IMI6.10.1 | **M** | Telepathology images are accessible and retained in accordance with facility retention requirements. | ATA CGT<br>GOBC MOH TP 5.1.7 | |
| IMI6.10.2 | | Annotations associated with an image used for diagnostic interpretation are maintained and retrievable with the original image. | ATA CGT<br>GOBC MOH TP 5.1.7 | |
| IMI6.10.3 | | Access to stored digitized images and metadata is monitored and documented for the designated life of the image. | ATA CGT<br>GOBC MOH TP 5.1.7 | |

# QUALITY ASSURANCE

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **QUA1.0** | | **QUALITY CONTROL SYSTEMS** | | |
| **QUA1.1** | | **Internal quality control (QC) systems verify the quality of results.** | | |
| QUA1.1.1 | **M** | QC procedures monitor the accuracy and precision of examination performance over time. | ISO 15189 5.6.2.1<br>CLSI C24-A3 6.3 | |
| QUA1.1.2 | **M** | The laboratory uses a graphic display of control results on control charts to aid in interpreting QC data. | CLSI C24-A3 8.5 | |
| QUA1.1.3 | **M** | Statistics (e.g. SD, CV and bias shift) are calculated monthly to define and monitor the analytic imprecision of numeric QC data. | ISO 15189 5.6.2.3 | |
| QUA1.1.4 | **M** | QC data is reviewed at defined intervals to detect trends in examination performance that may indicate problems in the examination system. When trends indicate there may be a problem, corrective action is taken and recorded. | ISO 15189 5.6.2.3 | |
| QUA1.1.5 | **M** | The frequency of QC review by medical directors, designates and supervisors is defined. | CAP CHM.14916 | |
| **QUA1.2** | | **There are procedures for the selection and performance of QC.** | | |
| QUA1.2.1 | **M** | The laboratory selects QC material that reacts to the examination system in a manner as close as possible to patient samples. | ISO 15189 5.6.2.2<br>CLSI C24-A3 6.2 | |
| QUA1.2.2 | | Concentrations of control materials are chosen at or near clinical decision values, where possible. | ISO 15189 5.6.2.2<br>CLSI C24-A3 6.2 | |
| QUA1.2.3 | **M** | QC materials are examined at a defined frequency that is based on the stability of the examination and the risk of harm to the patient from an erroneous result. | ISO 15189 5.6.2.2<br>CLSI C24-A3 6.2 | |
| QUA1.2.4 | **M** | QC is performed in the same manner as patient samples and rotated among all operators who perform the examination. | ISO 15189 5.6.2.2<br>CLSI C24-A3 6.2<br>CAP CHM.14800 | |
| QUA1.2.5 | **M** | Controls are used for all qualitative and quantitative examinations. | CAP CHM.13900 | REVISED |
| QUA1.2.6 | **M** | Commercial QC is performed according to the manufacturer's instructions. | CLSI C24-A3 6.2 | |
| QUA1.2.7 | **M** | The lot numbers of QC material are recorded. | CLSI C24-A3 8.1 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| QUA1.2.8 | **M** | QC is performed when a new reagent lot number is introduced, when a major preventive maintenance is performed, or when a critical part that may influence examination performance is replaced. | CLSI C24-A3 8.1 | |
| QUA1.2.9 | **M** | QC procedures are documented and include the frequency, type of material used, number of levels of controls and acceptable ranges or tolerance limits. | CLSI C24-A3 8.1, 8.2 | |
| **QUA1.3** | **There are procedures for the management of patient samples while QC problems are investigated.** | | | |
| QUA1.3.1 | **M** | QC results are verified for acceptability prior to reporting patient results. | CLSI C24-A3 8.4<br>CAP CHM.14900 | |
| QUA1.3.2 | **M** | There are procedures to prevent the release of patient results in the event of a QC failure. | ISO 15189 5.6.2.3 | |
| QUA1.3.3 | **M** | When QC is unacceptable, results are held until confirmed or invalidated by re-examination. | ISO 15189 5.6.2.3 | |
| QUA1.3.4 | **M** | When QC is unacceptable, the laboratory evaluates results from patient samples that were examined after the last successful QC event. | ISO 15189 5.6.2.3 | |
| QUA1.3.5 | **M** | There are criteria that define when supervisors or medical directors are to be notified of unacceptable control results. | CAP CHM.14916 | |
| QUA1.3.6 | **M** | QC problems, investigations and corrective actions are documented and retained. | ISO 15189 5.6.2.2 | |
| **QUA1.4** | **There are procedures for the use of moving averages and retained patient samples as QC.** | | | |
| QUA1.4.1 | **M** | If moving averages are used, more than 100 samples are run daily (long-term average) or the number of samples run daily has been established. | CLSI H26-A2 7.5.3.2<br>CAP HEM.25920<br>CAP HEM.25990 | |
| QUA1.4.2 | **M** | A supplemental QC routine (stabilized control material or retained patient samples) is employed if a technique of weighted moving averages derived from multiple batch analysis of patient samples is used to detect drift or shift in analyzer calibration. | CLSI H26-A2 7.5.3.2<br>CAP HEM.25920<br>CAP HEM.25990 | |
| QUA1.4.3 | **M** | If on-board moving average analysis is used to monitor only one measurand, additional QC techniques are used to monitor other measurands (e.g. using a moving average for CBC and additional QC for WBC differential parameters). | CLSI H26-A2 7.5.3.2<br>CAP HEM.25920<br>CAP HEM.25990 | |
| QUA1.4.4 | **M** | There is documentation of the method used to establish the moving average including the frequency of calculation, and a definition of the basis for selection of upper and lower limits. Control limits for moving averages are sensitive enough to detect significant calibration alterations or systematic error. | CLSI H26-A2 7.5.3.2<br>CAP HEM.25920<br>CAP HEM.25990 | REVISED |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| QUA1.4.5 | **M** | If retained patient samples are used to detect drift or shift in analyzer calibration, a supplemental QC routine (e.g. stabilized control material, moving averages) is employed. | CLSI H26-A2 7.5.3.2<br>CAP HEM.25920<br>CAP HEM.25990 | |
| QUA1.4.6 | **M** | Statistically defined limits are used to determine agreement of sequential examinations of patient samples. There is a defined range of values for which these limits are applicable. | CLSI H26-A2 7.5.3.2<br>CAP HEM.25920<br>CAP HEM.25990 | |

## QUA2.0 PROFICIENCY TESTING

| | | | | |
|---|---|---|---|---|
| **QUA2.1** | **Laboratories participate in mandated proficiency testing (PT) programs or establish alternate assessment.** | | | |
| QUA2.1.1 | **M** | The laboratory participates in all DAP-mandated PT appropriate to the laboratory's scope of testing.<br>*Guidance: When there is more than one automated analyzer used to detect or quantitate an individual measurand at one site, only one PT subscription per measurand is required.* | ISO 15189 5.6.3.1<br>CLSI QMS01-A4 5.7.3<br>CAP COM.01000 | |
| QUA2.1.2 | **M** | For quantitative and qualitative examinations where PT is not mandated by the DAP, the laboratory participates in a formal PT program or conducts an alternative assessment to confirm the accuracy of results. | ISO 15189 5.6.3.2<br>CLSI QMS01-A4 5.7.3 | |
| QUA2.1.3 | **M** | Any PT program or alternative assessment chosen by the laboratory provides clinically relevant challenges that mimic (to the extent possible) patient samples and has the effect of checking the entire examination process. | ISO 15189 5.6.3.1<br>CLSI QMS01-A4 5.7.3<br>CLSI GP27-A2 4.1 | |
| QUA2.1.4 | **M** | The laboratory has documented that the alternative assessment method is satisfactory for demonstrating the accuracy and reliability of results. | ISO 15189 5.6.3.2<br>CAP COM.01500 | |
| **QUA2.2** | **Proficiency testing samples are integrated into the routine laboratory workflow.** | | | |
| QUA2.2.1 | **M** | There is a documented process for PT participation that includes defined responsibilities and instructions for participation. | ISO 15189 5.6.3.1 | |
| QUA2.2.2 | **M** | PT samples are integrated into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. | ISO 15189 5.6.3.3<br>CLSI GP27-A2 4.2<br>CAP COM.01600 | |
| QUA2.2.3 | **M** | PT samples are examined using the same procedures as those used for patient samples by personnel who routinely examine patient samples. | ISO 15189 5.6.3.3<br>CLSI GP27-A2 4.2<br>CAP COM.01600 | |
| QUA2.2.4 | **M** | There is no communication with other participants about PT samples until after the final date for data submission. | ISO 15189 5.6.3.3 CAP COM.01800 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| **QUA2.3** | **Proficiency testing results are reviewed by the medical director or designate. Unacceptable results are investigated.** | | | |
| QUA2.3.1 | **M** | PT results are reviewed and discussed with relevant personnel. | ISO 15189 5.6.3.4 | |
| QUA2.3.2 | **M** | PT results are monitored by the medical director or designate within a defined time frame. This review is documented. | ISO 15189 5.6.3.4 | |
| QUA2.3.3 | **M** | The laboratory monitors the PT results and implements corrective actions when predetermined performance criteria are not fulfilled. | ISO 15189 5.6.3.4<br>CLSI GP27-A2 6<br>CAP COM.01700 | |
| QUA2.3.4 | **M** | When predetermined performance criteria are not fulfilled, personnel participate in the identification, implementation, recording and monitoring of corrective action and its effectiveness. | ISO 15189 5.6.3.4<br>CLSI GP27-A2 6<br>CAP COM.01700 | |
| QUA2.3.5 | **M** | Unacceptable PT results are investigated. This investigation is documented and retained. | ISO 15189 5.6.3.4<br>CLSI GP27-A2 6<br>CAP COM.01700 | |
| QUA2.3.6 | **M** | The returned results are evaluated for trends that indicate potential nonconformities and preventive action is taken to prevent occurrence. | ISO 15189 5.6.3.4<br>CLSI GP27-A2 6<br>CAP COM.01700 | |
| QUA2.3.7 | **M** | A record of corrective action is filed with the DAP within the required reporting time frame, when required. This record is retained by the laboratory. | DAP15 | REVISED |
| QUA2.3.8 | **M** | The authority to withdraw equipment or discontinue an examination in the event of serious PT or alternate assessment problems is defined. | DAP ACR | NEW |

## QUA3.0 VERIFICATION OF COMPARABILITY

| | | | | |
|---|---|---|---|---|
| **QUA3.1** | **There is a documented process for verifying the comparability of results.** | | | |
| QUA3.1.1 | **M** | There are procedures to establish the comparability of procedures, equipment and methods used, and establishing the comparability of results for patient samples. This is applicable to the same or different procedures, equipment, different sites or all of these. | ISO 15189 5.6.4 | |
| QUA3.1.2 | **M** | Comparability encompasses the entire range of clinically relevant values.<br>*Guidance: Freshly obtained patient samples are the preferred comparability material as commercial materials have had their matrices modified in ways that may significantly affect commutability with native clinical samples.* | ISO 15189 5.6.4<br>CLSI EP31-A-IR 6.1 | |
| QUA3.1.3 | **M** | Acceptability criteria are defined for comparability of procedures, equipment and methods. | CAP COM.04300 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| QUA3.1.4 | **M** | The laboratory documents, records and acts upon results from comparability. Any identified problems or deficiencies are addressed and records of action are retained. | ISO 15189 5.6.4<br>CAP COM.04300 | NEW |
| QUA3.1.5 | **M** | The laboratory notifies users of any differences in comparability of results and discusses any implications for clinical practice when examination systems provide different reference intervals for the same measurand and when examination methods are changed. | ISO 15189 5.6.4 | NEW |
| QUA3.1.6 | **M** | Instruments and methods are checked against each other at least twice a year for comparability of results.<br>*Guidance: Frequent monitoring generally involves comparing fewer samples more often while less frequent intervals require a larger number of samples due to the lower frequency of comparability. Periodic monitoring (e.g. quarterly, semi-annually) is performed when frequent monitoring is deemed unnecessary because the examination systems involved are stable and the risk of errors in clinical interpretation due to non-comparable results is low.* | CAP – COM.04250<br>CLSI EP31-A-IR 5.4 | LES1.5.1 |

# PRE-EXAMINATION

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **PRE1.0** | **SCOPE OF SERVICE** | | | |
| **PRE1.1** | **The laboratory provides information on available laboratory services to patients and users.** | | | |
| | There is information available for patients and users of laboratory services that includes: | | | |
| PRE1.1.1 | **M** | • a list of examinations that can be ordered as STAT | DAP15 | |
| PRE1.1.2 | **M** | • location(s) | ISO 15189 5.4.2a | |
| PRE1.1.3 | **M** | • hours of operation | ISO 15189 5.4.2c | |
| PRE1.1.4 | **M** | • instructions for completion of the request form | ISO 15189 5.4.2e | |
| | | • as appropriate, information on: | | |
| PRE1.1.5 | **M** | o primary sample volumes | ISO 15189 5.4.2b, d | |
| PRE1.1.6 | **M** | o special precautions | ISO 15189 5.4.2b, d | |
| PRE1.1.7 | **M** | o biological reference intervals | ISO 15189 5.4.2b, d | |
| PRE1.1.8 | **M** | o turnaround time | ISO 15189 5.4.2b, d | |
| PRE1.1.9 | **M** | o clinical decision values | ISO 15189 5.4.2b, d | |
| PRE1.1.10 | **M** | o examinations referred to other laboratories | ISO 15189 5.4.2b, d | |
| PRE1.1.11 | **M** | • instructions for preparation of the patient | ISO 15189 5.4.2f | |
| PRE1.1.12 | **M** | • instructions for patient-collected samples | ISO 15189 5.4.2g | |
| PRE1.1.13 | **M** | • instructions for transportation of samples and any special handling requirements | ISO 15189 5.4.2h | |
| PRE1.1.14 | **M** | • criteria for accepting and rejecting samples | ISO 15189 5.4.2j | |
| PRE1.1.15 | **M** | • factors known to significantly affect the performance of the examination or the interpretation of the results (e.g. lengthy delays between collection and examination, samples requiring protection from light) | ISO 15189 5.4.2k | |
| PRE1.1.16 | **M** | • availability of clinical advice on ordering of examinations and on interpretation of results | ISO 15189 5.4.2l | |
| PRE1.1.17 | **M** | • the laboratory's policy on protection of personal information | ISO 15189 5.4.2m | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| PRE1.1.18 | **M** | • the laboratory's complaint procedure | ISO 15189 5.4.2n | |

## PRE2.0 EXAMINATION REQUESTS

| PRE2.1 | The request form includes space for required information. | | |
|---|---|---|---|
| | | The request form or an electronic equivalent has space for the inclusion of patient identification. This information includes: | |
| PRE2.1.1 | **M** | • first and last name | ISO 15189 5.4.3a<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.2 | **M** | • date of birth | ISO 15189 5.4.3a<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.3 | **M** | • the location/contact details of the patient | ISO 15189 5.4.3a<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.4 | **M** | • unique identifier | ISO 15189 5.4.3a<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.5 | **M** | • gender | ISO 15189 5.4.3a<br>CLSI QMS01-A4 6.1.1 |
| | | The request form or an electronic equivalent has space for the inclusion of user information. This information includes: | |
| PRE2.1.6 | **M** | • user name | ISO 15189 5.4.3b<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.7 | **M** | • user contact information | ISO 15189 5.4.3b<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.8 | **M** | • user unique identifier | ISO 15189 5.4.3b<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.9 | **M** | • destination for the report | ISO 15189 5.4.3b<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.10 | **M** | The request form or an electronic equivalent has space for the inclusion of the type of primary sample and, where relevant, the anatomic site of origin.<br>*Guidance: It is not necessary to identify the primary sample, when the default is blood.* | ISO 15189 5.4.3c<br>CLSI QMS01-A4 6.1.1 |
| PRE2.1.11 | **M** | The request form or an electronic equivalent has space for the inclusion of the examination(s) requested. | ISO 15189 5.4.3d<br>CLSI QMS01-A4 6.1.1 |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| PRE2.1.12 | **M** | The request form or an electronic equivalent has space for the inclusion of clinically relevant information about the patient and the request, for examination performance and result interpretation purposes. | ISO 15189 5.4.3e<br>CLSI QMS01-A4 6.1.1 | |
| PRE2.1.13 | **M** | The request form or an electronic equivalent has space for the inclusion of the date and, where relevant, time of primary sample collection. | ISO 15189 5.4.3f<br>CLSI QMS01-A4 6.1.1 | |
| PRE2.1.14 | **M** | The request form or an electronic equivalent has space for the inclusion of the intended date and time of collection when appropriate (e.g. timed collections such as postprandial glucose). | CLSI QMS01-A4 6.1.1 | |
| PRE2.1.15 | | The request form or an electronic equivalent has space for the inclusion of the urgency of the request. | CLSI QMS01-A4 6.1.1 | |
| PRE2.1.16 | **M** | The request form or an electronic equivalent has space for the inclusion of additional locations the report is to be sent. | CLSI QMS01-A4 6.1.1 | |
| **PRE2.2** | **There are procedures for handling special requests.** | | | |
| PRE2.2.1 | | There is a documented process for handling patient anonymity that includes requests, sample collection and reporting, where required (e.g. HIV examinations). | CLSI QMS01-A4 6.1.1<br>CAP GEN.40750 | |
| PRE2.2.2 | **M** | There is a procedure that addresses handling verbal requests. | ISO 15189 5.4.3<br>CSA Z316.7 11.3.3 | |
| PRE2.2.3 | **M** | The procedure for verbal examination requests includes confirmation by request form or electronic equivalent within a given time. | ISO 15189 5.4.3 | |
| PRE2.2.4 | | There are documented processes to clarify the request if needed. | ISO 15189 5.4.3 | |

## PRE3.0 SAMPLE TRANSPORT

| | | | | |
|---|---|---|---|---|
| **PRE3.1** | **There are procedures for monitoring the transportation of samples.** | | | |
| | | There is a procedure for monitoring the transportation of samples to ensure they are transported: | | |
| PRE3.1.1 | **M** | • within a time frame appropriate to the nature of the requested examinations | ISO 15189 5.4.5a<br>CSA Z316.7 15.1.9 | |
| PRE3.1.2 | **M** | • within a defined temperature range and with the designated preservatives to maintain the integrity of samples | ISO 15189 5.4.5b<br>CSA Z316.7 15.1.9 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| PRE3.1.3 | **M** | • in a manner that ensures the integrity of the sample and the safety of the carrier, the general public and the receiving laboratory, in compliance with regulatory requirements (including TDG legislation) | ISO 15189 5.4.5c<br>CSA Z316.7 15.1.2 | |
| PRE3.1.4 | **M** | There are procedures for validation, use, cleaning and decontamination of pneumatic tube systems used for sample transport. | CSA Z316.7 15.2.1 | |
| PRE3.1.5 | **M** | Samples are centrifuged and separated at the collection site if they cannot be transported to the examination site within a defined time limit to protect the stability of the measurand. | CSA Z316.7 14.5.1<br>CLSI GP44-A4 5.3.2.2.1 | |
| PRE3.1.6 | **M** | Personnel preparing samples for transport and transporting patient samples to another facility are certified, or are supervised by personnel certified, in accordance with Transport of Dangerous Goods Regulations. | GOC TDG | MOVED |
| PRE3.1.7 | | Sites that submit samples to the laboratory have been provided with instructions on the safe transport of samples. | ISO 15190 22 | MOVED |
| PRE3.1.8 | **M** | Samples are transported in approved, leak-proof containers. | ISO 15190 22 | MOVED |
| PRE3.1.9 | **M** | There is a means of containment for samples being transported. | ISO 15190 22 | MOVED |
| PRE3.1.10 | **M** | Packaging is labeled with any appropriate safety warnings. | ISO 15190 22 | MOVED |
| PRE3.1.11 | **M** | There are procedures addressing emergencies during transportation (e.g. spillage). | GOC TDG Part 7<br>CLSI GP17-A3 5.6.3 | MOVED |
| PRE3.1.12 | **M** | Sample transport is in compliance with the *Transport of Dangerous Goods Act* and other relevant legislation. | GOC TDG Part 4 | MOVED |

## PRE4.0 SAMPLE RECEIPT AND PROCESSING

| PRE4.1 | | There are procedures for sample receipt. | | |
|---|---|---|---|---|
| PRE4.1.1 | **M** | There is a procedure for sample receipt that includes the systematic review for acceptability by trained personnel. | ISO 15189 5.4.6<br>ISO 15189 5.4.6e<br>CSA Z3167 14.3.1 | REVISED |
| PRE4.1.3 | **M** | Samples are unequivocally traceable, by request and labelling, to an identified patient. | ISO 15189 5.4.6a<br>CSA Z316.7 14.3.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| PRE4.1.4 | **M** | The date and time of sample receipt in the laboratory and the identity of receiving personnel is recorded.<br>*Guidance: When samples are sent to another laboratory for complete examination, and the laboratory is facilitating transportation only, no tracking is required.* | ISO 15189 5.4.6d<br>CSA Z316.7 14.3.1 | |
| PRE4.1.5 | **M** | The date and time of delivery of slides, images or other diagnostic material to pathologists is recorded. | ISO 15189 5.4.6d<br>ADASP | |
| **PRE4.2** | **There are processes for sample acceptance or sample rejection.** | | | |
| PRE4.2.1 | **M** | Sample rejection criteria are established and applied. | ISO 15189 5.4.6b<br>CSA Z316.7 13.4-5 | |
| PRE4.2.2 | **M** | Samples lacking proper identification are not processed, except if the sample is difficult or impossible to recollect or is irretrievable. | ISO 15189 5.4.6c<br>CSA Z316.7 12.1<br>CSA Z316.7 11.3.4 | |
| PRE4.2.3 | **M** | There is a documented process addressing correction of information on sample labels. | CSA Z316.7 12.2.2.3 | |
| PRE4.2.4 | **M** | There is a procedure to address unlabeled, mislabeled or illegibly labeled samples. | CSA Z316.7 13.6 | |
| PRE4.2.5 | **M** | There is a procedure for the special handling of suboptimal samples.<br>*Guidance: Not all unsuitable samples are discarded or not examined. The procedures for handling these samples should include what examinations may be performed, and how clinicians would be informed of the condition of the sample and any possible impact on the results.* | CSA Z316.7 13.4 | |
| PRE4.2.6 | **M** | Rejected samples are documented and users are notified when unacceptable samples are received. | ISO 15189 5.9.1a | |
| PRE4.2.7 | | Feedback related to sample quality is provided to the sample collector. | CLSI QMS01-A4 6.1.4 | |
| PRE4.2.8 | **M** | Sample rejection trends are monitored to determine the need for a review of pre-examination processes and collector education. | CSA Z316.7 13.3<br>CAP GEN.40505 | |
| PRE4.2.9 | **M** | There is a policy that defines who may request examinations as defined by legislation, rules and bylaws. | CAP GEN.40930 | |
| PRE4.2.10 | **M** | Requests that lack the necessary information or contain errors are reconciled prior to reporting. | CSA Z316.7 12.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| PRE4.2.11 | | Additional or substitute examinations are performed at the discretion of the medical director or designate.<br>*Guidance: When it is determined from the clinical information provided in a request that a different examination or product would be more appropriate, all reasonable steps are taken to contact the user before providing the different, examination, or product. This communication is recorded.* | DAP15 | |
| PRE4.2.12 | **M** | There is a policy that defines requests that need to be reviewed by a laboratory physician or designate (e.g. bone marrow examination, special coagulation examination). | DAP15 | |
| **PRE4.3** | **There are processes to review examinations and sample requirements.** | | | |
| PRE4.3.1 | **M** | Examinations provided by the laboratory are reviewed at a defined frequency to ensure that they are clinically appropriate for the requests received. | ISO 15189 4.14.2 | |
| PRE4.3.2 | | Sample volume, collection devices and preservative requirements for blood and other samples are reviewed at a defined frequency to ensure neither insufficient nor excessive amounts of sample are collected and that the sample is properly preserved. | ISO 15189 4.14.2<br>CSA Z316.7 6.5.2 | |
| **PRE4.4** | **There are procedures for the management of expedited examination requests.** | | | |
| PRE4.4.1 | **M** | There are procedures for the collection, transport, receipt, labeling, processing and reporting of expedited samples. | ISO 15189 5.4.6f<br>CSA Z316.7 14.2 | |
| PRE4.4.2 | **M** | The expedited request procedure includes details of any special labeling of the request form and sample, transfer of the sample to the appropriate laboratory section and any special reporting criteria to be followed. | ISO 15189 5.4.6f<br>CSA Z316.7 14.2 | |
| **PRE4.5** | **There are procedures for sample processing.** | | | |
| PRE4.5.1 | **M** | Blood samples are allowed to clot for a specified length of time prior to centrifugation. | CLSI GP44-A4 5.3.3.1 | REVISED |
| PRE4.5.2 | **M** | There are procedures for sample preparation prior to examination (e.g. centrifugation). | DAP15 | |
| PRE4.5.3 | **M** | Procedures for centrifugation are expressed in relative centrifugal force units. | CLSI GP44-A4 5.4.1.2 | |
| PRE4.5.4 | **M** | Samples are processed using aseptic techniques where necessary. | DAP15 | |
| PRE4.5.5 | **M** | Samples that are to be examined for thermolabile measurands are centrifuged in refrigerated centrifuges. | CLSI GP44-A4 5.3.3.2 | |
| PRE4.5.6 | **M** | All sample aliquots, slides and other portions are traceable to the primary sample and are identified with the same unique number. | ISO 15189 5.4.6<br>CSA Z316.7 14.3.2 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **PRE5.0** | **SAMPLE STORAGE AND DISCARD** | | | |
| **PRE5.1** | **There are procedures for sample storage.** | | | |
| PRE5.1.1 | **M** | There are procedures and facilities for storing patient samples to avoid deterioration, loss or damage during pre-examination activities and storage. | ISO 15189 5.4.7<br>CSA Z316.7 14.6 | REVISED |
| PRE5.1.2 | **M** | The length of time samples are to be retained has been defined based on the nature of the sample, the examination and any applicable requirements. | ISO 15189 5.7.2<br>CLSI QMS01-A4 6.3.3.1 | |
| PRE5.1.3 | **M** | The time limits for requesting additional examinations on a sample have been defined. | ISO 15189 5.4.7<br>CLSI QMS01-A4 6.3.3.1 | |
| PRE5.1.4 | **M** | There are procedures for identification, retention, indexing, access, storage, maintenance and safe disposal of samples. | ISO 15189 5.7.2<br>CLSI QMS01-A4 6.3.3.1 | |
| PRE5.1.5 | **M** | Samples are safely disposed of in accordance with regulations or recommendations for waste management. | ISO 15189 5.7.2 | |
| **PRE5.2** | **There are procedures for the reporting of results on samples referred to another laboratory.** | | | |
| PRE5.2.1 | **M** | The referring laboratory is responsible for ensuring that a report of the referral laboratory's examination results is provided to the user unless other arrangements have been documented. | ISO 15189 4.5.2 | |
| PRE5.2.2 | **M** | The laboratory establishes a process to report referral laboratory results taking into account turnaround times, measurement accuracy, transcription and interpretative skill requirements. | ISO 15189 4.5.2 | REVISED |
| PRE5.2.3 | **M** | When the referring laboratory prepares the report it contains all of the essential elements without alteration that could affect the clinical interpretation. The authors of any additional remarks are clearly identified. | ISO 15189 4.5.2 | |
| PRE5.2.4 | **M** | Reports indicate which examinations have been performed by a referral laboratory or consultant. | ISO 15189 4.5.2 | |
| PRE5.2.5 | **M** | Records of samples sent to other laboratories are maintained and include the patient name, the name of the other laboratory, and the date sent.<br>*Guidance: This does not apply to facilities that simply receive a sample from one laboratory and forward it on to another laboratory.* | DAP15v1.0 | REVISED |
| PRE5.2.6 | **M** | There is a procedure for tracking late or missing reports for samples sent for examination unless other arrangements for reporting have been documented. | DAP15 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| PRE5.2.7 | **M** | Requests and results of all referred samples are kept for a period established by the referring laboratory. | ISO 15189 4.5.1e | |
| PRE5.2.8 | **M** | The reporting process is not hindered by commercial or financial considerations where the interpretation and application of examination results needs collaboration between referring and referral laboratories. | ISO 15189 4.5.2 | |

# EXAMINATION

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **EXA1.0** | **EXAMINATION PROCEDURES** | | | |
| **EXA1.1** | **Laboratory procedures are documented and available for use.** | | | |
| EXA1.1.1 | **M** | All examination procedures are documented and written in a language commonly understood by personnel in the laboratory. | ISO 15189 5.5.3 | |
| | | In addition to document control identifiers, procedural documents contain the following where applicable: | | |
| EXA1.1.6 | **M** | • purpose | ISO 15189 5.5.3a | |
| EXA1.1.7 | | • principle and method | ISO 15189 5.5.3b | |
| EXA1.1.8 | **M** | • performance characteristics | ISO 15189 5.5.3c | |
| EXA1.1.9 | **M** | • type of sample container and additives | ISO 15189 5.5.3d,f | |
| EXA1.1.10 | **M** | • patient preparation | ISO 15189 5.5.3e | |
| EXA1.1.11 | **M** | • required equipment and reagents | ISO 15189 5.5.3g | |
| EXA1.1.12 | **M** | • environmental and safety controls | ISO 15189 5.5.3h | |
| EXA1.1.13 | **M** | • calibration procedures | ISO 15189 5.5.3i | |
| EXA1.1.14 | **M** | • procedural steps | ISO 15189 5.5.3j | |
| EXA1.1.15 | **M** | • QC procedures | ISO 15189 5.5.3k | |
| EXA1.1.16 | **M** | • interferences (e.g. lipemia, hemolysis, icterus, drugs) and cross reactions | ISO 15189 5.5.3L<br>CAP – COM.40500 | |
| EXA1.1.17 | **M** | • calculations | ISO 15189 5.5.3m | |
| EXA1.1.18 | **M** | • biological reference intervals or clinical decision values | ISO 15189 5.5.3n | |
| EXA1.1.19 | **M** | • reportable interval | ISO 15189 5.5.3o<br>CAP COM.40600 | |
| EXA1.1.20 | **M** | • instructions for determining quantitative results when a result is not within the measurement interval (analytical measurement range) | ISO 15189 5.5.3p | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| EXA1.1.21 | **M** | • critical values | ISO 15189 5.5.3q | |
| EXA1.1.22 | **M** | • clinical interpretation where necessary | ISO 15189 5.5.3r | |
| EXA1.1.23 | **M** | • potential sources of variation | ISO 15189 5.5.3s | |
| EXA1.1.24 | **M** | • references and related documents | ISO 15189 5.5.3t | |
| **EXA1.2** | **There are procedures for handling samples when examination results are outside the analytical measurement range.** | | | |
| | | For results that fall outside the analytical measurement range, procedures include: | DAP15 | |
| EXA1.2.1 | **M** | • when repeat examinations are to be performed | DAP15 | |
| EXA1.2.2 | **M** | • when samples should be diluted, concentrated or pretreated | DAP15 | |
| EXA1.2.3 | **M** | • the maximum dilution and diluent | DAP15 | |
| EXA1.2.4 | **M** | • when results are reported as greater than the upper limit or less than the lower limit | DAP15 | |

## EXA2.0 EXAMINATION SELECTION, VALIDATION AND VERIFICATION

| | | | | |
|---|---|---|---|---|
| **EXA2.1** | **There are procedures for the selection, and evaluation of examination procedures.** | | | |
| EXA2.1.1 | **M** | Equipment and measuring systems are approved by the national or provincial authority having jurisdiction over in vitro diagnostic measuring systems where applicable (e.g. Health Canada). | ISO 15189 5.5.1.1 | |
| EXA2.1.2 | **M** | The laboratory selects examination procedures which have been validated for their intended use. *Guidance: Preferred procedures include those specified by manufacturers for use in in vitro medical devices and those procedures that have been published in recommended textbooks, peer-reviewed literature or international consensus standards or guidelines, or national or regional regulations.* | ISO 15189 5.5.1.1 | |
| EXA2.1.3 | **M** | There are procedures for the evaluation of new methods. | CLSI QMS01-A4 – 6.2.1 | |
| **EXA2.2** | **There are processes for the verification of examination procedures.** | | | |
| EXA2.2.1 | **M** | The laboratory obtains information from the manufacturer for verifying the performance characteristics of the examination procedure. | CLSI QMS01-A4 – 5.7.2.2 | |
| EXA2.2.2 | **M** | Validated examination procedures used without modification are independently verified prior to use. | ISO 15189 5.5.1.2 | |
| EXA2.2.3 | **M** | The independent verification by the laboratory confirms, through obtaining objective evidence that performance characteristics have been met. | ISO 15189 5.5.1.2 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| EXA2.2.4 | **M** | Performance characteristics used in the verification process are relevant to the intended use of the examination. | ISO 15189 5.5.1.2 | |
| EXA2.2.5 | **M** | Verification uses the same material that will be used in the method. | CLSI EP14-A2, QMS01 A4 5.7.2.1 | |
| EXA2.2.6 | | Within regional networks there are documented processes for primary and secondary verification. *Guidance: Primary verification includes accuracy, precision, linearity, detection, correlation and carry-over. Secondary verification includes sample stability, interference, reference intervals.* | | |
| EXA2.2.7 | | When secondary verification occurs within a regional network the site performing secondary verification retains proof that performance expectations were achieved. | CLSI QMS01-A4 5.7.2.1-5.7.2.3 | REVISED |
| **EXA2.3** | **There are processes for the validation of examination procedures.** | | | |
| EXA2.3.1 | **M** | The laboratory validates examination procedures derived from non-standard methods; laboratory-designed or developed methods, standard methods used outside their intended scope, and validated methods that are subsequently modified. | ISO 15189 5.5.1.3 CLSI QMS01-A4 5.7.2.1-5.7.2.4 | |
| EXA2.3.2 | **M** | Validation is as extensive as necessary, and confirms through the provision of objective evidence that the specific requirements for the intended use of the examination have been fulfilled. | ISO 15189 5.5.1.3 | |
| EXA2.3.3 | **M** | Validation uses the same material that will be used in the method. | CLSI EP14-A2, QMS01 A4 5.7.2.1 | |
| **EXA2.4** | **The validation and verification of examination procedures is documented.** | | | |
| EXA2.4.1 | **M** | There are procedures for validation or verification of examination procedures. | CLSI QMS01-A4 5.7.2.1-5.7.2.3 | |
| EXA2.4.2 | **M** | Results of validation or verification are recorded and compared to another valid examination (e.g. an existing examination method, sample exchange with a laboratory performing the same type of examination using similar methodology). | CLSI QMS01-A4 5.7.2.1-5.7.2.3 | |
| EXA2.4.3 | **M** | Personnel with the required knowledge, expertise and authority review the results. The review is documented. | ISO 15189 5.5.1.3 | REVISED |
| EXA2.4.4 | **M** | The medical director or designate determines the method acceptability based upon statistical analysis and medical outcome decisions. | CAP COM.40000 | |
| EXA2.4.5 | **M** | Validation and verification, including approval by the medical director or designate, is completed prior to reporting patient results. Personnel involved in selection, verification and validation processes are recorded. Validation and verification documentation including approval is retained. | ISO 15189 5.5.1.1 CAP COM.40000 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| | | Where required, validation and verification studies include documentation of: | | REVISED |
| EXA2.4.6 | **M** | • measurement accuracy | ISO 5.5.1.3<br>CLSI EP15-A2 | |
| EXA2.4.7 | **M** | • measurement precision at clinical decision levels | ISO 5.5.1.3<br>CLSI EP05-A2 | REVISED |
| EXA2.4.8 | **M** | • linearity to determine the measuring interval | ISO 5.5.1.3<br>CLSI EP06-A2<br>CAP COM.40000 | |
| EXA2.4.9 | **M** | • detection and quantitation limits to estimate the lowest concentration that can be measured where clinically relevant | ISO 5.5.1.3<br>CLSI EP17-A2 | |
| EXA2.4.10 | **M** | • correlation to review comparison and bias of the laboratory's patient data | ISO 5.5.1.3<br>CLSI EP09-A2 | |
| EXA2.4.11 | **M** | • sample stability to determine the maximum age of samples that can be tested | CAP COM.40000 | |
| EXA2.4.12 | **M** | • interference to determine constant and/or proportional interferences in the absence of manufacturer data | ISO 5.5.1.3<br>CLSI EP07-A2<br>CAP COM.40000 | |
| EXA2.4.13 | **M** | • carry-over | CAP COM.40000 | |
| **EXA2.5** | **There are processes to address changes to examination procedures.** | | | |
| EXA2.5.1 | **M** | When changes are made to an examination procedure, the influence of such changes is documented, and a new validation is performed when required. | ISO 15189 5.5.1.3 | REVISED |
| EXA2.5.2 | **M** | The laboratory documents the procedure used for the validation of changes and results are recorded. | ISO 15189 5.5.1.3 | |
| EXA2.5.3 | **M** | Authorized personnel review the validation results. This review is recorded. | ISO 15189 5.5.1.3 | |
| EXA2.5.4 | **M** | When an existing examination procedure is changed so that the results or interpretations could be significantly different, the implications are explained to users of the laboratory services after validating the procedure or when reporting results. | ISO1 15189 – 5.5.3 | |

## EXA3.0 REFERENCE INTERVALS, MEASUREMENT OF UNCERTAINTY

| | |
|---|---|
| **EXA3.1** | **Biological reference intervals or clinical decision values are defined and communicated to users.** |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| EXA3.1.1 | **M** | The source for non-laboratory established biological reference intervals or clinical decision values is documented. | ISO 15189 5.5.2<br>CAP GEN.50000 | |
| EXA3.1.2 | **M** | In-house reference intervals are created with a statistically significant number of values to determine ranges for each reference population. | CAP COM.50100 | REVISED |
| EXA3.1.3 | **M** | Manufacturer's recommended reference intervals are verified when they are used. | CLSI EP28-A3C | |
| EXA3.1.4 | **M** | Reference intervals are differentiated for age, gender and clinical conditions, if relevant. | CLSI EP28-A3c | |
| EXA3.1.5 | **M** | Reference intervals established as clinical targets are based on accepted guidelines or consensus statements. | CLSI EP28-A3c | |
| EXA3.1.6 | **M** | When the laboratory changes pre-examination conditions or examination procedures, the associated reference intervals and clinical decision values are reviewed. | ISO 15189 5.5.2 | REVISED |
| EXA3.1.7 | **M** | When a particular biological reference interval or decision value is no longer relevant for the population served, changes are made and communicated to users. | ISO 15189 5.5.2<br>CLSI EP28-A3c -12.2 | REVISED |
| **EXA3.2** | **The laboratory determines measurement uncertainty.** | | | |
| EXA3.2.1 | **M** | The laboratory determines measurement uncertainty for each quantitative measurement procedure. | ISO 15189 5.5.1.4<br>ISO/IEC Guide 98-3 | |
| EXA3.2.2 | **M** | The performance requirements for measurement uncertainty for each quantitative measurement procedure are defined. | ISO 15189 5.5.1.4<br>ISO/IEC Guide 98-3 | |
| EXA3.2.3 | **M** | Estimation of measurement uncertainty is reviewed at a defined frequency. This is documented. *Guidance: Estimation of measurement uncertainty does not require reassessment unless the original conditions of estimation have changed.* | ISO 15189 5.5.1.4<br>ISO/IEC Guide 98-3 | |
| EXA3.2.4 | **M** | Measurement uncertainty is considered when interpreting measured quantitative values. | ISO 15189 5.5.1.4<br>ISO/IEC Guide 98-3 | |
| EXA3.2.5 | **M** | Measurement uncertainty is provided to users upon request. | ISO 15189 5.5.1.4<br>ISO/IEC Guide 98-3 | |
| EXA3.2.6 | | Where examinations include a measurement step but do not report a quantitative value, the laboratory calculates the measurement uncertainty where it has value in assessing the reliability of the examination procedure or has influence of the reported result (e.g. serology testing for immune status). | ISO 15189 5.5.1.4<br>ISO/IEC Guide 98-3 | |

# POST-EXAMINATION

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **POS1.0** | | **REPORTING OF RESULTS** | | |
| **POS1.1** | | **There are procedures for the review and reporting of results.** | | |
| POS1.1.1 | **M** | Results are legible, reviewed and evaluated in conformity with the clinical information available. | ISO 15189 5.7.1,5.9.1c<br>CLSI QMS01-A4 6.2.3 | |
| POS1.1.2 | **M** | There are procedures for the release of examination results, including details of who may release results to recipients. | ISO 15189 5.9.1 | |
| POS1.1.3 | **M** | Reports that must be reviewed by a laboratory physician or designate are defined. | ISO 15189 5.9.1 | |
| POS1.1.4 | **M** | There is a procedure to review the accuracy of transcribed laboratory results. | ISO 15189 5.8.1<br>CAP GEN.41440 | |
| POS1.1.5 | **M** | The individual reviewing the report is recorded. | ISO 15189 5.8.1<br>CLSI QMS01-A4 6.3 | |
| POS1.1.6 | **M** | Final reports are issued for all examinations or consultations. | ISO 15189 5.9.1(d)<br>CLSI QMS01-A4 6.3 | |
| POS1.1.7 | **M** | Interim reports are distributed when required. Interim reports are clearly identified and always followed by a final report issued to the user. | ISO 15189 5.9.1d<br>CLSI QMS01-A4 6.3 | REVISED |
| POS1.1.8 | **M** | Individualized narrative results identify the author. | CLSI QMS01-A4 6.3 | |
| POS1.1.9 | **M** | The use of abbreviations or acronyms is limited. | CLSI QMS01-A4 6.3 | |
| POS1.1.10 | **M** | There is a procedure for reporting of examination results that may indicate sexual abuse or exploitation of a child. | BC CFCSa Part3, Div1:14 | |
| POS1.1.11 | **M** | Results are reported to persons authorized to receive and use the information. | ISO 15189 5.9.1c<br>CLSI QMS01-A4 6.3.2 | REVISED |
| POS1.1.12 | **M** | Each examination result is reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure. | ISO 15189 5.8.1<br>ISO 15189 5.9.1c<br>CLSI QMS01-A4 6.3.2 | |
| POS1.1.13 | **M** | There are procedures for reporting results when examinations are performed in duplicate. Limits of agreement are defined | CAP HEM.33200 | NEW |
| **POS1.2** | | **The confidentiality of patient information is maintained.** | | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| POS1.2.2 | **M** | There are policies and procedures that minimize the risk of inappropriate release of patient information.<br>*Guidance: This includes the release of confidential patient information to health-care professionals, other service areas within the organization, to other organizations, to patients, family members; and the release of confidential patient information for research, education purposes or legal reasons.* | CAP GEN.41303<br>CLSI QMS01-A4-5.9.2 | |
| POS1.2.3 | **M** | There is a policy that identifies personal information (including results) that can be distributed by telephone, email, facsimile and web-based technology. | ISO 15189 5.9.1e | |
| **POS1.3** | **Examination data is retained.** | | | |
| POS1.3.1 | **M** | Medical records are stored according to British Columbia's revised *Limitation Act* (2013).<br>*Guidance: The medical record comprises all the clinical data and information related to the patient's diagnostic examination. The medical record contains all relevant documents for examination including, but not limited to: the request, hard copy or electronic worksheets and reports. Facilities and medical directors establishing retention times outside of the requirements of the* Limitation Act *should seek and act according to expert legal advice on this matter.* | ISO 15189 4.13<br>GOBC LA | |
| POS1.3.2 | **M** | The laboratory complies with any individual circumstances noted for permanent extended periods of retention (e.g. government directives). | DAP15 | |
| **POS1.4** | **There are processes to ensure examination reports are delivered.** | | | |
| POS1.4.1 | **M** | Verbal reports are followed by a written report and a record of all verbal reports is maintained. | ISO 15189 5.9.1e | |
| POS1.4.2 | **M** | There are documented processes to ensure that results distributed by telephone or electronic means reach only authorized recipients. | ISO 15189 5.9.1e | |
| POS1.4.3 | **M** | There is a documented process for notifying the requester when an examination is delayed that could compromise patient care. | ISO 15189 5.8.1 | |
| POS1.4.5 | **M** | There is a procedure for tracking late or missing reports. | DAP15 | |
| POS1.4.6 | | There are documented processes to check the receipt of hard copy reports. | DAP15 | |
| **POS1.5** | **Turnaround times for examinations are established and monitored.** | | | |
| POS1.5.1 | **M** | The laboratory establishes turnaround times for each of its examinations that reflect clinical needs, in consultation with users. | ISO 15189 4.14.7<br>CLSI QMS01-A4 6.3.2.1 | |
| POS1.5.2 | **M** | The expected turnaround time is defined for stat, urgent and routine requests. | DAP15 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| POS1.5.3 | **M** | The laboratory evaluates if established turnaround times are achieved at a defined interval. | ISO 15189 4.14.7<br>ISO 15189 5.9.1<br>CLSI QMS01-A4<br>6.3.2.1 | |

## POS2.0 REPORT FORMAT

| POS2.1 | Examination results are reported using a defined format. | | | |
|---|---|---|---|---|
| POS2.1.1 | **M** | The laboratory has defined and approved the format, medium (electronic or hard copy) and the method of reporting. | ISO 15189 5.8.1<br>CLSI QMS01-A4 6.3.2 | |
| POS2.1.2 | | The laboratory has collaborated with users to ensure report formats and communication mechanisms meet their needs. | ISO 15189 5.8.2<br>CLSI QMS01-A4 6.3.2 | |
| POS2.1.3 | **M** | Laboratory reports include a clear identification of the examination including, where appropriate, the examination procedure. | ISO 15189 5.8.3a<br>CLSI QMS01-A4 6.3.2 | |
| POS2.1.4 | **M** | Laboratory reports include the identification of the laboratory that issued the report. | ISO 15189 5.8.3b<br>CAP GEN.41096<br>CLSI QMS01-A4 6.3.2 | |
| POS2.1.5 | **M** | Laboratory reports include identification of all examinations that have been performed by a referral laboratory. | ISO 15189 5.8.3c<br>CLSI QMS01-A4 6.3.2 | |
| POS2.1.6 | **M** | Laboratory reports include the patient's first and last name on each page. | ISO 15189 5.8.3d | |
| POS2.1.7 | **M** | Laboratory reports include a unique personal identification number such as a provincial health number (PHN) or a facility-issued identification number on each page. | DAP15 | |
| POS2.1.8 | **M** | Laboratory reports include patient location. | ISO 15189 5.8.3d<br>CLSI QMS01-A4 6.3.2 | |
| POS2.1.9 | **M** | Laboratory reports include date of birth. | CLSI QMS01-A4 6.3.2 | |
| POS2.1.10 | **M** | Laboratory reports include gender. | CLSI QMS01-A4 6.3.2 | |
| POS2.1.11 | **M** | Laboratory reports include the user and contact details. | ISO 15189 5.8.3e | |
| POS2.1.12 | **M** | Laboratory reports include other report recipient(s). | | |
| POS2.1.13 | **M** | Laboratory reports include the date of sample collection and time of sample collection when relevant to patient care. | ISO 15189 5.8.3f<br>CLSI QMS01-A4 6.3.2 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| POS2.1.14 | **M** | Laboratory reports include the type of primary sample.<br>*Guidance: It is not necessary to identify the primary sample, when the default is blood.* | ISO 15189 5.8.3g<br>CLSI QMS01-A4 6.3.2 | |
| POS2.1.15 | **M** | Laboratory reports include the examination results reported in SI units, units traceable to SI units, or other applicable units. | ISO 15189 5.8.3i | |
| POS2.1.16 | **M** | Laboratory reports include the biological reference intervals or clinical decision values. | ISO 15189 5.8.3j | |
| POS2.1.17 | **M** | Laboratory reports include an interpretation of results, as well as information necessary for the interpretation of results where appropriate. | ISO 15189 5.8.3k<br>ISO 15189 5.8.2c<br>ISO 15189 5.8.2d | |
| POS2.1.18 | **M** | Laboratory reports include a diagnosis or conclusion where appropriate. | DAP15 | |
| POS2.1.19 | **M** | Laboratory reports include other comments such as cautionary or explanatory notes. | ISO 15189 5.8.3l<br>ISO 15189 5.9.1a | |
| POS2.1.20 | **M** | Laboratory reports include identification of examinations undertaken as part of a research or development program and for which no specific claims on measurement performance are available. | ISO 15189 5.8.3m | |
| POS2.1.21 | **M** | Laboratory reports include identification of the personnel reviewing the results and authorizing the release of the report.<br>*Guidance: If not contained in the report, it is available when needed.* | ISO 15189 5.8.3n | |
| POS2.1.22 | **M** | Laboratory reports include date of the report and time of release.<br>*Guidance: If not contained in the report, it is available when needed.* | ISO 15189 5.8.3o | |
| POS2.1.23 | **M** | Laboratory reports include the page number to total number of pages (e.g. Page 1 of 5). | ISO 15189 5.8.3p | |
| POS2.1.24 | **M** | Laboratory reports include flagging of high, low and critical results. | DAP15 | |
| POS2.1.25 | **M** | Laboratory reports include comparison with prior results when prior results are available and relevant (e.g. immune status). | DAP15 | |
| POS2.1.26 | | Laboratory reports include recommendations for repeat or follow-up examination when indicated. | DAP15 | |
| POS2.1.27 | **M** | Laboratory reports include comments on sample quality that could compromise examination results or sample suitability with respect to acceptance/rejection criteria. | ISO 15189 5.8.2a-b<br>CLSI QMS01-A4 6.3.2 | |

## POS3.0 CRITICAL RESULTS REPORTING, CORRECTED AND ADDENDUM REPORTS

| | |
|---|---|
| **POS3.1** | **There are procedures for reporting critical results.** |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| POS3.1.1 | **M** | Critical values are established for all examinations that may generate critical results.<br>*Guidance: Clinicians using laboratory services have been consulted in the determination of critical values, where applicable.* | ISO 15189 5.9.1b | |
| POS3.1.2 | **M** | The list of critical values is accessible to personnel. | DAP15 | |
| POS3.1.3 | **M** | There is a procedure on communication of critical results. | CAP COM.30000 | |
| POS3.1.4 | **M** | Critical results are reported to clinical personnel immediately by direct means. This includes results received on samples sent to referral laboratories. | ISO 15189 5.9.1b | |
| POS3.1.5 | **M** | There are documented processes to verify that the correct result has been completely and accurately received after verbal communication.<br>*Guidance: This applies to critical results that are only reported verbally.* | ISO 15189 5.9.1e<br>CAP COM.30100 | |
| POS3.1.6 | **M** | Contingency plans are available in the event that clinical personnel cannot be contacted. | DAP15 | |
| | | Notification and actions taken in response to critical results are documented including: | DAP15 | |
| POS3.1.7 | **M** | • the critical result(s) | CAP COM.30000 | |
| POS3.1.8 | **M** | • name of the person receiving the result | CAP COM.30000 | |
| POS3.1.9 | **M** | • date, time, and method of communication | CAP COM.30000 | |
| POS3.1.10 | **M** | • any difficulties encountered in the notification | ISO 15189 5.9.1b | |
| POS3.1.11 | **M** | • the responsible laboratory personnel involved | CAP COM.30000 | |
| POS3.1.12 | **M** | Criteria are established for the notification of a laboratory physician, in addition to clinical personnel. | ISO 15189 5.9.1b | |
| **POS3.2** | **There are procedures for corrected and addendum reports.** | | | |
| POS3.2.1 | **M** | There are procedures for corrected and addendum reports. | CLSI QMS01-A4 6.3.2.2 | |
| POS3.2.2 | **M** | Corrected and addendum reports are clearly identified and include the date and patient's identity. | ISO 15189 5.9.3a | |
| POS3.2.3 | **M** | Notification of clinical personnel is performed and recorded when there is a significant discrepancy between the original and the corrected or addendum report. | ISO 15189 5.9.3b<br>CLSI QMS01-A4 6.3.2.2 | |
| POS3.2.4 | **M** | The identity of the person making the change or addition and the date and time the change or addition was made, is recorded. | ISO 15189 5.9.3c, d<br>CLSI QMS01-A4 6.3.2.2 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| POS3.2.5 | **M** | The original report entries remain in the record when revisions are made. | ISO 15189 5.9.3c<br>CLSI QMS01-A4<br>6.3.2.2 | |
| POS3.2.6 | **M** | Results that have been reported and then revised are clearly identified and retained in subsequent cumulative reports. | ISO 15189 5.9.3 | |
| POS3.2.7 | **M** | A record is kept when the reporting system cannot capture amendments, changes or alterations. | ISO 15189 5.9.3c<br>CLSI QMS01-A4<br>6.3.2.2 | |

# SAMPLE COLLECTION

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **SCT1.0** | | **CONSENT** | | |
| **SCT1.1** | | **Procedures requiring informed consent are defined.** | | |
| SCT1.1.1 | **M** | The laboratory has defined specific procedures or services that require informed consent from patients (e.g. fine needle biopsy). Information is provided to the patient at a level that can be understood. | ISO 15189 5.4.4.1<br>CSA Z316.7 6.2.2, 11.6 | |
| **SCT2.0** | | **COLLECTION INSTRUCTIONS** | | |
| **SCT2.1** | | **There are sample collection instructions available for sample collectors.** | | |
| SCT2.1.1 | **M** | Sample collection procedures include the type and amount of primary sample to be collected with descriptions of the primary sample containers and any necessary additives. | ISO 15189 5.4.4.2c<br>ISO 15189 5.4.4.3c<br>ISO 15189 5.4.4.3d<br>CSA Z316.7 11.2 | |
| SCT2.1.2 | **M** | Sample collection procedures include the timing of collection, where needed. | ISO 15189 5.4.4.2d<br>CSA Z316.7 11.2 | |
| SCT2.1.3 | **M** | Sample collection procedures include providing clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs). | ISO 15189 5.4.4.2e<br>CSA Z316.7 11.2 | |
| SCT2.1.4 | **M** | Sample collection procedures include positive patient identification requirements for collecting a sample. | ISO 15189 5.4.4.3a<br>CSA Z316.7 11.2 | |
| SCT2.1.5 | **M** | Sample collection procedures include verification that the patient meets pre-examination requirements (e.g. fasting status, medication status). | ISO 15189 5.4.4.3c<br>CSA Z316.7 11.2 | |
| SCT2.1.6 | **M** | Sample collection procedures include instructions for labelling primary samples that provide an unequivocal link with the patient. | ISO 15189 5.4.4.3e<br>CSA Z316.7 11.2 | |
| SCT2.1.7 | **M** | Sample collection procedures include recording the identity of the sample collector and the collection date and when needed, the collection time. | ISO 15189 5.4.4.3f<br>CSA Z316.7 11.2 | |
| SCT2.1.8 | **M** | Sample collection procedures include information on proper storage conditions before collected samples are delivered to the laboratory. | ISO 15189 5.4.4.3g<br>CSA Z316.7 11.2 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SCT2.1.9 | **M** | Sample collection procedures include safe disposal instructions for materials used in the collection. | ISO 15189 5.4.4.3h<br>CSA Z316.7 11.2 | |
| SCT2.1.10 | **M** | Sample collection procedures include the order of draw. | CSA Z316.7 -11.8.2.4 | |
| SCT2.1.11 | **M** | Sample collection procedures include sample handling and transport. | ISO 15189 5.4.4.3d<br>CSA Z316.7 11.2 | |
| SCT2.1.12 | **M** | Sample collection procedures include recording deviation from documented collection procedures. | ISO 15189 5.4.4.2 | |
| SCT2.1.13 | **M** | Sample collection procedures include packaging of samples for transportation. | ISO 15189 5.4.5<br>CSA Z316.7 11.2 | |
| SCT2.1.14 | | Sample collection instructions and information are available in a variety of languages and formats that recognizes the population served. | CSA Z316.7 6.2.2 | |
| SCT2.1.15 | **M** | Sample collection procedures are available to all sample collectors. | ISO 15189 5.4.4.1<br>CSA Z316.7 11.2 | |

## SCT3.0 PATIENT IDENTIFICATION

| SCT3.1 | | Samples are traceable to an identified patient. | | |
|---|---|---|---|---|
| SCT3.1.1 | **M** | Positive patient identification using at least two unique patient identifiers is confirmed prior to all sample collection by the sample collector. | CSA Z316.7 11.4.1 | |
| SCT3.1.2 | **M** | In-patients have a facility identification band attached to their person at the time of sample collection and band information is confirmed verbally by the patient, if possible. | CSA Z316.7 11.4.1 | |
| SCT3.1.3 | **M** | Pediatric and other patients who cannot provide identification information are identified by a responsible adult. | CSA Z316.7 11.4.1 | |
| SCT3.1.4 | **M** | Patient identity information discrepancies are resolved prior to collecting the sample. | CSA Z316.7 11.4.1 | |
| SCT3.1.5 | **M** | Samples are labeled after the collection process, in the presence of the patient by the collector.<br>*Guidance: Pre-labeling of sample containers for patient collected samples is acceptable.* | CSA Z316.7 12.2 | |
| SCT3.1.6 | **M** | Primary sample containers are labeled with a minimum of two patient identifiers. | CSA Z316.7 12.2<br>CAP GEN.40491 | |
| SCT3.1.7 | **M** | When printed labels are affixed to sample containers after the primary sample has been labeled, they do not obscure the original label. | CSA Z316.7 12.2.1.3 | |
| SCT3.1.8 | **M** | Multiple samples collected at one time from the same patient, and similar samples collected at different times from the same patient are uniquely identified. | DAP15 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| SCT3.1.9 | **M** | A labeling system is defined by the laboratory for sample containers too small for all required information. | CSA Z316.7 12.2 | |
| SCT3.1.10 | **M** | A documented emergency identification method is used when the patient's identity is unknown. | CSA Z316.7 11.4 | |
| SCT3.1.11 | **M** | The emergency identification information is cross-referenced with the patient's name and identification number when that name and number become known. | CSA Z316.7 –11.4 | |

## SCT4.0 SAMPLE COLLECTION

| SCT4.1 | There are procedures for sample collection. | | | |
|---|---|---|---|---|
| SCT4.1.1 | **M** | In-date, leak-proof sample containers and kits appropriate for the examination are used. | DAP15 | REVISED |
| SCT4.1.2 | **M** | Sample collection carts and trays are clean, without clutter and have puncture-proof sharps discard containers. | DAP15 | |
| SCT4.1.3 | **M** | Collection equipment including phlebotomy chairs are used to reduce safety risks to patients and personnel. | CSA Z316.7 7.3 | |
| SCT4.1.4 | **M** | Arm supports are rigid and have fluid-resistant surfaces.<br>*Guidance: Pillows are not used during phlebotomy* | DAP15 | |
| SCT4.1.5 | **M** | Tourniquet application does not exceed one minute and vigorous hand exercise (pumping) is avoided prior to collection of the sample. | CSA Z316.7 11.8.2.1-2 | |
| SCT4.1.6 | **M** | Sample collection sites are appropriately selected and samples are collected away from a hematoma of any size. | CSA Z316.7 11.8.2.7 | |
| SCT4.1.7 | **M** | Phlebotomy sites are properly decontaminated. | DAP15 | |
| SCT4.1.8 | **M** | Sample containers are collected in the correct order. | CSA Z316.7 11.8.2.4 | |
| SCT4.1.9 | **M** | Sample containers are thoroughly but gently mixed according to the manufacturer's directions. | CSA Z316.7 11.8.2.3 | |
| SCT4.1.10 | **M** | Indwelling intravenous lines containing heparin are cleared by drawing six times the dead-space volume of the catheter prior to collection of the sample. | CSA Z316.7 11.8.4.3 | |
| SCT4.1.11 | **M** | There is a documented process to address instances when sample collection is difficult. | DAP15 | |
| SCT4.1.12 | **M** | A gauze pad or cotton ball is placed over the site and mild pressure is applied. After a defined time the sample collector observes the patient for excessive bleeding and development of a hematoma. | CSA Z316.7 11.13 | REVISED |
| SCT4.1.13 | **M** | Patients are discouraged from bending their arms up as a substitute for pressure. | CSA Z316.7 11.13 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| SCT4.1.14 | **M** | Post-phlebotomy care includes the use of adhesive bandages or hypoallergenic tape and gauze pads or cotton balls.<br>*Guidance: Gauze pads are preferred over cotton balls because of the possibility of dislodging the platelet plug at the venipuncture site.* | CSA Z316.7 11.13 | |
| SCT4.1.15 | **M** | Adhesive bandages are not used on children under two years of age.<br>*Guidance: Bandages are considered a choking hazard in young children. In neonates and very young infants, removal of an adhesive bandage may damage the skin.* | CLSI GP41-A6 7.12<br>CLSI GP42-A6 12.2 | |
| SCT4.1.16 | **M** | There is a documented emergency response process for patient adverse events.<br>*Guidance: Personnel know how to access emergency services or respond to medical emergencies (e.g. fainting, seizures, cardiac arrest).* | DAP15 | |
| **SCT4.2** | **There is a system to identify the sample collector.** | | | |
| SCT4.2.1 | **M** | The identity of the sample collector and the date and time of sample collection is recorded. | CSA Z316.7 12.2.1.1 | |

# Accreditation Standards 2015

Laboratory Medicine

## ANATOMIC PATHOLOGY STANDARDS

The anatomic pathology standards are used in conjunction with the general standards for each laboratory.

# ANATOMIC PATHOLOGY

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **ANP1.0** | **SAFETY** | | | |
| **ANP1.1** | **Formaldehyde and xylene exposure is controlled.** | | | |
| ANP1.1.1 | **M** | Initial formaldehyde monitoring is performed in new laboratories or when a change in production, equipment, personnel or processes result in new or additional exposure. | CLSI GP17-A3 9.1.4<br>CAP ANP.08216 | |
| ANP1.1.2 | **M** | Xylene exposure levels are monitored initially and when there are changes likely to increase exposure levels. | CLSI GP17-A3 9.1.4<br>CAP ANP.08216 | |
| ANP1.1.3 | **M** | Ventilation in the gross room and tissue storage areas ensures acceptable formaldehyde levels. This is monitored at a defined interval. | CAP ANP.08216 | REVISED |
| ANP1.1.4 | | Personnel at significant risk of exposure are identified and monitored. | CAP ANP.08216 | |
| ANP1.1.5 | **M** | Action limits for exposure are defined and consistent with WorkSafeBC guidelines.<br>*Guidance: Exposure limits are listed for eight-hour weighted average (TWA).The formaldehyde limit is 0.3 ppm TWA and xylene is 100 ppm TWA.* | GOBC OHSR<br>Part 5-Table 1 | |
| ANP1.1.6 | **M** | Periodic formaldehyde monitoring is performed according to WorkSafeBC guidelines.<br>*Guidance: Laboratories may perform periodic monitoring only if initial monitoring is less than the action limit.* | GOBC OHSR<br>Part 5 | |
| ANP1.1.7 | **M** | Corrective action occurs when exposure limits are exceeded. | CAP ANP.08216 | |
| ANP1.1.8 | **M** | Formaldehyde exposure is monitored if there are reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure. | CAP ANP.08216 | |
| **ANP2.0** | **PRE-EXAMINATION** | | | |
| **ANP2.1** | **There are guidelines for the collection of anatomic pathology samples.** | | | |
| ANP2.1.1 | **M** | Collection instructions for locations that send samples to anatomic pathology include information on the completion of the request form with relevant clinical information, sample containers, additives and fixatives. | ISO 15189 5.4.4.2<br>CAP GEN.40100 | |
| **ANP2.2** | **There are procedures for handling tissues that may contain radioactive material or tissues from suspected or known cases of prion disease.** | | | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP2.2.1 | **M** | There are procedures for the safe handling of tissues that may contain radioactive material (e.g. sentinel lymph nodes, breast biopsies, prostate seeds). | CAP ANP.11275 | |
| ANP2.2.2 | **M** | Laboratory personnel are notified prior to submission of samples from suspected or known cases of prion disease. | CAP ANP.24300 | |
| ANP2.2.3 | **M** | There are procedures that address the handling of tissue in suspected or known cases of prion disease. The tissue is visibly identified. Neuropathology tissues are treated with formic acid. All scraps of paraffin and unused sections are collected on a disposable sheet. Broken slides are decontaminated and discarded. Paraffin blocks are stored in a bag or box and labeled as a suspected or known cases of prion disease and the cut surfaces of blocks are resealed with wax. | CAP ANP.24300 | |

## ANP3.0 GROSS EXAMINATION

| | | | | |
|---|---|---|---|---|
| **ANP3.1** | **Gross examinations are performed by pathologists or qualified delegates.** | | | |
| ANP3.1.1 | **M** | All patient samples are grossly examined by a pathologist who may delegate this task to qualified personnel or a resident trainee with the appropriate supervision. | CAP ANP.11600 | |
| ANP3.1.2 | **M** | There is a list of samples that may be grossed by technologists or other non-pathologist laboratory personnel. | CAP ANP.11605 | |
| ANP3.1.3 | **M** | If samples are grossed by technologists or other non-pathologist laboratory personnel, there is a dissection manual that includes instructions for each sample type and specific indications when a pathologist is to be contacted for advice or assistance. | CAP ANP.11605 | |
| ANP3.1.4 | **M** | If samples are grossed by technologists or other non-pathologist laboratory personnel, there is a documented process to ensure competence that includes evaluation by a designated pathologist at a defined frequency. | CAP ANP.11640 | |
| **ANP3.2** | **There are procedures for the gross examination of tissues.** | | | |
| ANP3.2.1 | **M** | There is a tissue exclusion list that defines the types of tissues not requiring examination by the anatomic pathology laboratory. | CAP ANP.10016 | |
| ANP3.2.2 | **M** | All samples are assessed for the appropriate type and amount of fixative and nonconformities are documented. | CAP ANP.11475<br>CAP QMAP 49 | |
| ANP3.2.3 | **M** | A gross dissection and sample handling manual that includes all specialized diagnostic procedures is available. | CAP ANP.11670 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP3.2.4 | **M** | All instruments and work surfaces are cleaned between cases to prevent cross contamination. | DAP15 | |
| ANP3.2.5 | **M** | Multiple samples on the same case are clearly differentiated in dictation. | DAP15 | |
| ANP3.2.6 | **M** | Multiple coloured inks or dyes for marking tissue margins are available in the gross room. | DAP15 | |
| ANP3.2.7 | **M** | Samples are inked prior to cutting into the sample when appropriate. | DAP15 | |
| ANP3.2.8 | | Cassettes are not packed too tightly with tissue. | DAP15 | |
| **ANP3.3** | **There are procedures to maintain sample identity throughout all processes.** | | | |
| ANP3.3.1 | **M** | There are documented processes to reduce sample identification errors. | CAP ANP.21050 | |
| ANP3.3.2 | **M** | Multiple samples received from the same patient on the same day and from the same procedure, are all identified with the same accession or surgical case number and subcategorized by separate letters or numbers. | DAP APAC 2013 | |
| ANP3.3.3 | **M** | A unique case and block identifier is documented for each cassette. | CAP ANP.21050 | |
| ANP3.3.4 | **M** | Any additional blocks that are prepared later are documented. | CAP ANP.21350 | |
| ANP3.3.5 | **M** | Slides are identified with the case accession number, block designator and patient name. | CAP ANP.21050 | |
| ANP3.3.6 | **M** | Block and slide identification information is indelible, legible and able to withstand all stages of processing and conditions of storage. | CAP ANP.21050 | |
| ANP3.3.7 | **M** | Work lists are generated that include the case or surgical number and cassette identifier(s). | DAP15 | |

## ANP4.0 TISSUE PROCESSING, EMBEDDING, MICROTOMY, STAINING

| **ANP4.1** | **There are procedures to ensure the quality of tissue processing.** | | |
|---|---|---|---|
| ANP4.1.1 | **M** | Samples are fixed for a minimum of eight hours prior to processing and there is a documented process to record inadequate fixation.<br>*Guidance: If samples arrive unfixed, the laboratory notes the time the sample was fixed, particularly if a significant time has elapsed between sample collection and fixation*. | MOD PATH |
| ANP4.1.2 | **M** | New tissue processing schedules are validated against the standard laboratory processing schedule. | CAP ANP.23120 |
| ANP4.1.3 | **M** | Tissue processors are alarmed and monitored in case of malfunction. | CAP QMAP 77-78 |
| ANP4.1.4 | **M** | Tissue processor solutions are changed at defined intervals. | CAP ANP.23100 |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP4.1.5 | **M** | The quality of tissue processing is checked daily and recorded. | CLSI GP31-A 6.7.5.2 | |
| **ANP4.2** | **There are procedures to ensure the quality of tissue embedding.** | | | |
| ANP4.2.1 | **M** | Paraffin dispensers are clean and well maintained. | CAP ANP.23150 | |
| ANP4.2.2 | **M** | The temperature of paraffin dispensers is checked at a defined frequency, and this is documented. | CLSI GP31-A 6.7.6.2 | |
| ANP4.2.3 | **M** | The temperature of paraffin dispensers is adjusted for the type of paraffin used. | CAP ANP.23150 | |
| ANP4.2.4 | **M** | Work lists are available for embedding and include the number of tissue pieces per cassette and special embedding instructions. | DAP15 | |
| ANP4.2.5 | **M** | Only one cassette is opened at a time while embedding. | DAP15 | |
| ANP4.2.6 | **M** | There are documented processes to record and resolve any discrepancies identified during embedding. | DAP15 | |
| ANP4.2.7 | **M** | There are documented processes to provide feedback to personnel performing embedding. | DAP15 | |
| **ANP4.3** | **There are procedures to ensure the quality of tissue microtomy.** | | | |
| ANP4.3.1 | **M** | Flotation baths are kept clean and well-maintained and there is a procedure for preventing cross-contamination of paraffin sections in the bath. | CAP ANP.23350 | |
| ANP4.3.2 | | Microtomes are clean and well maintained. | CAP ANP.23400<br>CLSI GP31-A 6.7.1.4 | |
| ANP4.3.3 | **M** | Microtome blades are stored safely to avoid injury. | CAP ANP.24100<br>CLSI GP17-A3 9.1.2 | |
| ANP4.3.4 | | Work lists are available for embedding and include the number of slides to be cut. | DAP15 | |
| ANP4.3.5 | **M** | There are documented processes to record and resolve any discrepancies identified during microtomy (e.g. tissue slide mismatch). | CAP ANP.11734 | |
| ANP4.3.6 | | Like or similar samples are not cut consecutively. | DAP15 | |
| ANP4.3.7 | **M** | Section thickness is defined by tissue type and procedure. | CAP ANP.11716 | |
| **ANP4.4** | **There are procedures to ensure the quality of tissue staining.** | | | |
| ANP4.4.1 | **M** | Stains and reagents are maintained and replaced according to a documented schedule. | ISO 15189 5.3.2.7d<br>CAP ANP.11756 | |
| ANP4.4.2 | **M** | The quality of routine hematoxylin and eosin (H&E) staining is monitored using control slides on each day of staining. This is documented. | CAP ANP.11713<br>CAP QMAP 78-80 | |

| No. | Standard / Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP4.4.3 | **M** | Control slides are processed with every special stain or batch of stains and made available to pathologists. | CAP ANP.11713<br>CAP ANP.21450 | |
| ANP4.4.4 | **M** | The pH of buffers and reagents are monitored where appropriate. | CAP ANP.22500 | |
| ANP4.4.5 | | Microwave devices are monitored for reproducibility at least annually. | CLSI GP28-A<br>CAP ANP.28290 | |
| **ANP4.5** | **There are procedures to monitor slide quality.** | | | |
| ANP4.5.1 | **M** | There is a review of slide quality that includes tissue fixation, orientation, section thickness, inclusion of the entire tissue plane, the absence of folds and tears, the quality of staining and the quality of cover slipping. | CAP ANP.11734<br>CAP QMAP 78-80 | |
| ANP4.5.2 | **M** | The review of slide quality is performed and documented by a supervisor or designate. | CAP ANP.11713 | |
| **ANP4.6** | **There is space for the storage of samples.** | | | REVISED |
| ANP4.6.1 | | There is refrigerated storage room for large unfixed samples. | CAP ANP.11250 | |
| ANP4.6.2 | **M** | All patient materials (e.g. slides, paraffin blocks, wet tissue) are stored in an orderly manner in conditions that ensure optimal preservation. | CAP ANP.23700 | |

## ANP5.0 MICROSCOPIC EXAMINATION AND CONSULTATION

| | | | | |
|---|---|---|---|---|
| **ANP5.1** | **There are procedures for microscopic examination and diagnosis.** | | | |
| ANP5.1.1 | **M** | All microscopic examination for diagnosis other than exfoliative cytology is performed by a pathologist. | CAP ANP.23036<br>CAP ANP.11660 | |
| ANP5.1.2 | **M** | There are documented processes to support diagnostic interpretative work performed in smaller sites with few pathologists. | DAP15 | |
| ANP5.1.3 | | There is readily accessible peer diagnostic support. | DAP15 | |
| ANP5.1.4 | **M** | Pertinent previous cytological and histological material and reports are reviewed with the current material being examined and this review is documented. | CAP ANP.10050 | |
| ANP5.1.5 | | There are procedures to correlate the results of ancillary examinations with the morphological diagnosis (e.g. immunohistochemistry, flow cytometry). | CAP ANP.12400 | |
| **ANP5.2** | **There are procedures for internal and external consultations.** | | | |
| ANP5.2.1 | **M** | Intradepartmental and external consultations are documented. | CAP ANP.10150 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP5.2.2 | **M** | There is a tracking mechanism that monitors the use, circulation, referral, transfer and receipt of original slides and blocks sent for consultation. | CAP ANP.10260 | |
| ANP5.2.3 | **M** | Original materials including slides and blocks are promptly returned to the original institution and there is a record of that return. | CAP ANP.10250 | |
| ANP5.2.4 | **M** | There is a documented process to follow up on slides and blocks that have not been returned. | CAP ANP.10260 | |
| ANP5.2.5 | **M** | If original material is not returned, a letter is sent to the referring laboratory along with the consultation report, requesting permission to retain the slides and accepting transfer of stewardship of the original materials. | CAP ANP.10250 | |
| ANP5.2.6 | **M** | There is a documented process for resolving discrepancies between referring laboratories and referral laboratories. Significant discrepancies are documented and major discrepancies are resolved. An addendum report is issued and the responsible clinician is informed. | DAP15 | |
| ANP5.2.7 | **M** | A written report is issued for every extra-institutional consultation or review that is received and a copy of that written report is sent to the originating laboratory. | CAP ANP.10250 | |

## ANP6.0 REPORTS

| ANP6.1 | Pathology reports include all information relevant to the diagnosis (in addition to POS2.1). | | | |
|---|---|---|---|---|
| ANP6.1.1 | **M** | Pathology reports include site of origin, when applicable. | CAP ANP.12200 | |
| ANP6.1.2 | **M** | Pathology reports include the type, number, volume, size or weight of samples. | CAP ANP.12200 | |
| ANP6.1.3 | **M** | Pathology reports include any measurements of gross lesions when indicated. | CAP ANP.12200 | |
| ANP6.1.4 | **M** | Pathology reports include any block designations for special sections (e.g. margins of resection, deepest penetration of tumor). | CAP ANP.12200 | |
| ANP6.1.5 | **M** | Pathology reports include pertinent ancillary studies. | CAP ANP.12400 | |
| ANP6.1.6 | **M** | Pathology reports include gross descriptions if performed. | CAP ANP.12200 | |
| ANP6.1.7 | **M** | Extra-institutional consultations or reviews are included in the final report or as an addendum. | CAP ANP.10150 | |
| ANP6.1.8 | **M** | Diagnoses comply with recognized pathological entities, standard terminology and use clear and unambiguous language. | DAP15 | |
| ANP6.1.9 | **M** | Multiple diagnoses are clearly separated. | DAP15 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP6.1.10 | **M** | All reports containing interpretations by a pathologist indicate authorship and assurance that the contents of the report have been verified by the author. | CAP ANP.11660<br>CAP ANP.12170 | |
| ANP6.1.11 | | If a report is reviewed and approved by a pathologist other than the diagnosing pathologist, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performed final verification appear on the report. | CAP ANP.12170 | |
| **ANP6.2** | **Pathology reports use a structured format (e.g. synoptic reports).** | | | |
| ANP6.2.1 | **M** | Reporting on cancer diagnoses meets or exceeds provincial cancer reporting guidelines as established by provincial synoptic reporting committees or groups. | DAP15 | |
| ANP6.2.2 | **M** | Pathology results of major organ system malignancies are reported in a routine format including all of the appropriate prognostic variables. | CAP ANP.12385 | |
| ANP6.2.3 | | Scientifically validated data elements needed for standard systems of grading, staging and prognostication are included in the pathology report. | DAP15 | |
| ANP6.2.4 | | Data is displayed as a required checklist item (e.g. tumor size: 5.5 cm). | DAP15 | |
| ANP6.2.5 | | All data elements and responses are listed together in one location. | DAP15 | |
| ANP6.2.6 | **M** | Standardized synoptic reporting templates are updated to reflect changes. | DAP15 | |

## ANP7.0 INTRAOPERATIVE CONSULTATIONS

| | | | | |
|---|---|---|---|---|
| **ANP7.1** | **Intraoperative consultation is performed in a suitable area.** | | | |
| ANP7.1.1 | **M** | There is space to allow for safe working conditions, unobstructed movement, and the storage of supplies in the frozen section area. | ISO 15189 5.2.1<br>ISO 15190 6.2<br>CLSI QMS01-A4 5.3.1.1<br>CAP ANP.11756 | REVISED |
| ANP7.1.3 | **M** | Ventilation in the gross room and in tissue storage areas ensures acceptable formaldehyde levels. This is monitored at a defined interval. | ISO 15190 6.3.3<br>CLSI GP17-A3 4.2.4 | REVISED |
| ANP7.1.4 | | The pathologist performing an intraoperative consultation has access to the patient's history. | DAP15 | |
| **ANP7.2** | **There are procedures for reporting intraoperative consultations.** | | | |
| ANP7.2.1 | **M** | Intraoperative diagnosis by gross or frozen section examination is performed by a pathologist or by residents supervised by a pathologist. | CAP ANP.11660 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP7.2.2 | **M** | Measurements and description of the tissue are recorded prior to performing the frozen section. | CAP ANP.11600<br>CAP ANP.11670 | |
| ANP7.2.3 | **M** | The quality of sectioning and staining is adequate for intraoperative diagnoses. | CAP ANP.11810 | |
| ANP7.2.4 | **M** | Reports of intraoperative consultations always include positive patient identification and are documented on the patient chart within the perioperative time frame. | CAP ANP.11950 | |
| ANP7.2.5 | **M** | Verbal reports are communicated directly to the surgeon by a pathologist and always include positive patient identification. | CAP ANP.11900 | |
| ANP7.2.6 | | Contingency plans are available in the event that the requesting physician cannot be contacted. | DAP15 | |
| ANP7.2.7 | **M** | Any intraoperative diagnosis is a discrete part of the final report. | CAP ANP.12000 | |
| **ANP7.3** | **Intraoperative diagnoses are correlated with final diagnoses.** | | | |
| ANP7.3.1 | **M** | All frozen section slides are stained, mounted, permanently labeled and retained with the rest of the slides from the case. | CAP ANP.12050, | |
| ANP7.3.2 | **M** | Tissue remaining from the frozen section is processed and permanent sections are prepared and examined. | CAP ANP.12075 | |
| ANP7.3.3 | **M** | Discordance between the intraoperative and the permanent diagnosis is recorded and significant discordance is investigated. | CAP QMAP 50-51 | |
| ANP7.3.4 | | Cases of discordance are subcategorized (e.g. sampling error, interpretation error, labeling error). | DAP15 | |
| ANP7.3.5 | **M** | Significant discordance between intraoperative diagnosis and the permanent diagnosis is reconciled in writing (e.g. in the surgical pathology report). | CAP ANP.10100 | |
| **ANP7.4** | **There are procedures for cryostat use and decontamination.** | | | |
| ANP7.4.1 | **M** | There are decontamination guidelines for the cryostat. | CAP ANP.23410<br>CLSI M29-A3 10.2.2 | |
| ANP7.4.2 | **M** | Decontamination of the cryostat is performed and documented at defined intervals. | CAP ANP.23410<br>CLSI M29-A3 10.2.2 | |
| ANP7.4.3 | **M** | Requirements for the use of PPE while performing intraoperative consultations have been defined. | CLSI M29-A3 10.2.1 | |

## ANP8.0 IMMUNOHISTOCHEMISTRY (IHC)

| | |
|---|---|
| **ANP8.1** | **There are procedures for the validation or verification of new immunohistochemical examinations.** |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP8.1.1 | | Tissues used for validation or verification are processed with the same fixative and processing materials as the tissue that will be examined. | CAP ANP.22750 | |
| ANP8.1.2 | | Tissues used for validation or verification include high and low expressors for positive cases and span the expected range of clinical results (expression levels) for markers that are reported quantitatively. | CAP QMAP 95-96 | |
| ANP8.1.3 | **M** | A minimum of 20 positive and 20 negative tissues are examined for the validation or verification of predictive examinations.<br>*Guidance: This applies only to estrogen receptor and progesterone receptor and to HER2.* | CAP ANP.22750<br>CAP ANP.22973, 76<br>DAP APAC APR 2014 | |
| ANP8.1.4 | **M** | A minimum of 10 positive and 10 negative tissues are examined for the validation or verification of non-predictive factor examinations. | CAP ANP.22750 | |
| ANP8.1.5 | **M** | When the medical director determines that fewer cases are needed for validation or verification, the rationale for that decision is documented. | CAP QMAP 95-96 | |
| ANP8.1.6 | | Markers with both predictive and non-predictive applications are validated or verified as a predictive marker if used as such. | CAP QMAP 95-96 | |
| ANP8.1.7 | | Results of validation or verification are recorded and compared to another valid examination (e.g. an existing examination method, sample exchange with a laboratory performing the same type of examination using similar methodology). | CAP QMAP 95-96 | |
| ANP8.1.8 | | The medical director determines the number of positive and negative cases and the number of predictive and non-predictive markers used to validate immunohistochemistry examination on cytological samples or on decalcified tissues. | CAP QMAP 95-96 | |
| ANP8.1.9 | **M** | Validation or verification studies achieve a minimum 95% concordance rate. | CAP QMAP 95-96 | |
| ANP8.1.10 | **M** | Each new antibody or antibody clone is validated or verified for specific fixation and processing procedures including optimal titration, antigen retrieval, detection systems and fixation. | CAP ANP.22760 | |
| ANP8.1.11 | | Once optimized, panels of tissues are examined to determine the examination's sensitivity and specificity. | CAP QMAP 95-96 | |
| ANP8.1.12 | **M** | A full revalidation equivalent to the initial analytic validation is performed when the antibody clone is changed for an existing validated examination. | CAP IHC | |
| ANP8.1.13 | **M** | Performance of IHC antibodies on samples fixed in a medium other than 10% neutral buffered formalin are fully validated (25 to 100 cases) on tissues and slide positive controls fixed in that same medium. | CAP ANP.22300<br>CAP ANP.22983<br>CAP ANP.22985 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **ANP8.2** | **There are procedures for the verification of existing immunohistochemistry examinations.** | | | |
| ANP8.2.1 | **M** | The laboratory has defined the number of positive and negative cases used to verify examination performance when a new reagent lot is put into service. | CAP IHC | |
| ANP8.2.2 | **M** | New lot numbers of antibody and detection system reagents are examined in parallel with old lots. | CAP IHC | |
| ANP8.2.3 | **M** | Examination performance is verified with at least two known positives and two known negatives when any of the following has changed: antibody dilution; antibody vendor (same clone); incubation or retrieval times (same method). | CAP IHC | |
| ANP8.2.4 | **M** | Examination performance is verified with a defined number of cases (as determined by the medical director) when any of the following has changed: fixative type; antigen retrieval method; antigen detection system; tissue processing or examination equipment; environmental conditions (e.g. laboratory relocation); laboratory water supply. | CAP IHC | REVISED |
| **ANP8.3** | **The controls used for IHC examinations are defined.** | | | |
| ANP8.3.1 | | The laboratory uses a bank of high and low expressor tissue as positive controls.<br>*Guidance: Standardization of both high and low expressor positive controls is needed for diagnostic IHC. The use of IHC-negative controls, irrespective of type, although well established, is not standardized.* | CAP QMAP 97-100 | |
| ANP8.3.2 | **M** | Positive controls are used for each antibody.<br>*Guidance: A positive control is not required with tissues that are intrinsically positive.* | CAP ANP.22550 | |
| ANP8.3.3 | **M** | Positive tissue controls use the same epitope retrieval and immunostaining procedures as the patient tissue. | CAP ANP.22550 | |
| ANP8.3.4 | **M** | Positive tissue controls are included on the same slide as the patient tissue. | CAP ANP.22550 | |
| ANP8.3.5 | | Negatively staining background test tissues and on-slide control tissues are used as negative controls when assessing positive staining, and negative staining (alternate cell lineage marker) IHC slides. | CAP ANP.22570 | |
| ANP8.3.6 | | When only one cell lineage type (e.g. epithelial, mesenchymal, hematopoietic) is tested for by a set of IHC stains, a separate negative control slide consisting of a test tissue processed without a primary antibody is run. | CAP ANP.22570 | |
| ANP8.3.7 | | All cytology cell block preparations or other tissues without internal background tissue negative controls are run with a separate negative control slide consisting of a test tissue processed without a primary antibody. | CAP ANP.22570 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **ANP8.4** | **There are procedures for IHC examination and reporting.** | | | |
| ANP8.4.1 | **M** | The laboratory has defined a minimum fixation time of eight hours for Class II prognostic markers (HER2, ER, PgR). | CAP ANP.22983 | |
| ANP8.4.2 | **M** | Cytological materials collected in non-formalin fixative are post-fixed in 10% neutral buffered formalin prior to cell block preparation. | CAP ANP.22300 | |
| ANP8.4.3 | | Immunohistochemistry examinations performed on B-Plus fixed tissues use B-Plus fixed controls. | DAP15 | |
| ANP8.4.4 | **M** | If decalcified tissues are used for examination, fixation time prior to decalcification, the type of decalcifying reagent, the temperature and length of time of decalcification is recorded.<br>*Guidance: HER2 and ER/PgR examination are not performed on decalcified tissue.* | DAP15 | |
| ANP8.4.5 | **M** | Interpretation and quantitation of tumor biomarkers is performed using established diagnostic criteria and careful review of internal and external controls. | DAP15 | |
| ANP8.4.6 | | The laboratory has defined scoring criteria for the interpretation of Class II prognostic markers (e.g. Allred). | CAP ANP.22999, 23002, 23003 | |
| ANP8.4.7 | **M** | When applicable, reports contain IHC examinations that provide diagnostic predictive information independent of other histopathological findings. The criteria to determine a positive or a negative result and the scoring system and any indication of the differential diagnosis based on the immunohistochemistry are included. | CAP ANP.22969 | |

## ANP9.0 OTHER ANCILLARY EXAMINATIONS

| | | | | |
|---|---|---|---|---|
| **ANP9.1** | **There are procedures for the validation or verification of in-situ hybridization (ISH) examination.** | | | |
| ANP9.1.1 | **M** | The laboratory verifies probes developed by commercial kit manufacturers and validates laboratory-developed probes. | CAP ANP.22956<br>CLSI MM07-A2 8 | |
| ANP9.1.2 | **M** | A validation or verification series of 25 to 100 samples is performed to indicate the sensitivity and specificity of ISH antibodies and procedures. | CAP ANP.22750 | REVISED |
| ANP9.1.3 | **M** | Validation is performed if significant changes are made in ISH reagents or methods (e.g. antibody clone, antigen retrieval procedure, or detection system). | CAP ANP.22780 | |
| ANP9.1.4 | **M** | There are procedures for scoring ISH, and documenting results. | CAP ANP.22963<br>CLSI MM07-A2 8 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP9.1.5 | **M** | When normal chromosome targets are expected to be present in a sample, an internal control for that target is used during each hybridization. | CAP ANP.22964 | |
| ANP9.1.6 | **M** | If a probe is used that does not produce an internal control signal, another sample that is known to have the probe target is run in parallel with the patient sample. | CAP ANP.22964 | |
| ANP9.1.7 | **M** | The final report provides morphological interpretation and correlation of results for ISH examinations. | CAP ANP.22966<br>CAP ANP.22967<br>CLSI MM07-A2 10 | |
| **ANP9.2** | **There are procedures for immunofluorescence microscopy.** | | | |
| ANP9.2.1 | | When internal positive controls are absent, external positive controls are performed on day of use. | CAP ANP.21850 | |
| ANP9.2.2 | | A negative reagent control (patient tissue processed in an identical manner to the sample, but with the primary antibody omitted) is performed for each patient sample. | CAP ANP.21850 | |
| **ANP9.3** | **There are procedures for electron microscopy.** | | | |
| ANP9.3.1 | | There is adequate space for the electron microscope working area and the image processing area. | DAP15 | |
| ANP9.3.2 | **M** | Ultramicrotomes are clean and in good repair. Knives are sharp and free of nicks. | CAP ANP.53000<br>CAP ANP.23400 | |
| ANP9.3.3 | **M** | The electron microscope is maintained at defined intervals and magnification is calibrated after a major maintenance. | CAP ANP.53100<br>CAP ANP.53150 | |
| ANP9.3.4 | **M** | The electron microscope has been checked for radiation leakage at the time of installation and after major repair. | CAP ANP. 57100 | |
| ANP9.3.5 | **M** | Samples, blocks, slides, images and micrographs are labeled with Identifiers that link the sample to the patient at every stage of processing, examination, and storage. | CAP ANP.52000 | |
| ANP9.3.6 | **M** | Sections of embedded tissue (face sections and one micron sections prepared after trimming or ultra-thin sectioning) are reviewed by a pathologist to ensure that appropriate areas are selected. | CAP ANP.52100<br>CAP ANP.52150 | |
| ANP9.3.7 | | Slides and electron photomicrographs are reviewed to determine if the required quality for interpretation of ultra-structural changes has been achieved. | CAP ANP.52300 | REVISED |
| ANP9.3.8 | | Reports include correlation of electron microscopy findings with routine light microscope and other ancillary examinations. | CAP ANP.54000 | |
| ANP9.3.9 | **M** | There are procedures for the safe handling and disposal of osmium tetroxide, epoxy resins and other hazardous chemicals. | CAP ANP. 57000<br>CAP ANP. 57070 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **ANP10.0** | | **AUTOPSY**<br>**Assessment of the morgue and autopsy personnel will only occur in facilities where the laboratory is responsible for the morgue.** | | |
| **ANP10.1** | | **Autopsies and autopsy-related services are performed by pathologists or qualified delegates.** | | |
| ANP10.1.1 | **M** | All autopsy services are performed by a pathologist who may delegate this task to qualified non-pathologist personnel with the appropriate supervision. | CAP ANP.33050 | |
| ANP10.1.2 | **M** | Non-pathologist personnel performing autopsy services have appropriate academic qualifications, training and experience as defined by the medical director. | CAP ANP.33050 | |
| ANP10.1.3 | **M** | Non-pathologist personnel are supervised, directly or indirectly, by a pathologist. | CAP ANP.33050 | |
| ANP10.1.4 | **M** | Where autopsy services are performed by non-pathologist personnel, the laboratory has defined a list of procedures that may be performed with specific instructions and indications of when a pathologist is to be consulted. | DAP15 | |
| ANP10.1.5 | **M** | The performance of non-pathologist personnel who perform autopsy services is evaluated and documented by a pathologist at a defined frequency. | DAP15 | |
| **ANP10.2** | | **There are procedures to ensure the safety of personnel during autopsy processes.** | | |
| ANP10.2.1 | **M** | There are procedures for handling highly infectious cases and tissues (e.g. TB, rabies). | CAP ANP.34050 | |
| ANP10.2.2 | **M** | There are procedures for handling hazardous chemicals. | CAP ANP.34000 | |
| ANP10.2.3 | **M** | There are procedures for cleaning and disinfecting surfaces after use, and at defined intervals. | CAP ANP.34050<br>CLSI M29-A3 10.1.7 | |
| ANP10.2.4 | **M** | There are procedures to minimize aerosols when electric or mechanical saws are used. | CAP ANP.33650 | |
| ANP10.2.5 | **M** | Specific procedures ensure the safety of personnel when performing an autopsy or handling tissue from a case of suspected prion disease, including cleaning and decontamination of the area and tools. | CAP ANP.34150 | |
| ANP10.2.6 | **M** | There is signage at the entrance to the autopsy area indicating potential hazards and appropriate protective measures. | CAP ANP.34000 | |
| ANP10.2.7 | **M** | There are containers for waste and hazardous materials. | CAP ANP.33650 | |
| ANP10.2.8 | **M** | There are guidelines for the use of PPE in the morgue. | CAP ANP.33650 | |
| ANP10.2.9 | | There is an ergonomic system for lifting bodies. | DAP15 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **ANP10.3** | **Morgue services are provided in a secure area with suitable features.** | | | |
| ANP10.3.1 | **M** | Physical access to the morgue is restricted. | ISO 15190 6.3.8 | |
| ANP10.3.2 | **M** | Crypts or walk-in fridges have temperature monitors. | CAP ANP.32400 | |
| ANP10.3.3 | **M** | Ventilation in the morgue promotes good air distribution without generating undue turbulence at the working stations.<br>*Guidance: Ventilation in the morgue provides a minimum airflow of 12 air changes per hour (three of which are from outside).* | CAP ANP.32500<br>USACHPPM | |
| ANP10.3.4 | **M** | The accuracy of scales is verified annually. This is documented. | CAP ANP.32450 | |
| ANP10.3.5 | **M** | Knives and other instruments are stored safely. | | |
| ANP10.3.6 | **M** | The autopsy room has equipment and appropriate disinfectants for the decontamination of instruments and surfaces. | CAP ANP.33650<br>CLSI M29-A3 10.1.7 | |
| ANP10.3.7 | **M** | Instructions and sample containers for laboratory examinations are available (e.g. toxicology, microbiology). | CAP ANP.33650 | |
| **ANP10.4** | **There are procedures for conducting autopsies.** | | | |
| ANP10.4.1 | **M** | Autopsy policy identifies consent hierarchy. | CAP ANP.31070 | |
| ANP10.4.2 | **M** | There is a policy to assess the appropriateness of performing a hospital autopsy that is in compliance with applicable regulations.<br>*Guidance: The policy identifies autopsy requests that are subject to possible medical examiner or coroner jurisdiction.* | CAP ANP.30150 | |
| ANP10.4.3 | **M** | Patient records including the patient's chart are reviewed or clinical information is discussed with the attending physician prior to conducting the autopsy. | CAP ANP.33000 | |
| ANP10.4.4 | **M** | There are documented processes for the disposal of medications received in the morgue. | DAP15 | |
| ANP10.4.5 | **M** | A documented chain of evidence procedure has been established for coroner's cases. | DAP15 | |
| ANP10.4.6 | **M** | There are documented instructions addressing the receipt, storage and release of bodies. | DAP15 | |
| **ANP10.5** | **Autopsy reports include all information relevant to the case (in addition to POS2.1).** | | | |
| ANP10.5.1 | | Provisional and final autopsy reports include all pertinent findings. | DAP15 | |
| ANP10.5.2 | **M** | Provisional and final autopsy reports include the date and time of autopsy. | DAP15 | |
| ANP10.5.3 | **M** | Provisional and final autopsy reports include the date of report. | DAP15 | |

| No. | Standard / Criterion | | Reference | Change |
|---|---|---|---|---|
| ANP10.5.4 | **M** | Provisional and final autopsy reports include the name of the pathologist performing autopsy. | DAP15 | |
| ANP10.5.5 | **M** | Provisional autopsy reports include the preliminary cause of death (if any), and final autopsy reports include the cause of death. | CAP ANP.33100<br>CAP ANP.33350 | |
| ANP10.5.6 | | Final autopsy reports include the date and approximate time of death. | DAP15 | |
| ANP10.5.7 | **M** | Final autopsy reports include the name of the user. | DAP15 | |
| ANP10.5.8 | **M** | Final autopsy reports include gross anatomical findings, a microscopic examination where applicable, ancillary procedures and intra- and extra-departmental consultations. | CAP ANP.10150 | |
| **ANP10.6** | **There are procedures for communicating unexpected autopsy findings.** | | | |
| ANP10.6.1 | **M** | There are documented processes to communicate unexpected autopsy results that require notification of the coroner's office, results that may influence completion of the death certificate, finding a notifiable disease, or finding important information that was clinically unapparent. | CAP ANP.31100<br>GOBC PHA Part 1<br>CAP ANP.30100<br>DAP APAC | |
| ANP10.6.2 | | Autopsy findings are available for review by the institutional quality programs (or equivalent), and for reporting issues related to quality of care and risk management. | CAP ANP.30150 | |
| ANP10.6.3 | | Autopsy findings are available for clinical-pathology correlations and for the hospital infection control and prevention department. | CAP ANP.30100<br>GOBC PHA | |

# Accreditation Standards 2015

Laboratory Medicine

## CHEMISTRY STANDARDS

The chemistry standards are used in conjunction with the general standards for each laboratory.

# CHEMISTRY

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **CHE1.0** | | **THERAPEUTIC DRUG MONITORING (TDM) AND DRUG SCREENING** | | |
| **CHE1.1** | | **There are procedures for drug screening and TDM and reporting.** | | |
| CHE1.1.1 | **M** | The laboratory maintains secure access to restricted drugs used for calibration or controls. | DAP15 | |
| CHE1.1.2 | | TDM examination requests include the dose regimen and route of administration. | CLSI C52-A2 | |
| CHE1.1.3 | **M** | TDM examination requests include the time of last medication dose. | CLSI C52-A2<br>ISO 15189 5.4.4.2e | |
| CHE1.1.4 | **M** | Ethanol specificity evaluation studies have been performed and documented or the manufacturer's stated specificity has been evaluated. | DAP15v1.0 | REVISED |
| CHE1.1.5 | **M** | The extent of lactate dehydrogenase and lactate interferences with ethanol examination have been determined when an enzymatic examination is used. | DAP15 | |
| CHE1.1.6 | **M** | Therapeutic drug monitoring results are reported in relation to patient dosing and timing information, as required. | CLSI C52-A2<br>CAP CHM.29000 | |
| CHE1.1.7 | | Reports of urine screening for drugs of abuse include the substances or classes of substances examined, the cut-off concentration for a positive result for each drug, and a report status for positive results (e.g. unconfirmed or pending confirmation). | ISO 15189 5.8.3 | |
| **CHE2.0** | | **SWEAT CHLORIDE EXAMINATIONS** | | |
| **CHE2.1** | | **There are procedures for sweat collection.** | | |
| CHE2.1.1 | **M** | The sweat collection device is designed for use with the iontophoresis system so that the stimulation and collection areas are equivalent and the minimum acceptable sweat volume or weight can be achieved. | CLSI C34-A3 8.6.2<br>CAP CHM.29850 | |
| CHE2.1.2 | **M** | The iontophoretic current source is battery-powered to avoid the possibility of patient exposure to line voltage. | CLSI C34-A3 6.1.1<br>CAP CHM.29600 | |
| CHE2.1.3 | **M** | Sweat examinations are performed on patients greater than 48 hours old. | CLSI C34-A3 8.2<br>CAP CHM.29100 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE2.1.4 | **M** | Procedures for sweat collection and examination follow the manufacturer's recommendations or are in accordance with accepted practice and guidelines.<br>*Guidance: When collecting and analyzing sweat using Nanoduct®, Macroduct®, gauze or filter paper, processes to limit evaporation or contamination are clearly defined.* | CLSI C34-A3 8<br>CAP CHM.29200 | |
| CHE2.1.5 | **M** | Sweat stimulation and collection is from the patient's lower arm or upper leg using a site that is free from diffuse inflammation or rash. | CLSI C34-A3 8<br>CAP CHM. 29300 | |
| CHE2.1.6 | **M** | Electrodes used for stimulation are placed so that iontophoretic current never crosses the patient's trunk. | CLSI C34-A3 8<br>CAP CHM.29500 | |
| CHE2.1.7 | **M** | Sweat collection time does not exceed 30 minutes unless allowed for by the manufacturer's instructions. | CLSI C34-A3 8<br>CAP CHM.29900 | |
| CHE2.1.8 | **M** | Sweat samples are labeled with patient identification and labels are attached prior to determining the initial weight. | CLSI C34-A3 8<br>CAP CHM.30200 | |
| CHE2.1.9 | **M** | Collection procedures describe the recognition and treatment for skin reactions to pilocarpine or other reagents. | CLSI C34-A3 8<br>CAP CHM.30300 | |
| CHE2.1.10 | **M** | The incidence of insufficient sweat samples is routinely monitored.<br>*Guidance: The annual insufficient sample rate should not exceed 5% for patients older than three months and 10% for patients three months and younger. If these rates are exceeded, the collection procedure is reevaluated.* | CLSI C34-A3 8.7.1<br>CAP CHM.30150<br>CFFC Guideline 8 | |
| CHE2.1.11 | **M** | Multiple insufficient sweat samples are rejected and not pooled for examination. | CLSI C34-A3 8<br>CAP CHM.30100 | |
| **CHE2.3** | **There are procedures for sweat chloride examination and reporting.** | | | |
| CHE2.3.1 | **M** | The lower limit of the sweat chloride analytical measurement range (AMR) is less than or equal to 10 mmol/L. | CLSI C34-A3 9.7.3<br>CAP CHM.30550 | |
| CHE2.3.2 | **M** | If quantitative examination of sweat chloride is performed, the upper limit of the AMR is less than or equal to 160 mmol/L.<br>*Guidance: Sweat chloride concentrations greater than 160 mmol/L are not physiologically possible. Patients are reexamined when results are greater than 160 mmol/L.* | CLSI C34-A3 9.7.3<br>CAP CHM.30575 | |
| CHE2.3.3 | **M** | When sweat is collected from patients on gauze or filter paper, controls are placed directly onto the same collection material, eluted, and treated in the same manner as the patient sample. | CLSI C34-A3 12.1<br>CAP CHM.30600 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE2.3.4 | **M** | Two levels of controls (one in the negative range and one in the positive range) are examined at least once each day patient samples are examined. | CLSI C34-A3 12.1<br>CAP CHM.30600 | |
| CHE2.3.5 | **M** | Decision levels for patient results are provided when non-selective methods (e.g. osmolality, conductivity) are reported. A reference range is provided for sweat chloride reports. | CLSI C34-A3 9.5<br>CAP CHM.30700 | |
| CHE2.3.6 | **M** | Sweat chloride screening reports include a statement referring patients with borderline or positive results for a quantitative sweat chloride examination. | CLSI C34-A3 13<br>CAP CHM.30700 | |

## CHE3.0 RADIOIMMUNOASSAYS

| **CHE3.1** | **There are procedures for radioimmunoassay examinations.** | | | |
|---|---|---|---|---|
| CHE3.1.1 | **M** | The calibration of gamma counters and scintillation counters is verified on each day of use. Results are recorded and compared to previous results. | CAP CHM.15900 | |
| CHE3.1.2 | **M** | Acceptable background levels are defined and the background radioactivity in each well of a multi-well counter is determined on each day of use. | CAP CHM.16000 | |
| CHE3.1.3 | **M** | Counting times for quantitative examinations are long enough for statistical accuracy and precision. | CAP CHM.16200 | |

## CHE4.0 THIN LAYER CHROMATOGRAPHY

| **CHE4.1** | **There are procedures for thin-layer chromatography (TLC) examinations.** | | | |
|---|---|---|---|---|
| CHE4.1.1 | **M** | Fresh solvent mixtures are prepared as needed. | CAP CHM.16500 | |
| CHE4.1.2 | **M** | Calibrators include drugs or compounds that verify the chromatographic range of the TLC plate. | CAP CHM.16300 | |
| CHE4.1.3 | **M** | Calibrators examine all phases of the staining and development system. | CAP CHM.16300 | |
| CHE4.1.4 | **M** | Positive and negative controls are extracted and carried through the entire procedure on each day of patient examination. | CAP CHM.16400 | |

## CHE5.0 GAS CHROMATOGRAPHY/HIGH-PERFORMANCE LIQUID CHROMATOGRAPHY

| **CHE5.1** | **There are procedures for gas chromatography/high-performance liquid chromatography (GC/HPLC) examinations.** | | | |
|---|---|---|---|---|
| CHE5.1.1 | **M** | New column performance is verified prior to initial use. | CAP CHM.16850 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE5.1.2 | **M** | Reagents, solvents and gases are of the appropriate grade and quality for the examination. | CAP CHM.17100 | |
| CHE5.1.3 | **M** | Column and detector performance is monitored on each day of use. | CAP CHM.17000 | |
| CHE5.1.4 | **M** | Gas lines are checked for leaks every time tubing or a connection has been manipulated. | CAP CHM.17050 | |
| CHE5.1.5 | **M** | There are procedures for detection and evaluation of potential carry-over that includes reassessment of samples when necessary. | CLSI EP10-A3 4.2<br>CAP CHM.16800 | |
| CHE5.1.6 | **M** | Calibrators are run with each examination batch. | CAP CHM.16550 | |
| CHE5.1.7 | **M** | Controls are extracted and run through the entire procedure. | CAP CHM.16650 | |
| CHE5.1.8 | **M** | QC is performed on each day of patient examination. | CAP CHM.16650 | |
| CHE5.1.9 | **M** | For qualitative examinations, the negative and positive controls are at concentrations that confirm performance below and above the decision threshold for the measurand. | CAP CHM.16650 | |
| CHE5.1.10 | **M** | For quantitative examinations, at least one normal sample and at least one sample reflecting a disease range is included. | CAP CHM.16650 | |
| CHE5.1.11 | **M** | A control is included with each batch to evaluate hydrolysis effectiveness, if a hydrolysis step is required. | CAP CHM.16650 | |
| CHE5.1.12 | **M** | The sample run order, chromatographic peak shape, retention time, detector response for calibrators and controls are recorded. | CAP CHM.16770 | |

## CHE6.0 MASS SPECTROMETRY

| CHE6.1 | There are procedures for mass spectrometry (MS) examinations. | | | |
|---|---|---|---|---|
| CHE6.1.1 | **M** | Spectrometers are tuned on each day of patient examination, or according to the manufacturer's recommendations. Tune records are maintained. | CAP CHM.18600 | |
| CHE6.1.2 | **M** | Identification criteria for single stage and tandem MS are defined and documented. | CAP CHM.18700<br>CAP CHM.18800 | |
| CHE6.1.3 | **M** | Tolerance limits accurately reflect the limitations of the method employed and are supported by references from the literature or experimental data. | CLSI C50-A | |
| CHE6.1.4 | **M** | When tandem MS methods are used for quantitative purposes only, there is ancillary information and examination characteristics that verify this process. | CLSI C50-A | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE6.1.5 | | In tandem MS using multiple reaction monitoring, at least one transition is monitored for the internal standard and another transition is monitored for the measurand. | CLSI C50-A | |
| CHE6.1.6 | **M** | The procedure includes precautions to recognize ion suppression. | CAP CHM.18850 | |
| CHE6.1.7 | **M** | There is recovery of the internal standard or records for alternative methods used. | CAP CHM.18850 | |
| CHE6.1.8 | **M** | The total ion current intensity is monitored during analysis of the extracted matrix blank as part of LC/MS and tandem MS examination development. | CAP CHM.18850 | |
| CHE6.1.9 | **M** | An acceptable range of signal intensity of the ion transition(s) is selected to monitor each internal standard during the LC/MS and tandem MS examination of patient samples. | CAP CHM.18850 | |

## CHE7.0 INDUCTIVELY COUPLED PLASMA – MASS SPECTROMETRY

| CHE7.1 | There are procedures for inductively coupled plasma – mass spectrometry (ICP/MS) examinations. | | | |
|---|---|---|---|---|
| CHE7.1.1 | **M** | Spectrometers are tuned on each day of patient examination, or according to the manufacturer's recommendations. Tune records are maintained. | CAP CHM.20300 | |
| CHE7.1.2 | **M** | ICP/MS procedures include criteria to detect drift. | CAP CHM.2100 | |
| CHE7.1.3 | **M** | Criteria for the selection of isotopes and internal standards consider interferences (isobaric and polyatomic species) and relative abundances. | CAP CHM.21100 | |
| CHE7.1.4 | **M** | The purity of gases and reagents (including water) is defined and verified to identify and minimize interferences and sources of contamination. | CAP CHM.21300 | |
| CHE7.1.5 | **M** | The peak width is optimized. | CAP CHM.20500 | |
| CHE7.1.6 | **M** | Oxides and doubly charged species and any other common interferences are minimized. | CAP CHM.20600 | |
| CHE7.1.7 | **M** | The reaction or collision gases are optimized when a reaction or collision cell is utilized. | CAP CHM.20800 | |
| CHE7.1.8 | **M** | Potential sources of contamination have been evaluated. | CAP CHM.21200 | |
| CHE7.1.9 | **M** | Methods to limit and detect contamination are documented. | CAP CHM.21200 | |
| CHE7.1.10 | **M** | If a dual detector mode is used, cross-calibration is employed if the concentration range encompasses both modes. | CAP CHM.20700 | |
| CHE7.1.11 | **M** | All calibrators are verified. | CAP CHM.20700 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE7.1.12 | **M** | There is a procedure defining the use of matrix-matched controls, calibrators and blanks. When matrix matching is unnecessary, it is documented. | CAP CHM.21400 | |

## CHE8.0 ATOMIC ABSORPTION SPECTROPHOTOMETRY

| CHE8.1 | There are procedures for atomic absorption (AAS) examination. | | | |
|---|---|---|---|---|
| CHE8.1.1 | **M** | The burner head and aspirator are flushed thoroughly with water on each day of use. | CAP CHM.21600 | |
| CHE8.1.2 | **M** | The optical beam alignment is checked at a defined interval. | CAP CHM.21700 | |
| CHE8.1.3 | **M** | The atomizer is cleaned and flow rate optimized at a defined interval. | CAP CHM.21800 | |
| CHE8.1.4 | **M** | Automatic sampler systems are checked for precision at defined intervals. | CAP CHM.21900 | |
| CHE8.1.5 | **M** | The lamp's energy is verified and recorded for each run. | CAP CHM.22200 | |
| CHE8.1.6 | **M** | The blank value of a graphite tube is verified for each element examined when a graphite furnace is used. | CAP CHM.22000 | |
| CHE8.1.7 | **M** | There is a procedure for establishing quantitative examination calibration curves. | CAP CHM.22100 | |

## CHE9.0 ELECTROPHORESIS

| CHE9.1 | There are procedures for electrophoresis examinations. | | | |
|---|---|---|---|---|
| CHE9.1.1 | **M** | Criteria are established to determine if electrophoretic separations are acceptable. | CAP CHM.33600 | |
| CHE9.1.2 | **M** | Suitable control samples are run and reviewed with each batch of patient samples for all electrophoresis procedures. | CAP CHM.33500 | |
| CHE9.1.3 | **M** | Tolerance limits are set for controls where the electrophoretic bands are quantified. | CAP CHM.33700 | |

## CHE10.0 URINALYSIS

| CHE10.1 | There are procedures for macroscopic urinalysis examination. | | | |
|---|---|---|---|---|
| CHE10.1.1 | **M** | Refractometers are checked on day of use. This is documented. | CLSI GP16-A3<br>CAP URN.26100 | |
| CHE10.1.2 | **M** | Specific gravity determination by dipstick is performed according to the manufacturer’s recommendations. | CLSI GP16-A3 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE10.1.3 | | Macroscopic strips for urine examination include at a minimum: glucose; protein; blood or hemoglobin; nitrite; leukocyte esterase. | CLSI GP16-A3<br>CAP URN.30200 | |
| CHE10.1.4 | **M** | Criteria for identifying urine samples that may give erroneous results by a macroscopic strip reader are defined. | CLSI GP16-A3<br>CAP URN.31250 | |
| **CHE10.2** | **Microscopic urinalysis procedures are defined.** | | | |
| CHE10.2.1 | **M** | Microscopic urinalysis procedures define when a microscopic examination of urine sediment is performed (according to provincial requirements, when requested by a physician, when indicated by clinical status, when indicated by macroscopic strip results). | GOBC MOH UTI<br>CLSI GP16-A3<br>CAP URN.30700 | |
| CHE10.2.2 | **M** | The laboratory uses standardized criteria for identification of cellular and other constituents in urine. | CLSI GP16-A3<br>CAP URN.30700 | |
| CHE10.2.3 | **M** | There is a documented process to assess consistency among personnel performing urine sediment microscopy. | CLSI GP16-A3<br>CAP URN.30800 | |
| CHE10.2.4 | **M** | There are guidelines for the reporting of microscopic semi-quantitative measurements. | CLSI GP16-A3<br>CAP URN.30800 | |
| CHE10.2.5 | **M** | Microscopic results are correlated with macroscopic strip results and discrepant results are investigated. | CLSI GP16-A3<br>CAP URN.30850 | |
| CHE10.2.6 | **M** | Urine microscopic morphology systems are evaluated for limitations and potential erroneous results. Criteria used to identify urine samples that may give erroneous results by a morphology system are defined. | CLSI GP16-A3<br>CAP URN.31400 | |
| CHE10.2.7 | **M** | Reference materials of urine sediment elements are readily available. | CLSI GP16-A3<br>CAP URN.30750 | |

## CHE11.0 BLOOD GASES

| | | | | |
|---|---|---|---|---|
| **CHE11.1** | **There are procedures for blood gas examinations.** | | | |
| CHE11.1.1 | **M** | Ambient air contamination of blood gas samples prior to examination is prevented. | CLSI C46-A2<br>CAP CHM.34000 | |
| CHE11.1.2 | **M** | Materials used for calibration of pH, $CO_2$, and $O_2$ sensors conform with manufacturer's specifications or are traceable to NIST standard reference materials. | CLSI C46-A2<br>CAP CHM.34200 | |
| CHE11.1.3 | **M** | Blood gas instruments are calibrated according to the manufacturer's specifications at a minimum. | CLSI C46-A2<br>CAP CHM.34300 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE11.1.4 | **M** | A minimum of one QC sample for pH, $pCO_2$ and $pO_2$ (tonometered sample, liquid control material, or validated internal control) is examined every 8 hours of operation when samples are examined. | CLSI C46-A2<br>CAP CHM.34400 | |
| CHE11.1.5 | **M** | Control materials for pH, $pCO_2$ and $pO_2$ include both high and low values. | CLSI C46-A2<br>CAP CHM.34500 | |

## CHE12.0 PRENATAL SCREENING

| | | | | |
|---|---|---|---|---|
| **CHE12.1** | **Request forms for prenatal screening include space for the inclusion of required information.** | | | |
| CHE12.1.1 | **M** | The request form or an electronic equivalent has space for the inclusion of relevant patient information.<br>*Guidance: This information includes:*<br>• *first day of the last menstrual period (LMP)*<br>• *maternal weight*<br>• *the estimated date of confinement (EDC) or estimated gestational age by ultrasound*<br>• *clinical evidence of multiple gestations (e.g. twins).*<br>• *maternal birth date*<br>• *patient race*<br>• *history of medication to control diabetes at the time of conception*<br>• *indication if the request is for initial screening sample or repeat examination during the same pregnancy* | ISO 15189 5.4.3<br>CLSI I/LA25-A2<br>CAP CHM.31100, 31200, 31300, 31400, 31500, 31600, 31700 | |
| **CHE12.2** | **There are procedures for fetal trisomy and neural tube defect screening.** | | | |
| CHE12.2.1 | **M** | Median values have been established or medians from other sources have been verified for the population being screened. | CLSI I/LA25-A2<br>CAP CHM.31800 | |
| CHE12.2.2 | **M** | Medians are reverified when new reagent lots are introduced and at defined intervals. Medians are recalculated if necessary. | CLSI I/LA25-A2<br>CAP CHM.31900 | |
| CHE12.2.3 | | There is a documented process for the establishment and use of nuchal translucency (NT) values in screening panels, if used. | CLSI I/LA25-A2<br>CAP CHM.31950 | |
| CHE12.2.4 | | NT values used in screening panels are used for epidemiological monitoring. | CLSI I/LA25-A2<br>CAP CHM.31960 | |
| CHE12.2.5 | **M** | The percentages of women with screen-positive examination results for neural tube defects, Trisomy 21, and Trisomy 18 are calculated and reviewed at least quarterly. | CLSI I/LA25-A2<br>CAP CHM.32000 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE12.2.6 | **M** | Markers added to screening panels (e.g. dimeric inhibin A) are verified using the same requirements as established markers. | CLSI I/LA25-A2<br>CAP CHM.32100 | |
| CHE12.2.7 | **M** | Neural tube defect and Trisomy 21 risk calculations are initially verified for accuracy and reverified with any software updates or changes. | CLSI I/LA25-A2<br>CAP CHM.32200 | |
| CHE12.2.8 | **M** | Median amniotic fluid alpha-fetoprotein (AFAFP) values appropriate for the screened population are established. | CLSI I/LA25-A2<br>CAP CHM.32700 | |
| CHE12.2.9 | **M** | AFAFP medians are recalculated or reverified at defined intervals. | CLSI I/LA25-A2<br>CAP CHM.32800 | |
| CHE12.2.10 | **M** | If an amniotic fluid sample is visibly contaminated with blood when received, or reported as contaminated with blood on the requisition, the fluid is checked for fetal blood contamination if the AFAFP multiples of the median (MoM) is elevated. | CLSI I/LA25-A2<br>CAP CHM.33000 | |
| CHE12.2.11 | **M** | At least one amniotic fluid dilution control is processed with each analytic run of amniotic fluids. | CLSI I/LA25-A2<br>CAP CHM.33100 | |
| CHE12.2.12 | **M** | Acetylcholinesterase examination is performed on all amniotic fluids having an elevated AFAFP. | CLSI I/LA25-A2<br>CAP CHM.33200 | |
| CHE12.2.13 | **M** | Acetylcholinesterase-positive results are confirmed by addition of a specific inhibitor. | CLSI I/LA25-A2<br>CAP CHM.33400 | |
| **CHE12.4** | **There are procedures for prenatal screening reporting (in addition to POS10.1).** | | | |
| | | Prenatal screening reporting includes: | | |
| CHE12.4.1 | **M** | • a maternal race and weight and the presence of medication-dependent diabetes. | CLSI I/LA25-A2<br>CAP CHM.32300 | |
| CHE12.4.2 | **M** | • a family history of neural tube defect and the presence of multiple gestations, if known. | CLSI I/LA25-A2<br>CAP CHM.32300 | |
| CHE12.4.3 | **M** | • the first day of the last menstrual period or gestational age as determined by ultrasound examination | CLSI I/LA25-A2<br>CAP CHM.32300 | |
| CHE12.4.4 | **M** | • if the examination is on an initial or repeat sample. | CLSI I/LA25-A2<br>CAP CHM.32300 | |
| CHE12.4.5 | **M** | Examination results are reported as MoM. | CLSI I/LA25-A2<br>CAP CHM.32400 | |
| CHE12.4.6 | **M** | The report classifies a pregnancy as screen-positive or screen-negative for open neural tube defects, based on the AFAFP examination results. | CLSI I/LA25-A2<br>CAP CHM.32500 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CHE12.4.7 | **M** | The report classifies a pregnancy as screen-positive or screen-negative for fetal Trisomy 21 or Trisomy 18, based on the calculated risk. | CLSI I/LA25-A2<br>CAP CHM.32600 | |

## CHE13.0 NEWBORN SCREENING

| CHE13.1 | There are procedures for newborn screening. | | | |
|---|---|---|---|---|
| CHE13.1.1 | M | There are instructions for the proper collection, handling, transport, and submission of newborn screening samples. | ISO 15189 5.4.4.2e<br>CAP CBG.20110 | |
| CHE13.1.2 | M | There are procedures to monitor sample quality and provide timely notification of inadequate or unsuitable samples. | CAP CBG.20120 | |
| CHE13.1.3 | | There is a policy for reporting results that allows for patient follow-up within a defined timeframe to ensure maximum health benefit. | CAP CBG.20140 | |
| CHE13.1.4 | | In cases where follow-up activity is required, the timeline, steps, and instructions to complete required activities (e.g. repeat screen, confirmatory examination, clinical action and evaluation) are defined. | CAP CBG.20160<br>CLSI NBS02-A2 | |

# CYTOGENETICS STANDARDS

The cytogenetics standards are used in conjunction with the general standards for each laboratory.

# CYTOGENETICS

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **CYG1.0** | **SAMPLE SET-UP** | | | |
| **CYG1.1** | **There are procedures for setting up cultures.** | | | |
| CYG1.1.1 | **M** | Sample identity and integrity is maintained at all times during the pre-examination and examination steps, including sample receipt, processing, culture, cell preparation, images and worksheets. | CAP CYG.31400 | |
| CYG1.1.2 | **M** | The laboratory documents reagent lot numbers and media used. | CAP CYG.30350 | |
| CYG1.1.3 | | There is a method to mechanically and enzymatically disaggregate samples. | | |
| CYG1.1.4 | **M** | Multiple cultures are used for all sample types. | CAP CYG.40100 | |
| CYG1.1.5 | | Laboratory procedures specify a prioritization scheme when sample volume or cellularity is insufficient to set up all routine cultures. | DAP15 | |
| CYG1.1.6 | **M** | There are documented processes to verify changes in media components or media lots (e.g. lot number changes or changes in manufacturer). | DAP15 | |
| CYG1.1.7 | **M** | Media is labeled with the expiry date and not used after that date. | DAP15 | |
| CYG1.1.8 | **M** | Appropriate culture media is used depending on sample tissue type. | DAP15 | |
| CYG1.1.9 | | No aliquot is returned to the original container. | DAP15 | |
| CYG1.1.10 | | Only one sample is set up at one time. | DAP15 | |
| CYG1.1.11 | | Tubes, flasks and dishes are labeled prior to inoculation. | DAP15 | |
| CYG1.1.12 | **M** | All samples and cell cultures are manipulated in a biological safety cabinet. | DAP15 | |
| **CYG1.2** | **There are procedures to address suspected maternal cell contamination of prenatal samples.** | | | |
| CYG1.2.1 | **M** | There are procedures for the identification, handling and set up of cultures with known or suspected maternal cell contamination (MCC). | ACMG E3.3<br>ACMG G18.3 | |
| CYG1.2.2 | | Amniotic fluid and the cell pellet are viewed after centrifugation. | DAP15 | |
| CYG1.2.3 | **M** | Chorionic villi sampling (CVS) samples are viewed under a dissecting microscope. | DAP15 | |
| CYG1.2.4 | **M** | Concerns about MCC are conveyed to clinicians and referral laboratories. | DAP15 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| CYG1.2.5 | | Efforts are made to determine the tissue type selected for culture setup (e.g. products of conception, fetal organs). | DAP15 | |

## CYG2.0 CULTURE INCUBATION

| | | | | |
|---|---|---|---|---|
| **CYG2.1** | **There are procedures for the incubation of cultures.** | | | |
| CYG2.1.1 | **M** | The laboratory has defined when multiple cultures are incubated separately (e.g. amniocentesis samples, CVS). | DAP15 | |
| CYG2.1.2 | **M** | Incubation times are established according to clinical indications and sample type. | AGT 24-25 | |
| CYG2.1.3 | **M** | The laboratory documents the culture conditions, the incubation times for all preparations and the number of cultures. | DAP CGAC | |
| CYG2.1.4 | **M** | Temperatures of 37°C to 38°C are maintained, monitored and documented. | DAP15 | |
| CYG2.1.5 | **M** | $CO_2$ levels of 4–6% are maintained, monitored and documented. | DAP15 | |
| CYG2.1.6 | **M** | $O_2$ levels are maintained, monitored and documented in tri-gas incubators. | DAP15 | |
| CYG2.1.7 | **M** | Humidity levels of 90–95% are maintained, monitored and documented where appropriate. | DAP15 | |
| CYG2.1.8 | **M** | A minimum level of CO2 and N2 (tri-gas incubators only) has been defined and is maintained. | DAP15 | REVISED |
| CYG2.1.9 | **M** | Backup cultures for CVS and amniocytes are maintained until the final result has been reported. | DAP15 | |
| CYG2.1.10 | **M** | Incubators are on emergency backup power and have a monitored alarm system. | CAP CYG.40000<br>ACMG D1.2.1 | |
| CYG2.1.11 | **M** | There are procedures to be followed in the event of an alarm. | ACMG E4.1.1 | |
| **CYG2.2** | **There are procedures to prevent or address the contamination of cell cultures.** | | | |
| CYG2.2.1 | **M** | There is a schedule and a procedure for the routine cleaning of incubators. This is documented. | DAP15 | |
| CYG2.2.2 | **M** | There is a procedure to address the handling of cultures when contamination is discovered.<br>*Guidance: The procedure addresses handling contaminated, non-contaminated and new cultures.* | DAP15 | |
| CYG2.2.3 | **M** | There is a procedure for cleaning incubators after contamination. | DAP15 | |

## CYG3.0 HARVEST AND SLIDE PREPARATION

| | |
|---|---|
| **CYG3.1** | **There are procedures for culture harvest and slide preparation.** |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| CYG3.1.1 | **M** | Harvesting of all long-term cultures is performed in a manner that ensures that there is a backup.<br>*Guidance: Not all cultures from a single sample are harvested at one time.* | CAP CYG.40200 | |
| CYG3.1.2 | **M** | Variables are controlled to ensure optimal slide preparation. These include temperature, humidity and the quality of glass. | CAP CYG.61400 | |
| CYG3.1.3 | | There are procedures to address suboptimal culture harvest and slide preparation results on a case-by-case basis (e.g. over-spreading and under-spreading of metaphases, poor chromosome morphology). | DAP15 | |
| **CYG3.2** | **There are procedures for staining and banding.** | | | |
| CYG3.2.1 | | Giemsa banding, centromere banding and nuclear organizing region banding are performed. | ACMG E3.1.5 | |
| CYG3.2.2 | **M** | Examinations using G and R banding in addition to special stains and FISH are performed when indicated at the discretion of the laboratory director. | ACMG E3.1.3 | |
| CYG3.2.3 | **M** | An established method to assess the banding level of karyotypes is used and the bandwidth level resolution is documented. | DAP15 | |
| CYG3.2.4 | | There are procedures to address suboptimal staining and banding results on a case by case basis. | DAP15 | |
| CYG3.2.5 | **M** | The quality of banding and resolution is sufficient to render the reported interpretation, at the discretion of the cytogeneticist. | DAP15 | |
| **CYG3.3** | **There are procedures for the selection, counting, examination and karyotyping for each cytogenetic sample type.** | | | |
| CYG3.3.1 | **M** | The controls for each examination are documented. | DAP15 | |
| CYG3.3.2 | **M** | The number of cells to be examined in the evaluation and interpretation of peripheral blood samples, constitutional samples from individuals with suspected chromosome instability, neoplastic samples and prenatal samples is defined. | CAP CYG.41550 | |
| CYG3.3.3 | **M** | Additional metaphases and interphases are examined from multiple cultures to detect or exclude clinically significant mosaicism in prenatal samples using a published method. | DAP15 | |
| CYG3.3.4 | **M** | There are procedures for the examination of all cytogenetic sample types. | ACMG E3.1.6 | |
| CYG3.3.5 | **M** | Procedures specify the minimum number of karyograms per case for each sample type. | ACMG E3.1.6 | |
| CYG3.3.6 | **M** | There are documented criteria for performance of abbreviated examinations. | ACMG E3.2.2 | |
| CYG3.3.7 | **M** | Procedures specify that all karyotypes are checked by a second individual. | ACMG E3.1.7 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CYG3.3.8 | | Cells selected for examination have chromosomes that are well spread with few crossovers and kinks, sharply banded with adequate length. Crossover areas are fully examined by viewing the same area in at least two other cells. | DAP15 | |

## CYG4.0 EXAMINATION

| CYG4.1 | | The laboratory documents the microscopic examination of cells. | | |
|---|---|---|---|---|
| CYG4.1.1 | **M** | The number of cells counted is documented. | CAP CYG.31875 | |
| CYG4.1.2 | **M** | The sex chromosome complement is documented. | DAP15 | |
| CYG4.1.3 | **M** | The number of cells examined microscopically is documented. | DAP15 | |
| CYG4.1.4 | **M** | The electronically karyotyping of cells is documented. | DAP15 | |
| CYG4.1.5 | **M** | The crossover(s) for each cell counted, examined, and karyotyped is documented. | DAP15 | |
| CYG4.1.6 | **M** | The microscopic coordinates of each cell examined is documented. | DAP15 | |
| CYG4.1.7 | **M** | There is a documented process to ensure correct cell identification if re-examination is required. | DAP15 | |
| CYG4.1.8 | **M** | Band by band comparison of each homologous chromosomal pair occurs in fully examined cells. | DAP15 | |

## CYG5.0 FLUORESCENCE IN SITU HYBRIDIZATION (FISH)

| CYG5.1 | | There are procedures for the validation and verification of FISH probes. | | |
|---|---|---|---|---|
| CYG5.1.1 | **M** | Laboratory-modified examination methods are validated prior to reporting patient results (e.g. changed methodology such as a decreased amount of probe used). | ACMG E.9.2.1.2<br>CAP CYG.46799<br>CLSI MM07-A2 – 8.4 | REVISED |
| CYG5.1.2 | **M** | There are procedures for the verification of all FISH probes. | ACMG E.9.2.1.1<br>CAP CYG.42700<br>CLSI MM07-A2 | |
| CYG5.1.3 | **M** | The laboratory documents the probes used including lot number, expiry date. | ACMG E9.7.2 | |
| **CYG5.2** | | **There are procedures for scoring FISH results and monitoring FISH performance.** | | |
| CYG5.2.1 | **M** | There are procedures for scoring all FISH results on different sample types and indications. | CLSI MM07-A2 – 9.2<br>CAP CYG.43000 | |
| CYG5.2.2 | **M** | Interphase FISH results are scored by two different individuals. | CLSI MM07-A2 – 9.3 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CYG5.2.3 | **M** | FISH results are scored as instructed by the manufacturer. | DAP15 | |
| CYG5.2.4 | **M** | There are defined criteria for the selection of FISH probes to ensure the probe used is for the intended target. | CLSI MM07-A2 – 11.3 | |
| CYG5.2.5 | **M** | Examination results and controls are monitored. | CAP CYG.42750 | |
| CYG5.2.6 | **M** | Each lot of FISH probes is checked for acceptable performance. | CAP CYG.42775 | |
| CYG5.2.7 | | A known positive control is used for each interphase FISH examination when available and appropriate. | DAP15 | |
| CYG5.2.8 | **M** | At least one cell is documented for examinations with normal results, and at least two cells are documented for examinations with abnormal results. | CAP CYG.43300 | |
| CYG5.2.9 | **M** | For examinations where multiple chromosomal loci are targets as part of a single examination, an image of at least one cell is documented for each target (e.g. sub-telomere FISH). | DAP15 | |

## CYG6.0 MICROARRAY

| | | | | |
|---|---|---|---|---|
| **CYG6.1** | **There are procedures for the verification and monitoring of microarray examination.** | | | |
| CYG6.1.1 | **M** | Microarray pre-examination components are verified and monitored (e.g. nuclear extraction, purification, quantitation and equipment). | ACMG E13 | |
| CYG6.1.2 | **M** | Microarray examination components are verified and monitored (e.g. fragmentation of DNA by sonification-enzyme digestion, new lots of reagents and arrays, equipment, upgrades to software). | CAP CYG.49500<br>CAP CYG. 49550 | |
| CYG6.1.3 | **M** | Microarray post-examination components are verified and monitored (e.g. visual inspection of hybridized array images, evaluation of QC data calculated from examination software, genomic gains and losses called by the microarray software algorithm). | CAP CYG. 49525<br>CAP CYG. 49575 | |
| CYG6.1.4 | **M** | Corrective action is taken when components fail to meet established criteria. This is documented. | CLSI MM12-A – 6.1 | |
| CYG6.1.5 | | An internal database is established to identify common copy number variations specific to the patient population and recurrent false positives associated with a particular platform. | DAP15 | |

## CYG7.0 INTERPRETATION

| | | | | |
|---|---|---|---|---|
| **CYG7.1** | **There are procedures for the interpretation of cytogenetic examinations when required.** | | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CYG7.1.1 | **M** | When a histopathological or cytological interpretation is required, a qualified pathologist is involved. | CAP CYG.47866 | |
| CYG7.1.2 | **M** | When a cytogenetic interpretation is required, a qualified cytogeneticist is involved. | CAP CYG.47875 | |
| CYG7.1.3 | | The medical review of cytogenetics examinations is performed in a manner that meets clinical needs. | DAP15 | |
| CYG7.1.4 | **M** | All cytogenetics results (e.g. karyotypes, diagnostic findings) are reviewed by a cytogeneticist. | DAP15 | |
| CYG7.1.5 | **M** | Discrepant outcomes are investigated and documented. | DAP15 | |

## CYG8.0 REPORTS

| CYG8.1 | Reports include all relevant patient and laboratory data. | | | |
|---|---|---|---|---|
| CYG8.1.1 | **M** | Cytogenetics reports include the number of cells examined. | ACMG E3.1.1 | |
| CYG8.1.2 | **M** | Cytogenetics reports include the band level resolution. | CAP CYG.32071 | |
| CYG8.1.3 | | Cytogenetics reports include special banding if performed. | CAP CYG.32100 | |
| CYG8.1.4 | **M** | Cytogenetics reports include an examination summary. | CAP CYG.32250 | |
| CYG8.1.5 | **M** | Cytogenetics reports include clinical indications for examination. | CAP CYG. 49600 | |
| CYG8.1.6 | **M** | Cytogenetics reports include the source and identification of any FISH probe used. | CAP CYG.31875 | |
| CYG8.1.7 | **M** | Cytogenetics reports include a cytogeneticist signature or electronic equivalent. | DAP15 | |
| CYG8.1.8 | | Cytogenetics reports include reference to genetic follow-up procedures (e.g. family studies, ultrasound, amniocentesis, family counselling). | DAP15 | |
| CYG8.1.9 | **M** | Cytogenetics reports include identification of sample quality or integrity issues that may contribute to a compromised result (e.g. delays in transit). | ISO 15189 5.8.2a-b | |
| CYG8.1.10 | | Cytogenetics reports include clinical information correlated with the cytogenetics findings and relevant previous examinations. | DAP15 | |
| CYG8.1.11 | **M** | Cytogenetics reports include reporting of karyotypes according to the most recent issue of the International System for Human Cytogenetic Nomenclature (ISCN). | DAP15 | |
| CYG8.1.12 | | Cytogenetics reports include failure to achieve the required banding resolution or the required number of metaphases when indicated. | DAP15 | REVISED |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| CYG8.1.13 | | Cytogenetics reports include abnormal FISH results suggestive of mosaicism in conjunction with confirmatory cytogenetic examination. | DAP15 | |
| CYG8.1.14 | | Cytogenetics reports include limitations of FISH examination, when appropriate. | DAP15 | |
| CYG8.1.15 | | Cytogenetics reports include description of the chromosome result and any changes from previous cytogenetics examinations. | DAP15 | |
| CYG8.1.16 | | Cytogenetics reports include interpretive comments about possible diagnoses, prognosis or other clinical correlations. | DAP15 | |
| **CYG8.2** | **Turnaround times for cytogenetics examinations have been established.** | | | |
| CYG8.2.1 | **M** | There are established turnaround times (consistent with CCMG guidelines) for interim and final reports. | ISO 15189 4.14.7 | |
| CYG8.2.2 | **M** | Turnaround times are monitored and documented. Identified problems are addressed. | DAP15 | |

# Accreditation Standards 2015

Laboratory Medicine

## CYTOLOGY STANDARDS

The cytology standards are used in conjunction with the general standards for each laboratory.

# CYTOLOGY

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|

## CYT1.0 PERSONNEL, FACILITIES, EQUIPMENT AND SUPPLIES

| | | | | |
|---|---|---|---|---|
| **CYT1.1** | **There are procedures for cytopathology screening.** | | | |
| CYT1.1.1 | **M** | Negative exfoliative cytology samples are signed out by a certified cytotechnologist at the discretion of the medical director. All other samples are signed out by a pathologist. | CAP CYP.07465<br>CSC 8.13 | |
| CYT1.1.2 | **M** | There is a list of samples and results that can be signed out by cytotechnologists. | CAP CYP.07465<br>CSC 8.13 | |
| CYT1.1.3 | **M** | Criteria are established for pathologist review of slides. | CAP CYP.07465<br>CSC 8.13 | |
| CYT1.1.4 | **M** | A quiet, dedicated area is provided for the microscopic examination of cytology samples. | CSC 3.3.1 | |
| CYT1.1.5 | **M** | Microscopes have the necessary objectives for cytological examination. | CSC 3.3.2 | |
| **CYT1.2** | **Cytological stains and solutions are labeled and maintained.** | | | |
| CYT1.2.1 | **M** | Cytological working solutions and stains are labeled with contents, expiration date or date filtered or changed. | CAP CYP.03900 | |
| CYT1.2.2 | **M** | Recycling systems for alcohols are used according to the manufacturer's recommendations. Recycled alcohols are checked prior to use. | CAP COM.30600 | |

## CYT2.0 PRE-EXAMINATION

| | | | | |
|---|---|---|---|---|
| **CYT2.1** | **The adequacy of cytology samples is assessed.** | | | |
| CYT2.1.1 | **M** | There are documented criteria to assess cytology sample adequacy.<br>*Guidance: For some sample types, certain cells should be present in sufficient numbers for the sample to be considered adequate (e.g. alveolar macrophages in sputum samples).* | CAP QMAP 117-118 | |
| CYT2.1.2 | | Samples with atypical cells are categorized as satisfactory. | CAP QMAP 117-118 | |
| CYT2.1.3 | | Reports clearly distinguish samples that are unsatisfactory or suboptimal. | CAP CYP.07452 | |
| CYT2.1.4 | | Reports on unsatisfactory samples indicate whether the sample was rejected or evaluated. | CAP QMAP 117-118 | |
| **CYT2.2** | **There are procedures for processing cytology samples.** | | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CYT2.2.1 | **M** | Protective surface coatings are removed from slides prior to staining. | CLSI GP23A 9.4.3.2 | |
| CYT2.2.2 | **M** | Fixation times are defined and monitored. | CLSI GP23A 9 | |
| CYT2.2.3 | | There are procedures to address suboptimal results in processing (e.g. unequal dispersal of cells in preparations from liquid-based systems). | CSC 10.7 | |
| CYT2.2.4 | **M** | Appropriately sized coverslips are used to cover as much material as possible. | DAP15 | |
| **CYT2.3** | **There are procedures for staining cytology samples.** | | | |
| CYT2.3.1 | **M** | A Papanicolaou stain or acceptable alternative is used. | CAP CYP.07439<br>CAP CYP.07685<br>CLSI G15 A3 11.1.3 | |
| CYT2.3.2 | | A sequence is used to ensure that paucicellular samples are stained before highly cellular samples. | CAP ANP.12096<br>CAP QMAP 114<br>CSC 5.5 | |
| CYT2.3.3 | **M** | Stains are filtered or changed frequently enough to reduce the possibility of cross-contamination. | CAP QMAP 114 | |
| CYT2.3.4 | **M** | The date and number of times the stains are filtered or changed are recorded. | CAP QMAP 114 | |
| CYT2.3.5 | | When cross-contamination is identified or suspected, the samples with possible contaminants are compared with other cases stained that day. Repeat slides are prepared as necessary. | CAP QMAP 114 | |
| CYT2.3.6 | **M** | When cross-contamination is identified, resolution of the case is documented. | CAP QMAP 114 | |
| **CYT2.4** | **There are procedures for the review of the quality of cytological staining.** | | | |
| CYT2.4.1 | **M** | Slide staining is assessed on each day of staining. | CAP CYP.04300<br>CSC 13.1 | |
| CYT2.4.2 | | There are procedures to recognize and address suboptimal staining results.<br>*Guidance: Slide staining assessment includes predicted staining characteristics, cellular detail, the clarity of cells and the clarity of the smear background.* | CAP CYP.04300<br>CSC 13.1 | |
| CYT2.4.3 | | The occurrence and resolution of any staining problem is recorded. | DAP15 | |
| CYT2.4.4 | | A quality assessment of stains using case material is performed annually.<br>*Guidance: Most stains used in the cytology laboratory are not subject to outdating. Acceptable performance of such stains is confirmed at least annually. Cytology stains undergoing daily quality review are exempt from annual assessment.* | CAP CYP.03925 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|

## CYT3.0 EXAMINATION

| | | | | |
|---|---|---|---|---|
| **CYT3.1** | **There is a process to monitor the automated screening of slides.** | | | |
| CYT3.1.1 | **M** | There is a documented process for the ongoing monitoring of automated slide screening. | CAP QMAP 127-128 | |
| CYT3.1.2 | **M** | Tolerance limits for determination of sample adequacy and for diagnostic accuracy are defined. | CAP QMAP 127-128 | |
| CYT3.1.3 | **M** | Automated slide examination data summaries are performed. This information is reviewed by the medical director. | CAP QMAP 127-128 | |
| CYT3.1.4 | **M** | There is a procedure to handle slides that are not successfully screened by automated slide screening. | CAP CYP.05292 | |
| CYT3.1.5 | **M** | When slides are screened using automated screening technology, personnel have received technical and interpretive training.<br>*Guidance: Training includes verification of instrumentation, troubleshooting, review and interpretation of instrument data, and handling positive or suspicious results.* | CAP GEN.55450<br>CAP CYP.05257 | |
| **CYT3.2** | **Workload limits are defined and monitored.** | | | |
| CYT3.2.1 | **M** | Maximum daily workload limits have been established. | CAP CYP.08575 | |
| CYT3.2.2 | **M** | The number of slides screened by each cytotechnologist and the number of hours each cytotechnologist examines slides is recorded daily and monitored. | ASC DWG | |
| CYT3.2.3 | **M** | The number of slides screened per hour is calculated, monitored and recorded for each cytotechnologist. | ASC DWG | |
| CYT3.2.4 | **M** | Cytotechnologists with duties in addition to screening have a proportionate number of slides reduced from their workload. | ASC DWG | |

## CYT4.0 POST-EXAMINATION

| | | | | |
|---|---|---|---|---|
| **CYT4.1** | **There are procedures for reporting cytopathology results.** | | | |
| CYT4.1.1 | **M** | Cytopathology reports include the anatomical site. | CAP CYP.05300 | |
| CYT4.1.2 | | Cytopathology reports include the volume, color and consistency of the sample and an assessment of sample adequacy when appropriate. | CAP QMAP 116<br>CSC 10.0 | |

| No. | Standard / Criterion | | Reference | Change |
|---|---|---|---|---|
| CYT4.1.3 | **M** | Cytopathology reports include the number of slides received. | CAP QMAP 116<br>CSC 10.0 | |
| CYT4.1.4 | **M** | Cytopathology reports include any ancillary procedures performed (e.g. TB, flow cytometry). | CAP QMAP 116<br>CSC 10.0 | |
| CYT4.1.5 | **M** | Each separately submitted sample is recognized in the diagnostic report. | CAP QMAP 116<br>CSC 10.0 | |
| CYT4.1.6 | **M** | All reports containing interpretations by a pathologist indicate authorship. | CAP CYP.05316 | |
| CYT4.1.7 | **M** | Reporting of cytology results is clear, concise, consistent and easily interpretable (e.g. the Bethesda System). | CSC 10.5, 10.6<br>CAP CYP.06100 | |
| CYT4.1.8 | **M** | Reports include an interpretation of the morphological findings and standard descriptive terminology. | CAP CYP.06100 | |
| CYT4.1.9 | | Reports state the interpretation representing the highest degree of abnormality. | CAP CYP.06100<br>CSC 10.4 | |
| CYT4.1.10 | **M** | Diagnoses comply with recognized pathological entities, standard terminology and use clear, unambiguous language. | CAP CYP.06100 | |
| CYT4.1.11 | **M** | Reports specify a reason when a definite diagnosis cannot be rendered (e.g. inconclusive, indeterminate or non-diagnostic). | CAP CYP.06100 | |
| CYT4.1.12 | | Follow-up recommendations are made in compliance with established guidelines when available (e.g. Bethesda classification system for thyroid cytology or BC Cervical Cancer Screening guidelines). | CAP CYP.06100 | |
| CYT4.1.13 | | When an assessment of fine needle aspirate (FNA) adequacy performed, the assessment is documented in the cytopathology report. | CAP CYP.06100 | |
| CYT4.1.14 | **M** | Reports identify screening and interpreting individuals including the screening cytotechnologist's name or unique identifier when signed out by a cytotechnologist. | CAP CYP.05316<br>CSC 10.3 | |
| CYT4.1.15 | | Reports identify automated screening devices when used, and any subsequent verification by a cytotechnologist or pathologist. | CAP CYP.05316<br>CSC 10.3 | |
| **CYT4.2** | **There are procedures for reviewing cytopathology results.** | | | |
| CYT4.2.1 | **M** | Pathologists sign off all cases reviewed by pathologists. | CAP CYP.05332<br>CAP CYP.07670<br>CSC 10.3 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CYT4.2.2 | | If a report is reviewed and approved by a pathologist other than the diagnosing pathologist, the names and responsibilities of both the pathologist who made the diagnosis and the pathologist who performed final verification appear on the report. | CAP CYP.05332<br>CAP CYP.07670<br>CSC 10.3 | |
| CYT4.2.3 | **M** | Intradepartmental and external consultations are documented. | CAP CYP.02100 | |

## CYT5.0 NON-GYNECOLOGICAL CYTOLOGY

| | | | | |
|---|---|---|---|---|
| **CYT5.1** | **There are processes to ensure sample integrity and viability.** | | | |
| CYT5.1.1 | **M** | Unfixed urine and cerebral spinal fluids (CSF) samples for cytology examination are refrigerated if processing cannot be performed in one hour. | CLSI GP23 A 3.1 | |
| CYT5.1.2 | **M** | Unfixed cytology samples, other than urine and CSF, are refrigerated if processing cannot be performed within four hours. | CLSI GP23 A 3.1 | |
| CYT5.1.3 | **M** | There are policies and procedures to handle cytology samples in off-hours. | CLSI GP23 A 3.1 | |
| **CYT5.2** | **Cytopathology examinations are correlated with clinical information and histological results.** | | | |
| CYT5.2.1 | **M** | Personnel screening or examining cytology slides have access to the patient history, including cytopathology and surgical pathology results. | CAP QMAP 131 | |
| CYT5.2.2 | **M** | Cytological results are correlated with histological results and any available ancillary examinations where possible. | CAP CYP.07675<br>CAP CYP.06850 | |
| CYT5.2.3 | **M** | FNA diagnoses are correlated with surgical diagnoses using a minimum six-month follow-up period where appropriate. | CSC 14.3.4 | |
| **CYT5.3** | **Non-gynecological cytology samples are reviewed.** | | | |
| CYT5.3.1 | **M** | Slide review includes random case or selected case re-screening.<br>*Guidance: If re-screening selected cases, there is a documented process to identify the cases for re-screening.* | CSC 13.3 | |
| CYT5.3.2 | | Slide review includes correlation between cytotechnologist and pathologist re-screening. | DAP15 | |
| CYT5.3.3 | **M** | There is a review of previous abnormal or negative cases with documentation. | CAP CYP.07600<br>CAP QMAP 125-126 | |
| CYT5.3.4 | **M** | The percentage of major discrepancies is monitored and documented. | CSC 14.3 | |

| No. | Standard<br>Criterion | Reference | Change |
|---|---|---|---|
| CYT5.3.5 | There is a documented process to record, analyze and communicate sample adequacy data by submitting physician. | CSC 14.3 | |

## CYT6.0 GYNECOLOGICAL CYTOLOGY

| | | | |
|---|---|---|---|
| **CYT6.1** | **Gynecological examination requests include specific clinical information.** | | |
| CYT6.1.1 | Gynecological cytology requests contain specific clinical information.<br>*Guidance: This clinical information may include:*<br>• *the date of commencement of last menstrual period*<br>• *hormonal status (e.g. gravid, postmenopausal)*<br>• *history of cervicovaginal intraepithelial neoplasia, cervicovaginal malignancy or any other genital or extragenital malignancy*<br>• *abnormal clinical findings, patient symptoms and the appearance of the cervix*<br>• *the presence of an intrauterine device*<br>• *history of exogenous hormone therapy*<br>• *human papillomavirus (HPV) immune status*<br>• *the date of last gynecological smear and history with dates of any previous pertinent surgical pathology or cytopathology reports*<br>• *history of systemic chemotherapy, pelvic radiotherapy, gynecological surgery, cryosurgery, electrosurgery or laser surgery* | | CLSI GP15-A3 6.2 |
| **CYT6.2** | **There are procedures to assess the adequacy of gynecological cytology samples.** | | |
| CYT6.2.1 | In gynecological samples that are adequate for evaluation, the presence or absence of the endocervical/transformation zone component and any relevant sample aspects are described. | | CLSI MM13-A 6 |
| CYT6.2.2 | There is a procedure to prevent cross contamination of samples when residual liquid-based cytology material is used for amplified molecular examinations. | | CSC 5.5 |
| **CYT6.3** | **There are processes for gynecological re-screening.** | | |
| CYT6.3.1 | **M** Slide review ensures evaluation of every cytotechnologist.<br>*Guidance: The review process is documented (e.g. a minimum of 10% of negative screens, a rapid review of 100% of negative screens).* | | CAP CYP.07478<br>CAP CYP.07480<br>CSC 13.2.1<br>CAP QMAP 120-127 |
| CYT6.3.2 | **M** There is a documented process to define and select high-risk cases for random re-screening. | | CAP CYP.07478 |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| CYT6.3.3 | **M** | Re-screening data is used to calculate a discrepancy rate-over-call and a discrepancy rate-under-call. | CAP CYP.07655 | |
| CYT6.3.4 | **M** | The proportion of slides re-screened is calculated per technologist and per the total volume on a monthly or quarterly basis. | CAP CYP.07655 | |
| CYT6.3.5 | **M** | Slide review data is examined and categorized (e.g. complete agreement, minor discrepancy, and major discrepancy). Discrepancies identified during re-screening are reviewed and recorded. | CSC 13.2.1 | |
| CYT6.3.6 | **M** | The rate of referral cases by each cytotechnologist to a pathologist is monitored. | CAP QMAP 120-127 | |
| CYT6.3.7 | **M** | There is a documented process to record, analyze and communicate sample adequacy data by submitting physician. | CAP QMAP 120-127 | |
| CYT6.3.8 | | The relative rates of atypical squamous cells of undetermined significance to squamous intraepithelial lesions (ASCUS to SIL) are monitored. | CAP CYP.07600<br>CAP QMAP 125-126 | |
| CYT6.3.9 | **M** | The rate of low-grade squamous intraepithelial lesions to high-grade squamous intraepithelial lesions (LSIL to HSIL) is monitored. | CAP CYP.07600<br>CAP QMAP 125-126 | |
| **CYT6.4** | **There are procedures for review, interpretation and result correlation of gynecological samples.** | | | |
| CYT6.4.1 | **M** | Criteria for a pathologist review and interpretation of gynecological slides are defined. | CAP CYP.07465<br>CSC 8.13.1 | |
| CYT6.4.2 | | Gynecological cytopathology findings are correlated with available clinical information including a targeted re-screening of high risk cases (e.g. a previous abnormality, diethylstilbestrol exposure). | CAP CYP.07569<br>CAP QMAP 120-121 | |
| CYT6.4.3 | **M** | Cytological results are correlated with the histological diagnosis if possible. There is a documented process to resolve discrepancies between histological and cytological results. | CAP CYP.01900<br>CAP CYP.07543<br>CAP QMAP 120-121 | |
| CYT6.4.4 | **M** | When significant atypia is identified, a five-year retrospective review is performed on negative cytology material. | CAP CYP.07517 | |
| CYT6.4.5 | **M** | Follow-up histological reports or material is obtained and reviewed. This is documented. If a follow-up histological report or material is not available, this is documented. | CAP CYP.07543<br>CAP CYP.07556 | |
| CYT6.4.6 | **M** | A corrected report is issued if a significant discrepancy that would affect patient care is discovered. | CAP CYP.07530 | |
| CYT6.4.7 | | The number and percentage of positive cases of high-risk human papillomavirus examinations performed on ASCUS cases is recorded. | CAP CYP.07653 | |

# Accreditation Standards 2015

Laboratory Medicine

## HEMATOLOGY STANDARDS

The hematology standards are used in conjunction with the general standards for each laboratory.

# HEMATOLOGY

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **HEM1.0** | | **CELL COUNTS** | | |
| **HEM1.1** | | **There are procedures for the collection and handling of samples for blood cell counts.** | | |
| HEM1.1.1 | **M** | Samples for complete blood counts and blood film morphology are collected in potassium EDTA. | CLSI H26-A2 5.4.3<br>CAP HEM.22050 | |
| HEM1.1.2 | **M** | All blood samples are mixed thoroughly and immediately prior to examination. | CLSI GP41-A6 8.9.1-12 | |
| HEM1.1.3 | **M** | Samples collected in capillary tubes for microhematocrits or capillary dilution systems are obtained in duplicate. | CAP HEM.22100 | |
| HEM1.1.4 | **M** | There are documented processes to address samples with significant hemolysis or interfering lipemia. | DAP15 | |
| **HEM1.2** | | **There are procedures for manual hematocrits and cell counts on blood and body fluids.** | | |
| HEM1.2.1 | **M** | The constant packing time is established prior to use and reassessed when there has been a change in either centrifugation speed or time. | CLSI H07-A3 7.2<br>CAP HEM.32150 | |
| HEM1.2.2 | **M** | The lines of counting chambers are bright, clean and free of scratches. | DAP15 | |
| HEM1.2.3 | **M** | Each body fluid sample is counted in duplicate when using a standard hemocytometer. Limits of agreement have been defined. | CAP HEM.33200 | |
| HEM1.2.4 | **M** | An appropriate dilution has been defined and both chambers of the hemocytometer are counted when manual counting methods are performed. | DAP15 | |
| HEM1.2.5 | **M** | Cell counts are correlated with stained slides. | CAP HEM.33300 | |
| HEM1.2.6 | | There are procedures to address low cell counts (e.g. increasing the number hemocytometer squares counted, using a lower sample dilution). | CAP HEM.33250 | |
| HEM1.2.7 | | Manual cell count procedures ensure that dilution fluids and reagents are free of contaminants. | CAP HEM.33300 | |
| HEM1.2.8 | | There is an additional procedure beyond unstained bright-field microscopy to ensure accurate distinction of erythrocytes from other cell types (e.g. acid rinsing). | | |
| HEM1.2.9 | **M** | Reticulocyte examination is based on a minimum sample size of 1,000 red blood cells (RBC). | CLSI H44-A2 6.4<br>CAP HEM.35300 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM1.2.10 | **M** | Manual reticulocyte counts are reported as absolute values ($X10^9$/L) except where calculation is not possible. | CLSI H44-A2 6.4 | |
| **HEM1.3** | **There are procedures for automated cell counts.** | | | |
| HEM1.3.1 | **M** | Background counts are performed on the diluent fluid and lysing agent on each day of testing. | CAP HEM.35414 | |
| HEM1.3.2 | **M** | Upper and lower limits of all reportable parameters on automated cell counters are defined. | CAP HEM.30250 | |
| HEM1.3.3 | | There are procedures to handle flagged results. | CAP HEM.34200 | |
| HEM1.3.4 | **M** | There are procedures to address specific issues (e.g. lipemia, cold agglutinins) affecting automated cell counts. If results cannot be verified, only valid parameters are reported. | CAP HEM.30150 | |
| HEM1.3.5 | **M** | There are mechanisms for detecting clotted samples. | CAP HEM.22150 | |
| HEM1.3.6 | **M** | There are procedures to monitor the accuracy of red cell indices when results are questionable. | CAP HEM.30200 | |
| HEM1.3.7 | **M** | There are procedures for reporting significant numbers of unlysed RBC, giant platelets or platelet clumps that may lead to spuriously high white blood cell (WBC) counts. | CAP HEM.30350 | |
| HEM1.3.8 | **M** | There are procedures for reporting WBC counts in the presence of nucleated red cells, megakaryocytes, or WBC clumping. | CAP HEM.30100 | |
| HEM1.3.9 | **M** | There are procedures for the review of cell count data flagged by an automated differential counter. | CAP HEM.34200 | |
| HEM1.3.10 | **M** | A platelet estimate is provided when other cells or cell fragments are detected or suspected. | CAP HEM.30300 | |
| HEM1.3.11 | **M** | Lower reportable ranges are established for automated cell counters used to perform fluid cell counts and there are procedures to address fluid cell count results that fall outside reportable ranges. | CAP HEM.35452 | |
| HEM1.3.12 | | There are procedures to detect and address results in body fluid cell counts affected by interfering substances. | DAP15 | |
| HEM1.3.13 | **M** | There is a procedure to detect and report cell clumps in body fluids that may give an inaccurate cell count. | CAP HEM.35471 | |
| **HEM1.4** | **QC procedures for automated hematology analyzers are defined.** | | | |
| HEM1.4.1 | **M** | A minimum of two different stabilized control samples are run during each 24 hours of examination. | CLSI H26-A2 7.5.1<br>CAP HEM.25850 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM1.4.2 | **M** | For pattern recognition microscopy systems, QC is done by periodic processing of prepared control slides. | DAP15 | |
| HEM1.4.3 | **M** | For flow-through systems QC is performed using a commercial product on each day of use. | CAP HEM.34100 | |
| HEM1.4.4 | **M** | QC procedures for automated differential counters define limits of agreement with WBC subclasses from commercially available material or manually counted blood films. | DAP15 | |

## HEM2.0 MICROSCOPY

| HEM2.1 | There are procedures for blood and body fluid film examination. | | | |
|---|---|---|---|---|
| HEM2.1.1 | **M** | There are guidelines for the preparation of peripheral blood films. | CAP HEM.34200 | |
| HEM2.1.2 | **M** | Peripheral blood films are adequately stained, precipitate free and have good cell distribution. | CAP HEM.34300 | |
| HEM2.1.3 | **M** | There is a procedure for blood film examination and reporting WBC, RBC and platelets. | CAP HEM.34500 | |
| HEM2.1.4 | **M** | Criteria are established for pathologist review of peripheral blood and body fluid films. | CAP HEM.34600<br>CAP HEM.35585 | |
| HEM2.1.5 | **M** | Body fluid films are adequately stained, have adequate cell distribution, cell yield and minimal morphological distortion. | CAP HEM.35547 | |
| HEM2.1.6 | | When body fluids are examined in more than one area of the laboratory, there is a mechanism to ensure consistency of results when a malignancy is suspected. | CAP HEM.35604 | |
| HEM2.1.7 | **M** | Reference materials of blood and body fluid cell morphology are readily available. | CAP HEM.35623 | |
| HEM2.1.8 | **M** | There is a documented process to ensure consistency of morphological observation and grading among all personnel performing blood and body fluid cell differentials and morphologies. | CAP HEM.34400<br>CAP HEM.35566 | |

## HEM3.0 COAGULATION

| HEM3.1 | There are procedures for the collection and handling of samples for coagulation examination. | | | |
|---|---|---|---|---|
| HEM3.1.1 | **M** | Coagulation samples are collected into 3.2% buffered citrate anticoagulant. | CLSI H21-A5 5.3.1.3<br>CAP HEM.22748 | |
| HEM3.1.2 | **M** | Prothrombin time (PT) examination is performed within 24 hours and samples are stored at 18°C to 24°C prior to examination. | CLSI H21-A5 7.1.1<br>CAP HEM.22912 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM3.1.3 | **M** | Activated partial thromboplastin times (aPTT) examination is performed within four hours and the samples are stored at 18°C to 24°C prior to examination. | CLSI H21-A5 7.1.1<br>CAP HEM.22912 | |
| HEM3.1.4 | **M** | Other coagulation examinations are performed within defined time frames and stored at defined temperatures. | CLSI H21-A5 7.1.1<br>CAP HEM.22912 | |
| HEM3.1.5 | **M** | If a coagulation examination cannot be performed within these timeframes, platelet poor plasma is removed from the cells and frozen at -20°C for up to two weeks or -70°C for up to six months. | CLSI H21-A5 7.1.1<br>CAP HEM.22912 | REVISED |
| HEM3.1.6 | **M** | Methods used to produce platelet-poor plasma are verified semi-annually and centrifuges used to produce platelet-poor plasma are verified at a defined interval. | CLSI H21-A5 6.2<br>CAP HEM.37175 | |
| HEM3.1.7 | **M** | There is a procedure for handling samples with elevated hematocrits. | CLSI H21-A5 7.1.1<br>CAP HEM.22830 | |
| HEM3.1.8 | **M** | Samples for coagulation examination are not stored in a frost-free freezer. | CLSI H21-A5 7.1.1 | |
| HEM3.1.9 | | Samples for coagulation examination are stored in polypropylene tubes and not polystyrene tubes. | CLSI H21-A5 5.3.1.2 | |
| **HEM3.2** | **There are procedures for the calculation of international normalized ratios (INR).** | | | |
| HEM3.2.1 | **M** | The International Sensitivity Index (ISI) and geometric mean used to determine the INR are validated and documented. | CLSI H54-A 4.3.2 | |
| HEM3.2.2 | **M** | The INR is calculated using the validated ISI and geometric mean. This is documented. | CLSI H54-A<br>CAP HEM.23290 | |
| HEM3.2.3 | **M** | The appropriate geometric mean of the PT is used in the INR calculation. | CLSI H54-A<br>CAP HEM.23360 | |
| HEM3.2.4 | **M** | The calculation of the INR is checked when the instrument is serviced, when there is a software upgrade or when there is a laboratory information system (LIS) upgrade and the INR is calculated by the LIS. | CLSI H54-A 7.3.2<br>CAP HEM.23430 | |
| HEM3.2.5 | **M** | The ISI is validated when there is a change in lot or type of PT reagent or a change in instrument. *Guidance: If the INR is directly measured from a calibration curve, the calibration curve must be re-established with every lot number change of the PT reagent.* | CLSI H54-A 7.3.2<br>CAP HEM.23430 | |
| **HEM3.3** | **There are procedures for coagulation examinations.** | | | |
| HEM3.3.1 | **M** | Routine coagulation examinations are checked with two levels of control material during each eight hours of patient examination, after a reagent change and after instrument maintenance. | CAP HEM.37300 | |
| HEM3.3.2 | | The aPTT-based heparin therapeutic range is established and validated. | CLSI H47-A2 10.7<br>CAP HEM.23453 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM3.3.3 | | There is a documented process for handling PT and aPTT examinations when the readable range of a photo-optical instrument is exceeded. | CAP HEM.37400 | |
| HEM3.3.4 | | There are defined criteria to determine if electrophoretic separations are satisfactory for coagulation examination performed by electrophoresis. | CAP HEM.37910 | |
| HEM3.3.5 | **M** | Quantitative D-dimer examinations used to rule out deep vein thrombosis or pulmonary embolus have been validated for use in the evaluation of venous thromboembolism. | CAP HEM.37925<br>CLSI H59-A 6.1 | |
| HEM3.3.6 | **M** | The report units (unit type and unit of magnitude), the reference range and the cut-off value are reported for D-dimer examinations. | CAP HEM.37924<br>CLSI H59-A 9.2 | |
| **HEM3.4** | **There are procedures for performing specialized platelet examinations.** | | | |
| HEM3.4.1 | **M** | Platelet function examinations are completed within four hours of sample collection. | CLSI H58-A<br>CAP HEM.38028 | |
| HEM3.4.2 | **M** | Blood samples for platelet aggregation and platelet function examinations are stored at room temperature prior to examination. | CLSI H58-A<br>CAP HEM.38013 | |
| HEM3.4.3 | | The platelet concentration has been defined for platelet aggregation examinations performed by an optical aggregation method. | CAP HEM.38035 | |
| HEM3.4.4 | | Reports of platelet aggregation examinations indicate if the sample platelet concentration is below the optimal concentration. | CAP HEM.38035 | |
| **HEM3.5** | **There are procedures for coagulation factor and mixing examinations.** | | | |
| HEM3.5.1 | **M** | For coagulation endpoint-based factor examinations three or more points are plotted for the standard curve. | CLSI H48-A 11<br>CAP HEM.37940 | |
| HEM3.5.2 | **M** | The standard curves are verified with at least two reference points for each factor examination for every eight hours of examination. | CLSI H48-A 11<br>CAP HEM.37960 | |
| HEM3.5.3 | **M** | Three or more dilutions are plotted for each factor examination. | CLSI H48-A 11<br>CAP HEM.37980 | |
| HEM3.5.4 | **M** | Apparent inhibitor effects are reported when factor examinations are performed. | CAP HEM.37982 | |
| HEM3.5.5 | **M** | Commercial product or pooled plasma from at least 20 healthy donors is utilized for mixing examinations. | CLSI H47-A2 9.5<br>CAP HEM.37991 | |
| HEM3.5.6 | | For samples with positive mixing examination results (suggestive of an inhibitor) there is either a procedure to detect heparin or other antithrombotic drugs that inhibit coagulation, or the result is reported with a comment that the effect of inhibitor drugs cannot be excluded. | CAP HEM.38002 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|

## HEM4.0 BLOOD PARASITES

| | | | |
|---|---|---|---|
| **HEM4.1** | **There are procedures for blood parasite examination.** | | |
| HEM4.1.1 | **M** | Malarial examination are handled as STAT. | CLSI M15-A 2.1 |
| HEM4.1.2 | **M** | Both thick and thin films are used in examinations for blood parasites. | CLSI M15-A 6<br>CAP HEM.34724 |
| HEM4.1.3 | **M** | Blood films for malarial parasites are prepared within two hours of collection or the delay in preparation time is noted on the report. | CLSI M15-A 5.3 |
| HEM4.1.4 | **M** | An adequate number of fields (approximately 300) are assessed under a 100X oil-immersion objective when examining a film for malaria. An estimation of the time required to examine the minimum number of fields as a substitute may be provided. | CLSI M15-A 11<br>CAP HEM.34872 |
| HEM4.1.5 | **M** | When measurements are required ocular micrometers are available for determining the size of parasites. | CLSI M15-A 3.2<br>CAP HEM.34660 |
| HEM4.1.6 | **M** | Ocular micrometers are calibrated for the individual microscope used. | CAP HEM.34665 |
| HEM4.1.7 | **M** | There are adequate reference materials to assist in the identification and reporting of blood parasites. | DAP15 |
| HEM4.1.8 | | Rapid malarial examinations are used as an alternative or complementary examination where appropriate.<br>*Guidance: Where personnel do not have the expertise to examine films for malaria or where there is a delay in the examination or confirmation of malaria, rapid examinations should be considered.* | DAP15 |
| HEM4.1.9 | **M** | Results reported from a rapid malarial examination indicate the species of malaria detected and the species of malaria that the examination is capable of detecting. | DAP15 |
| HEM4.1.10 | **M** | There is a defined process for the medical review of all new positive malarial examinations. | DAP15 |
| HEM4.1.11 | **M** | Species identification and the level of parasitemia is reported on malaria-positive examinations. | CLSI M15-A 14<br>CAP HEM.34687 |

## HEM5.0 BONE MARROW EXAMINATIONS

| | | | |
|---|---|---|---|
| **HEM5.1** | **There are procedures for bone marrow examination.** | | |
| HEM5.1.1 | **M** | The preparation and staining of bone marrow slides are satisfactory for interpretation. | CAP HEM.36100 |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM5.1.2 | **M** | Bone marrow biopsy or particle sections are used in conjunction with the aspirate film, the peripheral blood film and the CBC results to evaluate the bone marrow findings whenever possible. | CAP HEM.36150<br>CAP HEM.36200 | |
| HEM5.1.3 | **M** | Ancillary examinations (e.g. cytogenetics, molecular genetics, flow cytometry) are performed after medical review on a case by case basis. | DAP15 | |
| HEM5.1.4 | **M** | Cytochemical stains are checked for intended reactivity on each day of use.<br>*Guidance: QC slides are stained along with the sample*. | CAP HEM.36800 | |
| HEM5.1.5 | **M** | There are procedures to correlate the results of ancillary examinations with the morphological interpretation. | CAP HEM.36325 | |
| HEM5.1.6 | **M** | When samples are examined by different sections of the laboratory, there are procedures to correlate data and report results. | DAP15 | |

## HEM6.0 HEMOGLOBINOPATHY EXAMINATIONS

| HEM6.1 | There are procedures for hemoglobinopathy examination. | | | |
|---|---|---|---|---|
| HEM6.1.1 | **M** | Abnormal hemoglobins found in screening methods are further investigated using appropriate techniques to identify specific hemoglobin variants. | DAP15 | |
| HEM6.1.2 | **M** | Hemoglobinopathy investigation includes fluid phase separation techniques (e.g. capillary zone electrophoresis, HPLC). | DAP15 | |
| HEM6.1.3 | | Hemoglobinopathy investigation includes other mechanisms to provide further investigation (e.g. gel electrophoresis, referral laboratories) when fluid phase separation and clinical correlation cannot identify an abnormal hemoglobin. | DAP15 | |
| HEM6.1.4 | | Hemoglobinopathy investigation includes Hemoglobin H screening (incubated reticulocytes), where indicated. | DAP15 | |
| HEM6.1.5 | | Hemoglobinopathy investigation includes hemoglobin A2, where indicated. | DAP15 | |
| HEM6.1.6 | **M** | Hemoglobin variants are quantified. | DAP15 | |
| HEM6.1.7 | **M** | Hemoglobin A, F, S and C controls are used. | CAP HEM.35927 | |
| HEM6.1.8 | **M** | Age-appropriate reference values are used in the investigation of infants. | DAP15 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **HEM7.0** | | **SEMEN EXAMINATION** | | |
| **HEM7.1** | | **There are instructions for the collection of semen samples.** | | |
| HEM7.1.1 | | Collection instructions include prompt delivery of a semen sample to the laboratory, abstinence prior to collection, avoidance of contaminants, collection of the entire ejaculate, use of a supplied container, and the maintenance of sample temperature. | WHO EPHS 2.2.1, 2.2.5<br>CAP HEM.35680 | |
| HEM7.1.2 | | There are documented processes to record sample information including the method of collection, the sample container if different from a laboratory supplied container, the number of days of abstinence and any collection or transport problems. | DAP15 | |
| HEM7.1.3 | **M** | The date and time of collection and receipt are recorded for semen samples. | WHO EPHS 2.2<br>CAP HEM.35699 | |
| **HEM7.2** | | **There are procedures for the examination of semen samples.** | | |
| HEM7.2.1 | | Semen samples are given sufficient time for liquefaction and abnormalities are noted. | WHO EPHS 2.3.1<br>CAP HEM.35718 | |
| HEM7.2.2 | **M** | Sample volume is measured and documented. | WHO EPHS 2.3.4 | |
| HEM7.2.3 | | Sample pH is measured and documented when necessary. | WHO EPHS 2.3.5 | |
| HEM7.2.4 | **M** | There is an additional procedure besides unstained bright-field microscopy to ensure accurate distinction of cell types.<br>*Guidance: A phase-contrast microscope is recommended for all examinations of unstained preparations of fresh semen.* | WHO EPHS 2.4 | |
| HEM7.2.5 | **M** | Wet preparations are scanned at an approximate total magnification of X100 for the presence of mucous, aggregation, agglutination and cells other than spermatozoa. | WHO EPHS 2.4 | |
| HEM7.2.6 | | The stains and slide preparations used and slide preparations are capable of demonstrating cellular characteristics. | WHO EPHS 2.14<br>CAP HEM.35908 | |
| HEM7.2.7 | **M** | Procedures include a concentration step for the detection of both motile and non-motile sperm in post-vasectomy and azoospermic samples. | WHO EPHS 2.9, 2.10<br>CAP HEM.35661 | |
| HEM7.2.8 | **M** | There are procedures for the examination and reporting of motility, counts and for sperm morphology based on a recognized reference (e.g. Kruger) motility and counts. | WHO EPHS 2.5, 2.7.1<br>2.13 | |
| HEM7.2.9 | **M** | Semen samples for the investigation of infertility are reviewed by a pathologist. | CAP HEM.35870 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM7.2.10 | | Reference materials of sperm morphology are readily available. | WHO EPHS 2.16<br>CAP HEM.35889 | |

## HEM8.0 FLOW CYTOMETRY

| | | | | |
|---|---|---|---|---|
| **HEM8.1** | **There are procedures for monitoring flow cytometer performance.** | | | |
| HEM8.1.1 | **M** | There are procedures for monitoring fluidics, optical alignment where applicable, and instrument reproducibility at least daily or after each time the flow cytometer is restarted. This monitoring is documented. | CAP FLO.25150<br>CLSI H43-A2 | |
| HEM8.1.2 | **M** | Standards for each fluorochrome, (e.g. fluorescent beads), are run each day that the instrument is used as part of the calibration process. The results are recorded.<br>*Guidance: This is performed after changes in dye lot numbers, laser changes and PMT changes.* | CAP FLO.30250<br>CLSI H42-A2 | |
| HEM8.1.3 | **M** | There are procedures to determine color compensation settings. | CAP FLO.30260<br>CLSI H43-A2 | |
| HEM8.1.4 | **M** | The acceptable and constant laser current is defined for laser instruments. | CAP FLO.30270 | |
| **HEM8.2** | **There are procedures for flow cytometer examination and reporting of blood lymphocyte subset enumeration.** | | | |
| HEM8.2.1 | **M** | Appropriate gating techniques to select the cell population of interest are used.<br>*Guidance: Laboratories must use CD45 as well as FSC vs. SSC parameters when examining for lymphoma and leukemia.* | CAP FLO.30460 | |
| HEM8.2.2 | **M** | The lymphosum of CD3+, CD19+, (CD3-16+, 56+) is equal to the purity of the gate greater than 95.5%. | CLSI H42-A2 14.1<br>CAP FLO.30470 | |
| HEM8.2.3 | **M** | There is a procedure to distinguish fluorescence negative and positive cell populations. | CAP FLO.30480 | |
| HEM8.2.4 | **M** | Samples for lymphocyte immunophenotyping are processed by whole blood, stain lyse method. | CLSI H42.A2 10 | |
| HEM8.2.5 | **M** | Absolute numbers and percentages are reported for each of the lymphocyte populations and for T-cell subpopulations in cases being investigated for inherited or acquired immunodeficiency.<br>*Guidance: This is not relevant for suspected lymphoma cases.* | CLSI H42-A2 16.4 | |
| **HEM8.3** | **There are procedures for flow cytometer examination and reporting of CD4 enumeration.** | | | |
| HEM8.3.1 | **M** | White blood cell counts and differential counts are performed on blood samples drawn at the same time as the samples for CD4+, CD3 and CD8 panels (for dual platform only). | CLSI H42.A2 8.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM8.3.2 | **M** | The laboratory measures and reports the viability of CD34+ cells in samples aliquoted at the time of processing of hematopoietic progenitor cells, apheresis products, and cord blood products. | CAP FLO.30564 | |
| HEM8.3.3 | **M** | Appropriately conjugated Class II or Class III anti-CD34 monoclonal antibodies are used. | CAP FLO.30578 | |
| HEM8.3.4 | **M** | A statistically valid number of events are collected to ensure clinically relevant precision and accuracy. | CAP FLO.30585 | |
| HEM8.3.5 | **M** | The performance of reagents and staining procedures is verified by the use of positive or normal controls where available (e.g. CD 103). | CAP FLO.23737 | |
| HEM8.3.6 | **M** | For single platform quantitation and dual platform quantitation of CD34+ stem cell concentrations, at least two levels of positive cellular controls are examined at least daily or each time the flow cytometer is restarted. | CAP FLO.23800 | |
| **HEM8.4** | **There are procedures for flow cytometer examination and reporting of leukemia and lymphoma.** | | | |
| HEM8.4.1 | **M** | There is a defined process to determine when the percentage of viable cells in each sample should be examined. | CLSI H42.A2<br>CAP FLO.30610 | |
| HEM8.4.2 | **M** | Antibodies appropriate for the clinical situation are used. | CLSI H43-A2 11.3.2<br>CAP FLO.30640 | |
| HEM8.4.3 | **M** | Cell concentrations are adjusted for optimal antibody staining. | CLSI H43-A2 9.3<br>CAP FLO.30670 | |
| HEM8.4.4 | **M** | Procedures include a washing step to ensure that immunoglobulin staining is intrinsic and not extrinsic (cytophilic). | CLSI H432-A2 9.5<br>CAP FLO.30720 | |
| HEM8.4.5 | **M** | There are procedures to distinguish abnormal cells of interest from normal cells based on their light scatter and fluorescence properties. | CLSI H43-A2 13.2<br>CAP FLO.30730 | |
| HEM8.4.6 | **M** | There is a procedure to distinguish fluorescence negative and positive cell populations. | CLSI H43-A2 11<br>CAP FLO.30760 | |
| **HEM8.5** | **There are procedures for flow cytometry examination and reporting of DNA and cell cycle examination.** | | | |
| HEM8.5.1 | **M** | Samples processed for DNA content and cell cycle examination contain the neoplastic cells of interest. | CAP FLO.31000 | |
| HEM8.5.2 | **M** | Cellular debris and aggregates are accounted for. | CAP FLO.31010 | |
| HEM8.5.3 | **M** | Criteria are established for determining acceptable linearity for DNA examination using cells or particles of known relative fluorescence. | CAP FLO.31020 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| HEM8.5.4 | **M** | Sample treatment with nucleic acid dye includes treatment with RNAse if the dye is not specific for DNA. | CAP FLO.31100 | |
| HEM8.5.5 | **M** | There are documented criteria that specify the type of neoplasms acceptable for DNA examination. | CAP FLO.31150 | |
| HEM8.5.6 | **M** | There are documented criteria for acceptability of histograms for interpretation. | CAP FLO.31200 | |
| HEM8.5.7 | **M** | The concentration of nucleic acid-specific dye has been determined to be a saturating concentration. | CAP FLO.31300 | |
| HEM8.5.8 | **M** | Staining and examination procedures are based upon established, referenced methodology. | CAP FLO.31350 | |
| HEM8.5.9 | **M** | Examination criteria are established for identification of an aneuploid cell population in the examination sample. | CAP FLO.31400 | |

# Accreditation Standards 2015

Laboratory Medicine

## MICROBIOLOGY STANDARDS

The microbiology standards are used in conjunction with the general standards for each laboratory.

# MICROBIOLOGY

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|

## MIC1.0 REGULATORY REQUIREMENTS

| | | | |
|---|---|---|---|
| **MIC1.1** | **The laboratory complies with regulations.** | | |
| MIC1.1.1 | **M** | Laboratories are licensed and compliant under the *Human Pathogens and Toxins Act (HPTA)*. | GOC HPTA 18 (7) |
| MIC1.1.2 | **M** | There is a designated individual to oversee biosafety and biosecurity practices (biological safety officer) where required by the *HPTA*. | GOC HPTA 36 |
| MIC1.1.3 | **M** | There is a current list of all personnel working with risk groups 3 or 4 pathogens as specified in the HPTA.<br>*Guidance: This does not apply to personnel who incidentally recover risk group 3 or 4 pathogens from clinical samples.* | GOC HPTA 31 |
| MIC1.1.4 | **M** | There is security clearance for personnel with access to select toxins, and for personnel working with risk group 3 or 4 pathogens, as specified in the *HPTA*. | GOC HPTA 33 |
| MIC1.1.5 | **M** | Laboratories submit isolates or biological products (e.g. DNA, toxins) to reference laboratories for further identification, confirmation and examination as required. | DAP15 |
| MIC1.1.6 | **M** | Laboratories report notifiable diseases according to Communicable Disease Regulations. | GOBC PHA Part 1 |

## MIC2.0 SAFETY

| | | | |
|---|---|---|---|
| **MIC2.1** | **There are procedures to minimize the risk of exposure to infectious agents.** | | |
| MIC2.1.1 | **M** | The laboratory has assessed fulfilment of the Canadian Biosafety Standards and Guidelines relevant to the type of examination performed, to minimize exposure to infectious agents. | GOBC WCB-CE<br>GOC CBSG 4.1.1-10 |
| MIC2.1.2 | **M** | There are containment measures where recovery of highly infectious agents is likely (e.g. *Brucella,* dimorphic fungi).<br>*Guidance: This does not apply to facilities who incidentally recover risk group 3 or 4 pathogens from clinical samples.* | MCM CH10<br>GOC CBSG 3.1-3.8 |
| MIC2.1.3 | **M** | Biosafety audits are performed at a defined interval to identify and resolve hazards in equipment, work methods and practices specific to the microbiology laboratory. | GOC CBSG 4.1-4.11 |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC2.1.4 | **M** | There is a procedure for handling requests for the isolation or identification of potential bioterrorism agents. | MCM CH12 | |
| MIC2.1.5 | **M** | There are procedures for recognition and handling of isolates that may be used as potential bioterrorism agents. | CAP MIC.18968 | |
| MIC2.1.6 | **M** | The laboratory's role is clearly defined in any plans to prepare and respond to a bioterrorism event. | CAP MIC.18976 | |
| MIC2.1.7 | **M** | Laboratory procedures comply with all federal and provincial guidelines for handling, processing, and disposal of samples that may contain high-risk emerging pathogens. | MCM CH12<br>CAP MIC.63220<br>CAP MIC.64620 | |
| MIC2.1.8 | **M** | Microbiological loop sterilization is performed in a way that prevents spattering of material. | CLSI GP17-A3 6.2.1.1 | |
| MIC2.1.9 | **M** | Microbiology samples, isolates, contaminated materials and supplies are disposed of in accordance with biohazard containment requirements. | MCM CH12 | MOVED |
| MIC2.1.10 | **M** | All discarded microbiology laboratory samples, cultures and contaminated waste are made intrinsically biologically safe prior to leaving the facility.<br>*Guidance: Biologically safe may result from processing by autoclave, or other approved technology, or by packaging in appropriate containers.* | MCM CH12 | MOVED |
| MIC2.1.11 | **M** | Laboratories working with viable biological agents have design characteristics appropriate to the containment of microorganisms of moderate to high risk. | ISO 15190 6.3.6 | MOVED |
| MIC2.1.12 | **M** | Laboratories designed to work with organisms of risk group III or above include design characteristics for greater containment. | ISO 15190 6.3.6 | MOVED |
| MIC2.1.13 | **M** | There are appropriate containment facilities where there is an increased probability of the isolation of a highly infectious agent requiring a higher level of biosafety practice. | ISO 15190 6.3.6 | MOVED |
| MIC2.1.14 | **M** | Level III biosafety containment facilities participate in annual self-testing with report submission to the Public Health Agency of Canada. | GOC CBSG | MOVED |

## MIC3.0 QUALITY CONTROL

| MIC3.1 | | There are procedures for the quality control of media. | | |
|---|---|---|---|---|
| MIC3.1.1 | **M** | All QC of media is recorded. | CAP MIC.21200<br>CLSI M22-A3 5.3.1-5 | |
| MIC3.1.2 | | The manufacturer's QC specifications for each type of media, and certification details for each lot number of exempt media are retained. | CAP MIC.21200<br>CLSI M22-A3 5.3.1-5 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC3.1.3 | **M** | Testing of exempt media used for fastidious organisms, specialty testing or reactions not tested by the manufacturer is performed and documented. | CAP MIC.21240<br>CLSI M22-A3 5.3.1-5 | |
| MIC3.1.4 | **M** | There is a record of the assessment of the ability of non-exempt media to support growth using a standardized inoculum of the appropriate reference strain. | CAP MIC.21300<br>CAP MIC.41200<br>CLSI M22-A3 5.3.1-5 | |
| MIC3.1.5 | **M** | There is a record of assessment of the biochemical reactivity of non-exempt media using a standardized inoculum of the appropriate reference strain. | CAP MIC.21300<br>CAP MIC.41200<br>CLSI M22-A3 5.3.1-5 | |
| MIC3.1.6 | | Upon receipt, media is visually assessed, including sterility. | CAP MIC.31400<br>CLSI M22-A3 5.3.1-5 | |
| MIC3.1.7 | **M** | All media deficiencies and any actions taken are documented. | CLSI M22-A3 5.3.1-5 | |
| MIC3.1.8 | **M** | Each shipment of media is examined for problems such as breakage, contamination, appearance and evidence of freezing or overheating. | CAP MIC.21220<br>CLSI M22-A3 5.3.2 | |
| MIC3.1.9 | **M** | Media is visually assessed prior to use (e.g. expiry, surface contamination). | CAP MIC.21420<br>CAP MIC.31460 | |
| **MIC3.2** | **There are procedures for quality control of identification and susceptibility testing.** | | | |
| MIC3.2.1 | **M** | All QC testing of identification and susceptibility testing is performed using reference organisms. Reference organisms are maintained according to published guidelines. | CAP MIC.21460<br>CAP MIC.41250 | |
| MIC3.2.2 | **M** | QC of identification systems (e.g. API strips) is performed according to the manufacturer's recommendations. | CAP MIC.21200 | |
| MIC3.2.3 | **M** | QC of individual identification tests is performed according to the manufacturer’s recommendations or at time of use (e.g. oxidase, optochin). | CAP MIC10060 | |
| MIC3.2.4 | **M** | QC of new reagent lots and shipments is performed prior to use. | CLSI M22-A3 – 5.3.1 | |
| MIC3.2.5 | **M** | QC of new lots of susceptibility disks or media is performed prior to use. | CAP MIC.21910<br>CLSI M02-A11 15 | |
| MIC3.2.6 | **M** | Susceptibility examination QC is performed every day the examination is performed, or weekly if the laboratory has documented satisfactory performance with daily QC tests. | CAP MIC.21910<br>CLSI M02-A11 15 | |
| MIC3.2.7 | **M** | The intended reactivity of reagents, disks, and strips is verified and documented with each new batch, lot number and shipment, and at a frequency defined by the medical director. | CAP MIC.21624<br>CAP MIC 21840<br>CLSI M02-A11 15.7 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC3.2.8 | **M** | QC of beta-lactamase (other than cefinase) is performed on each day of use. QC of beta-lactamase (using cefinase) is performed on each new lot number, batch and shipment, or at a frequency defined by the medical director. | CAP MIC.21632 | |
| MIC3.2.9 | **M** | QC of the intended reactivity of antisera is performed for each new batch, lot number and shipment. Subsequent QC is performed at a defined frequency thereafter. | CAP MIC.21628 | |
| **MIC3.3** | **There are procedures for the quality control of stains.** | | | |
| MIC3.3.1 | **M** | Gram stain controls are performed at defined intervals.<br>*Guidance: Personnel who examine Gram stains infrequently perform controls on each day of use. This includes laboratories where Gram stains are not done daily and where personnel perform Gram stains only on a STAT basis. Personnel examining Gram stains more frequently (permanent personnel working only in Microbiology) may reduce the frequency of controls as determined by the medical director.* | CAP MIC.21540 | |
| MIC3.3.2 | **M** | Non-immunofluorescent, non-immunologic-based stains other than Gram stains are checked with controls on each day of use, and for each new batch, lot number and shipment. | CAP MIC.21560 | |
| MIC3.3.3 | **M** | Fluorescent stain reactivity is checked at each time of use. | CAP MIC.21570 | |
| MIC3.3.4 | **M** | Mycology stain reactivity is checked at each time of use. | CAP MIC.41370<br>CAP MIC.41390 | |
| MIC3.3.5 | **M** | There is a documented process to ensure consistency of morphological observations and grading among all personnel examining Gram and other organism stains. | CAP MIC.11350 | |
| **MIC3.4** | **There are procedures for the QC of microbial identification systems (MIS).** | | | |
| MIC3.4.1 | **M** | The intended reactivity of reagents and substrates used in a microbial identification system (MIS) is checked with each new lot number, each shipment and at a frequency defined by the medical director.<br>*Guidance: This applies to commercial systems which have not developed a streamlined QC process, user-developed identification systems, or a commercial system use that is modified from the manufacturer's instructions in any way.* | CAP MIC.21626<br>CLSI M50-A 5,6,7 | |
| MIC3.4.2 | **M** | The laboratory has verified the performance of the examination system in use prior to the implementation of streamlined QC. Documentation of the streamlined QC verification is retained. | CAP MIC.21626<br>CLSI M50-A 5,6,7 | |
| MIC3.4.3 | **M** | Streamlined QC is performed as specified by the manufacturer without modification. The QC is reviewed and this is documented. | CAP MIC.21626<br>CLSI M50-A 5,6,7 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC3.4.4 | **M** | Key indicator strains, reagents, substrates used, and the expected results have been provided by the manufacturer when streamlined QC is used. | CAP MIC.21626<br>CLSI M50-A 5,6,7 | |
| **MIC3.5** | **There are procedures for the QC of incubation environments.** | | | |
| MIC3.5.1 | **M** | Anaerobic systems (e.g. jars, chambers, bags) are checked for adequate anaerobic conditions at defined intervals. | CAP MIC.21812 | |
| MIC3.5.2 | **M** | $CO_2$ incubators and jars are checked for adequate $CO_2$ levels at least weekly.<br>*Guidance: It is acceptable to monitor and record $CO_2$ levels from digital readout, however the laboratory must verify that the readout is accurate by initial calibration or Fyrite.* | CAP MIC.21813 | |
| MIC3.5.3 | **M** | Incubation conditions are checked to ensure adequate environments for microaerophilic organisms (e.g. *Campylobacter jejuni*) at defined intervals. | CAP MIC.21815 | |

## MIC4.0 SAMPLE COLLECTION

| | | | | |
|---|---|---|---|---|
| **MIC4.1** | **Collection instructions for microbiology samples are defined (in addition to SCT2.1).** | | | |
| MIC4.1.1 | **M** | Collection instructions include the use and availability of transport media and collection systems as required. | MCM CH16, 76, 112,<br>CAP MIC.13250, 75 | |
| MIC4.1.2 | **M** | High priority samples are defined (e.g. CSF from patients with suspected meningitis, surgical samples, intraocular samples). | MCM CH16, 76, 112,<br>CAP MIC.13250, 75 | |
| MIC4.1.3 | **M** | Collection instructions include details on storage or preservation of samples if processing is delayed. | MCM CH16, 76, 112,<br>CAP MIC.13250, 75 | |
| **MIC4.2** | **Collection instructions for ocular samples are defined.** | | | |
| MIC4.2.1 | | Eye swabs are taken prior to the application of topical anesthetic. | MCM CH16 | |
| MIC4.2.2 | **M** | Corneal or conjunctival scrapings are immediately inoculated onto appropriate media at the bedside. | MCM CH16 | |
| MIC4.2.3 | **M** | Aqueous and vitreous aspirates are transported to the laboratory, preferably in the collection syringe. Transport media is used for other ocular samples where appropriate. | MCM CH16 | |
| MIC4.2.4 | **M** | Aqueous aspirates, vitreous aspirates, biopsy material and enucleations are transported to the laboratory immediately after collection. Other ocular samples are transported to the laboratory within 24 hours. | MCM CH16 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **MIC4.3** | | **Collection instructions for urine and enteric samples are defined.** | | |
| MIC4.3.1 | | Sample collection instructions provide direction for the collection of different urine samples (e.g. midstream, catheter). | MCM CH16, 112 | |
| MIC4.3.2 | | There are guidelines restricting ordering fecal samples for culture from patients hospitalized for more than three days. | MCM CH16 | |
| MIC4.3.3 | **M** | Sample collection instructions include choosing portions of fecal samples with mucous or blood. | MCM CH16 | |
| MIC4.3.4 | | Collection instructions include conditions when rectal swabs are acceptable (e.g. recovery of *Neisseria gonorrhoeae*, screening of vancomycin resistant enterococcus (VRE). | MCM CH16 | |
| MIC4.3.5 | | There are guidelines for ordering fecal samples submitted for routine parasitology and for ordering fecal samples for parasite examination from patients hospitalized more than four days. | MCM CH130<br>CAP MIC.52190 | |
| MIC4.3.6 | **M** | Parasitology sample collection instructions specify fecal samples are placed into preservative within 30 minutes of collection. | CLSI M28-A2 5.1.2, 5.2 | |
| MIC4.3.7 | **M** | Sample collection instructions specify fecal samples should not be contaminated with urine or water. | CLSI M28-A2 5.1.2, 5.2 | |
| **MIC4.4** | | **Collection instructions for CSF samples and blood cultures are defined.** | | |
| MIC4.4.1 | **M** | Collection instructions for CSF samples include a defined container sequence. | MCM CH16 | |
| MIC4.4.2 | **M** | Instructions include storing and transporting CSF samples at room temperature. | MCM CH16 | |
| MIC4.4.3 | **M** | Blood culture collection instructions include information on timing, number, and sample volumes for adult and pediatric age groups. | MCM CH16<br>CLSI M47-A 5 | |
| MIC4.4.4 | **M** | Blood culture collection instructions include information on disinfection of the collection site prior to collection. | MCM CH16<br>CLSI M47-A 5 | |
| MIC4.4.5 | **M** | Blood culture collection instructions include information on distribution of blood between aerobic and anaerobic blood culture bottles. | MCM CH16<br>CLSI M47-A 5 | |
| MIC4.4.6 | | Blood culture collection instructions include information on collection of blood cultures from intravascular access devices. | MCM CH16<br>CLSI M47-A 5 | |
| **MIC4.5** | | **Collection instructions for wound samples are defined.** | | |
| MIC4.5.1 | | Collection instructions provide guidance to distinguish deep wounds from superficial wounds and subsequent handling requirements. | MCM CH16 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC4.5.2 | **M** | Specialized transport media is used to facilitate the recovery of anaerobes where indicated by clinical conditions. | MCM CH16 | |
| **MIC4.6** | **Collection instructions for mycobacteriology and virology samples are defined.** | | | |
| MIC4.6.1 | **M** | Mycobacteriology sample collection instructions include the number, timing and minimum volume of samples. | MCM CH28, 30<br>CAP MIC.31100 | |
| MIC4.6.2 | | Mycobacteriology sample collection instructions include collection in sealed, leak-proof containers and prompt transport to the laboratory. | MCM CH28, 30<br>CAP MIC.33050 | |
| MIC4.6.3 | | Viral culture sample collection instructions include the use of viral transport media. | MCM CH76<br>CAP MIC.13175 | |

## MIC5.0 SAMPLE WORKUP

| MIC5.1 | There are procedures for the workup of samples. | | | |
|---|---|---|---|---|
| MIC5.1.1 | **M** | Procedures are available for handling special requests including the isolation of uncommon organisms from any body site (e.g. *Corynebacterium diphtheria* from throat cultures). | MCM CH16, 26 | |
| MIC5.1.2 | **M** | Sample specific procedures define when a direct Gram-stained smear is examined. | MCM CH16 | |
| MIC5.1.3 | **M** | Sample specific procedures define suitable media including enriched or selective media. | MCM CH16 | |
| MIC5.1.4 | **M** | Sample specific procedures define the appropriate environments, temperatures and times for incubation. | MCM CH16 | |
| MIC5.1.5 | **M** | Sample specific procedures define specific criteria for the evaluation and work up of each type of culture. | MCM CH16 | |
| MIC5.1.6 | **M** | Sample specific procedures define potential pathogens. | MCM CH16 | |
| MIC5.1.7 | **M** | Sample specific procedures define identification procedures. | MCM CH16 | |
| MIC5.1.8 | **M** | Sample specific procedures define criteria for antimicrobial susceptibility testing. | MCM CH16 | |
| MIC5.1.9 | **M** | Sample specific procedures define requirements to send samples, isolates or products to a reference laboratory (e.g. confirmation, uncommon pathogen).<br>*Guidance: Laboratories must be able to transport samples, cultures and products to a reference laboratory.* | MCM CH16 | |
| MIC5.1.10 | **M** | Sample specific procedures define when interim reports are issued. | MCM CH16 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **MIC5.2** | **There are procedures for the interpretation and reporting of direct Gram-stained smears.** | | | |
| MIC5.2.1 | **M** | Direct Gram stains are examined and reported when appropriate. | DAP15 ver1.0 | |
| MIC5.2.2 | **M** | The laboratory has established guidelines to assist in the interpretation and reporting of direct Gram-stained smears including the quantitation of organisms and cells, the Gram stain reaction, the cellular morphology and the presumptive identification of organisms. | CAP MIC.21530 | |
| MIC5.2.3 | **M** | Laboratory procedures include the correlation of direct Gram stain results with the workup of cultures and the reporting of results. | CAP MIC.21530 | |

## MIC6.0 EXAMINATION PROCEDURES

| | | | | |
|---|---|---|---|---|
| **MIC6.1** | **There are examination procedures for sputum, nose and throat samples.** | | | |
| MIC6.1.1 | **M** | A quality assessment of expectorated sputum to determine the acceptability of the sample for culture is performed. The examination requester is notified to submit another sample if clinically indicated. | CAP MIC.22100 | |
| MIC6.1.2 | | Additional confirmatory examinations are performed on group A *Streptococcus* direct antigen negative throat samples. | MCM CH16, 20, 26<br>CAP MIC.22140 | |
| MIC6.1.3 | **M** | There are procedures for the detection, isolation and/or identification of *Legionella* species, *Bordetella pertussis* and *Neisseria gonorrhoeae* where indicated. | MCM CH16, 20, 26, 32, 43, 45 | |
| MIC6.1.4 | **M** | There are criteria for acceptance of a nasal sample. | MCM CH16, 20, 26 | |
| **MIC6.2** | **There are examination procedures for ocular samples.** | | | |
| MIC6.2.1 | **M** | There is a procedure for the detection, isolation and/or identification of *Neisseria gonorrhoeae* in neonates. | DAP | |
| MIC6.2.2 | **M** | There are procedures for the detection, isolation and/or identification of *Actinomyces* and fungi in ocular samples, if indicated. | MCM CH16, 32, 49, 76, 112, 132 | |
| MIC6.2.3 | **M** | There are procedures for the detection and identification of routine and unusual pathogens in corneal and conjunctival scrapings, and aqueous and vitreous aspirates, if indicated. | MCM CH16, 32, 49, 76, 112, 132 | |
| **MIC6.3** | **There are examination procedures for urine samples.** | | | |
| MIC6.3.1 | **M** | There are procedures for the work-up of different types of urine samples (e.g. chronic indwelling catheter urines, suprapubic aspiration). | MCM CH16, 76, 112, 130 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC6.3.2 | **M** | Urine colony counts are reported as CFU/L (e.g. $10^6$/L). | CAP MIC.22200 | |
| **MIC6.4** | **There are examination procedures for genital samples.** | | | |
| MIC6.4.1 | **M** | Screening of vaginal samples for *Candida* is performed by microscopic evaluation. | | |
| MIC6.4.2 | **M** | The diagnosis of bacterial vaginosis includes microscopic examination of a Gram-stained smear interpreted according to established guidelines. | CAP MIC.22280 | |
| MIC6.4.3 | **M** | Vaginal samples are screened for *Trichomonas vaginalis* when indicated. | DAP PLAC | |
| MIC6.4.4 | **M** | There are procedures for non-microscopic or non-culture diagnosis of *Trichomonas vaginalis.* | CLSI MM19A 11.4.7.1 | |
| MIC6.4.5 | **M** | Examination of prenatal group B *Streptococcus* screening swabs adheres to established guidelines. | CAP MIC.22273 | |
| MIC6.4.6 | **M** | There are procedures for the detection, isolation and identification of *Neisseria gonorrhoeae* and *Chlamydia trachomatis.* | CAP MIC.22285 | |
| MIC6.4.7 | **M** | There are procedures for susceptibility and epidemiological examination of *Neisseria gonorrhoeae* isolates. | MCM CH16, 76, 112, 1 | |
| MIC6.4.8 | **M** | All requests for *Lymphogranuloma venereum* examination are forwarded to the BC Centre for Disease Control or other acceptable referral laboratory. | MCM CH16, 76, 112, 1 | |
| **MIC6.5** | **There are examination procedures for enteric bacterial pathogens in fecal samples.** | | | |
| MIC6.5.1 | **M** | Procedures include the use of selective enrichment and differential media to allow recovery of small numbers of enteric pathogens. | MCM CH16, 76, 130 | |
| MIC6.5.2 | **M** | Procedures include the referral of isolates for confirmation and epidemiological examination when appropriate. | MCM CH16, 76, 130 | |
| MIC6.5.3 | **M** | There is a procedure for the detection, culture or referral of *Clostridium difficile*. | MCM CH50<br>CAP MIC.22440 | |
| MIC6.5.4 | **M** | Reports for routine bacterial cultures of feces list the specific organisms for which the sample was examined. | CAP MIC.22336 | |
| **MIC6.6** | **There are examination procedures for CSF and other sterile fluid samples.** | | | |
| MIC6.6.1 | **M** | Procedures include examination of direct Gram stains on all CSF and sterile fluid samples. | MCM CH16 | |
| MIC6.6.2 | **M** | Procedures include criteria to prioritize examinations and the reporting of results on small sample volumes (e.g. routine culture, TB, mycology and virology ordered). | MCM CH16 | |

| No. | Standard / Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC6.6.3 | **M** | Procedures include centrifuging CSF and sterile fluid samples under sterile conditions prior to smear preparation and using the sediment to inoculate media. | MCM CH16<br>CAP MIC.22495 | |
| MIC6.6.4 | **M** | Procedures include criteria defining the use of cultures with available antigen detection systems. | MCM CH16<br>CAP MIC.22550 | |
| MIC6.6.5 | **M** | Procedures include handling positive CSF and other sterile fluid direct examination and cultures as critical results. | | |
| **MIC6.7** | **There are examination procedures for blood cultures.** | | | |
| MIC6.7.1 | **M** | Blood culture systems are capable of detecting aerobic and anaerobic organisms. | CAP MIC.22600<br>MCM CH3 | |
| MIC6.7.2 | **M** | Procedures include the automated screening of blood cultures.<br>*Guidance: Non-automated blood cultures are obsolete. Manual methods to culture some pathogens such as Aspergillus and Fusarium may be used to supplement automated methodology but routine manual screening of blood cultures should only be considered following a catastrophic event.* | MCM CH3<br>CAP MIC.22620 | |
| MIC6.7.3 | **M** | Procedures include the subculture of suspected positive and positive blood cultures in a biological safety cabinet. | MCM CH3 | |
| MIC6.7.4 | **M** | Procedures include handling positive blood cultures as critical results. | MCM CH3 | |
| MIC6.7.5 | **M** | Procedures include immediate referral of isolates to a reference laboratory for identification and susceptibility testing if the laboratory is not equipped to perform these tasks. | MCM CH3 | |
| MIC6.7.6 | **M** | The contamination rate of blood cultures is documented and feedback is provided to sample collectors as appropriate. | MCM CH3<br>CAP MIC.22630 | |
| MIC6.7.7 | **M** | The laboratory has established other quality monitors for blood cultures (e.g. single bottle inoculations, positivity rate). | MCM CH3<br>CAP MIC.22630 | |
| **MIC6.8** | **There are examination procedures for wound cultures.** | | | |
| MIC6.8.1 | | There are guidelines for the reporting of normal skin flora. | MCM CH16, 47 | |
| MIC6.8.2 | **M** | Procedures include examination for aerobic pathogens and anaerobic pathogens when indicated. | MCM CH16, 47<br>CAP MIC.22700 | |
| MIC6.8.3 | **M** | Procedures include the referral of samples or isolates to a reference laboratory for identification and/or susceptibility testing if the laboratory is not equipped to perform these tasks. | MCM CH16, CH47<br>CAP MIC.22700 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|

## MIC7.0 MALDI-TOF IDENTIFICATION

| | | | | |
|---|---|---|---|---|
| **MIC7.1** | **There are procedures for matrix-assisted laser desorption/ionization (MALDI-TOF) examination.** | | | |
| MIC7.1.1 | **M** | MALDI-TOF verification is performed using microorganisms expected to be encountered. | CAP MIC.22840 | |
| MIC7.1.2 | **M** | There is a procedure for calibration of the MALDI-TOF laser. | CAP MIC.16595 | |
| MIC7.1.3 | **M** | MALDI-TOF controls are examined at defined intervals. | CAP MIC.16605 | |
| MIC7.1.4 | **M** | There is a procedure for the review of MALDI-TOF results in conjunction with other laboratory data prior to reporting. | CAP MIC.22850 | |

## MIC8.0 ANTIMICROBIAL SUSCEPTIBILITY TESTING, REPORTING RESULTS

| | | | | |
|---|---|---|---|---|
| **MIC8.1** | **There are procedures for antimicrobial susceptibility testing (AST).** | | | |
| MIC8.1.1 | **M** | AST procedures are consistent with relevant current standards and guidelines. | CAP MIC.21943 | |
| MIC8.1.2 | **M** | Only pure cultures are used for AST. | CAP MIC.21820 | |
| MIC8.1.3 | **M** | The inoculum size used for AST is controlled using a turbidity standard or other acceptable method. | CAP MIC.21940<br>CLSI M02-A11 8.1 | |
| MIC8.1.4 | **M** | AST procedures include the number and type of antimicrobials tested against specific organisms from specific body sites. | CLSI M02-A11<br>CLSI M100-S24<br>CAP MIC.21943 | |
| MIC8.1.5 | **M** | Antimicrobial cascades (the antimicrobials reported for organisms isolated from different sites of infection) are defined. | CLSI M02-A11 | |
| MIC8.1.6 | **M** | AST procedures include when a specific susceptibility testing system or method is to be used. | CLSI M02-A11 | |
| MIC8.1.7 | **M** | Procedures include criteria for AST of anaerobes. | | |
| MIC8.1.8 | **M** | AST procedures include methods to detect important types of antibiotic resistance (e.g. MRSA, VRE). | CLSI M02-A11 | |
| MIC8.1.9 | **M** | There are procedures for testing supplemental antimicrobials on isolates resistant to routinely tested antimicrobials. | CAP MIC.21944 | |
| MIC8.1.10 | **M** | Criteria for interpretation of the endpoint or zone size in AST systems are defined. | CLSI M02-A11 9.3<br>CAP MIC.21930 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC8.1.11 | **M** | There are procedures for investigating unusual or inconsistent antimicrobial testing results.<br>*Guidance: When unusual or inconsistent results are encountered, results are investigated to ensure accuracy (e.g. Imipenem-resistant Escherichia coli, Vancomycin-resistant Staphylococcus aureus).* | CAP MIC.21950<br>CLSI M02-A11 16.2 | |
| **MIC8.2** | **There are procedures for reporting microbiology results and data.** | | | |
| MIC8.2.1 | **M** | Microorganisms are reported as clinically appropriate. Specific pathogens are ruled out, as clinically appropriate. | DAP15 ver1.0 | |
| MIC8.2.2 | **M** | The results of susceptibility testing are only reported on pathogens. | CAP MIC.21943 | |
| MIC8.2.3 | **M** | The results of susceptibility tests with appropriate antimicrobials are reported and the results of susceptibility tests with inappropriate antimicrobials are suppressed. | CAP MIC.21943 | |
| MIC8.2.4 | **M** | Susceptibility reports interpret AST results as susceptible, intermediate or resistant in accordance with current relevant standards. | CLSI M02-A11 14 | |
| MIC8.2.5 | **M** | Explanatory or interpretive comments are provided when required or when appropriate. | DAP15 ver1.0 | |
| MIC8.2.6 | **M** | AST information is forwarded to infection control personnel or public health personnel in accordance with facility and government reporting requirements. | GOBC PHA | |
| MIC8.2.7 | **M** | Cumulative antimicrobial susceptibility test data (antibiograms) are maintained and reported at defined frequencies to promote antimicrobial stewardship.<br>*Guidance: Cumulative data should be reported annually, at a minimum, to the appropriate group or committee.* | CAP MIC.21946<br>CLSI M39-A3 8 | |

## MIC9.0 MYCOBACTERIOLOGY

| MIC9.1 | There are pre-examination procedures for mycobacteriology. | | | |
|---|---|---|---|---|
| MIC9.1.1 | **M** | Samples for mycobacteriology are centrifuged in a double closure system (in sealed screw-capped tubes within safety-capped cup or rotor enclosures that provide aerosol containment). | CAP MIC.33100 | |
| MIC9.1.2 | | Class II A2 biological safety cabinets are used for handling mycobacteriology samples and cultures.<br>*Guidance: In Class II type A2 cabinets, all biologically contaminated ducts are under negative pressure or are surrounded by negative pressure ducts.* | WHO MLM 4.1<br>GOBC WCB-LH | |
| MIC9.1.3 | **M** | There are defined criteria indicating samples that require concentration prior to preparation of acid-fast bacilli (AFB) smear examination and culture. | CAP MIC.32200<br>CLSI M48-A 6<br>CLSI M48-A 7.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC9.1.4 | **M** | Samples that typically have normal flora are decontaminated prior to concentration. | CLSI M48-A 7.1 | |
| **MIC9.2** | **There are procedures for rapid detection of *Mycobacterium*.** | | | |
| MI9.2.1 | **M** | Acid-fast smears or PCR examination used for rapid detection are processed as soon as possible. *Guidance: Laboratories performing rapid detection of mycobacteria may need to offer this on a STAT basis.* | CLSI M48-A 7.1 | |
| MI9.2.2 | **M** | Positive acid-fast results are reported within 24 hours of sample receipt. | CAP MIC.31200<br>CLSI M48A 7.1.7 | |
| MI9.2.3 | | If the laboratory employs a fluorochrome acid-fast staining method, positive fluorochrome acid-fast smears are confirmed by a second slide reader or an alternate method. | CAP MIC.32100 | |
| **MIC9.3** | **There are procedures for *Mycobacterium* culture and susceptibility testing** | | | |
| MIC9.3.1 | **M** | A culture is performed on all requests for *Mycobacteria tuberculosis* regardless of the smear or molecular examination result. | MCM CH28, 29, 30<br>CLSI M48-A 7.3 | |
| MIC9.3.2 | **M** | Procedures include inoculation onto media that supports the optimal growth of the majority of clinically relevant *Mycobacterium* species. | MCM CH28, 29,<br>30CLSI M48-A 7.3 | |
| MIC9.3.3 | | Procedures specify the use of two types of media, including liquid media or a comparable culture method. | CAP MIC.32250<br>CLSI M48-A 7.3 | |
| MIC9.3.4 | **M** | Optimal temperature and incubation periods are maintained based on the media used and the mycobacterial species suspected to be present. | CAP MIC.32320<br>CLSI M48-A 7.3 | |
| MIC9.3.5 | **M** | Solid media is examined after one week of incubation and weekly thereafter until the end of the defined incubation period. | MCM CH28, 29,<br>30CLSI M48-A 7.3 | |
| MIC9.3.6 | **M** | Commercial liquid media systems are examined according to the manufacturer's recommendations. | MCM CH28, 29, 30<br>CLSI M48-A 7.3 | |
| MIC9.3.7 | **M** | Suspected *Mycobacterium* growth and suspected contamination are confirmed by an acid-fast stain. | MCM CH28, 29, 30<br>CLSI M48-A 7.3 | |
| MIC9.3.8 | **M** | There are differential examinations to accurately and rapidly identify and differentiate the different species of mycobacteria. | MCM CH28, 29, 30<br>CAP MIC.32420<br>CLSI M48-A7.3 | |
| MIC9.3.9 | **M** | Samples with contamination are reprocessed, re-cultured and re-incubated. | MCM CH28, 29, 30<br>CLSI M48-A 7.3 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC9.3.10 | **M** | Instrument negative tubes are visually checked prior to discard. | MCM CH28, 29, 30<br>CLSI M48-A 7.3 | |
| MIC9.3.11 | | A control strain that is susceptible to all anti-mycobacterial agents is tested with each new batch or lot number of media and antimicrobial agents. | CAP MIC.31680 | |
| MIC9.3.12 | **M** | Storage conditions and retention times for positive cultures are defined. | MCM CH28, 29, 30<br>CLSI M48-A 7.3 | |
| **MIC9.4** | **There are procedures for nucleic acid sequencing of *Mycobacterium*.** | | | |
| MIC9.4.1 | **M** | The nucleic acid sequencing method has been verified using known strains of *Mycobacterium* expected to be encountered. | CLSI MM18-A<br>5.4,5.5,5.6<br>CLSI MM19-A 11.4.7.6 | |
| MIC9.4.2 | **M** | The purity of cultures used for nucleic acid sequencing is verified. | CLSI MM18-A<br>5.4,5.5,5.6<br>CLSI MM19-A 11.4.7.6 | |
| MIC9.4.3 | **M** | The database used for nucleic acid sequences has been verified. | CLSI MM18-A<br>5.4,5.5,5.6<br>CLSI MM19-A 11.4.7.6 | |
| MIC9.4.4 | **M** | Nucleic acid sequencing results are reviewed in conjunction with other laboratory data prior to reporting results. | CLSI M48A 7.3.9 | |
| **MIC9.5** | **There are procedures for reporting *Mycobacterium*.** | | | |
| MIC9.5.1 | **M** | All positive acid fast bacilli smears are reported to users as a critical value. | DAP PLAC | |
| MIC9.5.2 | **M** | Mycobacteria growth confirmed by acid-fast smear is reported immediately in an interim report that indicates final identification is pending. | CLSI M48A 7.3.9 | |
| MIC9.5.3 | **M** | M. tuberculosis complex (MTBC) or non-tuberculosis mycobacteria (NTM) are reported when confirmed. | CLSI M48A 7.3.9 | |
| MIC9.5.4 | **M** | Speciation and susceptibility testing of mycobacteria is reported when complete. | CLSI M48A 7.3.9 | |

## MIC10.0 MYCOLOGY

| | | | | |
|---|---|---|---|---|
| **MIC10.1** | **There are procedures for the direct examination, culture and susceptibility testing of fungi.** | | | |
| MIC10.1.1 | **M** | All mycology samples and moulds are manipulated in a biological safety cabinet. | CAP MIC.43100<br>CAP MIC.43250 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC10.1.2 | **M** | Direct examinations are performed when indicated. A direct stain is available for tissue and sterile body fluids. | MCM CH114 | |
| MIC10.1.3 | **M** | Suitable selective media and incubation temperatures are defined for the growth and isolation of clinically significant fungi. | MCM CH112<br>CAP MIC.42050 | |
| MIC10.1.4 | **M** | Safety precautions prevent the accidental opening of a plate (e.g. taping lid). | MCM CH112<br>CAP MIC.43050 | |
| MIC10.1.5 | **M** | Mycology slide cultures are not performed with dimorphic fungi. | CAP MIC.43150 | |
| MIC10.1.6 | **M** | Mycelia are always submerged in a liquid medium such as lactophenol cotton blue when preparing and examining tease or transparent adhesive tape preparations. | CAP MIC.43200 | |
| MIC10.1.7 | **M** | Criteria for the identification of fungi are defined. | MCM CH112<br>CAP MIC.42250 | |
| MIC10.1.8 | **M** | Differential procedures (e.g. slide culture, differential agars) are performed where appropriate. | MCM CH112<br>CAP MIC.42250 | |
| MIC10.1.9 | **M** | Sufficient reference materials are available to assist in the identification of fungi. | CLSI M27-A3 | |
| MIC10.1.10 | **M** | Suspected dimorphic fungi are immediately referred for confirmatory examination. | MCM CH112<br>CAP MIC.42550 | |
| MIC10.1.11 | **M** | Laboratory antifungal susceptibility testing procedures are consistent with current guidelines. | CLSI M27-A3 | |
| MIC10.1.12 | **M** | There are criteria for the determination of the endpoint or zone size in antifungal susceptibility testing systems. | CLSI M27-A3 | |
| MIC10.1.13 | **M** | Positive and negative controls are used with mycology nucleic acid probes at a defined frequency. | MCM CH114<br>CAP MIC.41270 | |

## MIC11.0 PARASITOLOGY

| MIC11.1 | There are procedures for parasitology examination. | | | |
|---|---|---|---|---|
| MIC11.1.1 | **M** | Procedures for the examination of unpreserved stools for intestinal parasites include a macroscopic examination and a wet preparation for motility. | MCM CH132<br>CAP MIC.52100<br>CLSI M28-A2 – 7.1, 7.2 | |
| MIC11.1.2 | **M** | Procedures for the examination of preserved stools for intestinal parasites include microscopic examination of both a concentrated sample and a stained smear. | MCM CH132, 138<br>CAP MIC.52100 | |
| MIC11.1.3 | **M** | Commercial fecal enzyme immunoassay or immunofluorescent detection assays are performed and quality controlled according to the manufacturer's instructions. | CLSI M28-A2 7.1, 7.2,8 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC11.1.4 | **M** | Controls are performed every day that routine permanent smears of patient samples are stained. | DAP15 ver1.0 | |
| MIC11.1.5 | **M** | Stains other than routine permanent stains for the detection of parasites (e.g. acid fast, fluorescent) are checked with control organisms or material, each time the stain is used. | CAP MIC.51170 | |
| MIC11.1.6 | **M** | Ocular micrometers are used for accurate measurement and individually calibrated for the microscope used.<br>*Guidance: Ocular micrometers are calibrated initially and each time the eyepieces or objectives are changed.* | CAP MIC.51210<br>CAP MIC.51220<br>CLSI M28-A2 2.2 | |
| MIC11.1.7 | **M** | There are procedures for the identification of macroscopic parasites (e.g. pinworm, proglottids). | CLSI M28-A2 2.2 | |
| MIC11.1.8 | **M** | There are procedures for the identification of ectoparasites (e.g. scabies, lice, ticks). | CLSI M28-A2 2.2 | |

## MIC12.0 VIROLOGY

| | | | | |
|---|---|---|---|---|
| **MIC12.1** | **There are procedures for quality control of virus culture media, reagents and supplies.** | | | |
| MIC12.1.1 | | The laboratory ensures commercial cell culture tubes, flasks, shell vials and cluster trays meet the expected criteria for virus isolation. | CLSI M41-A 5<br>CAP MIC.61050 | |
| MIC12.1.2 | | Continuous cell lines are checked for contamination. | CLSI M41-A 5.1.5<br>CAP MIC.61150 | |
| MIC12.1.3 | **M** | Uninoculated cell culture monitoring is performed at a defined frequency to detect non-specific degeneration. | CAP MIC.61320<br>CLSI M41-A 5.4.4 | |
| MIC12.1.4 | **M** | Media and diluents are checked for sterility and pH. | CAP MIC.61330<br>CLSI M41-A 5.3.1.1 | |
| MIC12.1.5 | | Red cell suspensions for quantitative serological examination are standardized. | CAP MIC.61340 | |
| MIC12.1.6 | **M** | The laboratory maintains cell lines for all types of samples examined and for all viruses reported by the laboratory. | CAP MIC.61180<br>CLSI M41-A 7 | |
| MIC12.1.7 | **M** | Each new lot and shipment of reagents that detect multiple viruses is verified for each individual virus prior to use. | CAP MIC.61380 | |
| MIC12.1.8 | **M** | There are growth and maintenance records of cell types, passage number, source and media used. | CAP MIC.61300<br>CLSI M41-A –5.3.1 | |
| **MIC12.2** | **There are procedures for virus culture.** | | | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC12.2.1 | | Laboratory algorithms define the examination of choice based upon sample type, diagnosis and suspected viruses. | MCM CH78<br>CAP MIC.62500 | |
| MIC12.2.2 | **M** | The incubation time for tube monolayer cultures is sufficient to recover the virus. | MCM CH77<br>CAP MIC.61210 | |
| MIC12.2.3 | | Spin-amplified shell vials are incubated for 24 to 48 hours or other period defined by the medical director. | CAP MIC.61210 | |
| MIC12.2.4 | **M** | The frequency of examination for cytopathic effect (CPE) is defined. | MCM CH77<br>CLSI M41-A 7.4 | |
| MIC12.2.5 | | Procedures define further manipulation of cell cultures demonstrating unusual CPE. | MCM CH77<br>CLSI M41-A 7.4 | |
| MIC12.2.6 | **M** | Positive and negative controls for immunofluorescent and immunochromatic testing are performed when using pooled reagents and for virus specific reagents, where appropriate. | MCM CH77<br>CAP MIC.61370 | |
| MIC12.2.7 | **M** | There are procedures for the confirmation of positive hepatitis and positive HIV serology. | DAP PLAC | |
| MIC12.2.8 | **M** | Negative antigen detection examinations are confirmed by culture or molecular examination. | DAP PLAC | |
| **MIC12.3** | **There are procedures for reporting virus cultures.** | | | |
| MIC12.3.1 | | Viral screening reports indicate which viruses are included in screening. | CAP MIC.62400 | |

## MIC13.0 MOLECULAR MICROBIOLOGY

| | | | | |
|---|---|---|---|---|
| **MIC13.1** | **There are procedures to ensure the quality of molecular examination.** | | | |
| MIC13.1.1 | **M** | The adequacy of nucleic acid isolation or preparation is evaluated with each examination by the use of positive and negative controls run in parallel with patient samples.<br>*Guidance: Controls are processed through all steps of the examination.* | CLSI MM03-A2 15.1, 15.3<br>CAP MIC.64025 | |
| MIC13.1.2 | | The laboratory monitors and records the adequacy of DNA extraction, including failure rates. | CLSI MM03-A2 15.1, 15.3<br>CAP MIC.64025 | |
| MIC13.1.3 | | Acceptable inhibition rates are established or provided by the manufacturer. | MCM CH4<br>CAP MIC.63278 | |
| MIC13.1.4 | | There are processes to identify and investigate false positive results of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* examinations. | MCM CH4<br>CAP MIC.63252 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC13.1.5 | **M** | All targets detected by multiplex examinations are individually verified for each new shipment and lot number. | CLSI MM19-A 8.7<br>CAP MIC.63580 | |
| MIC13.1.6 | | Verification of rare organism or subtype examination is performed at least annually. | CLSI MM19-A 8.7<br>CAP MIC.63580 | |
| **MIC13.2** | **There are procedures to prevent sample degradation and cross-contamination of molecular examinations.** | | | |
| MIC13.2.1 | **M** | There are procedures to prevent sample degradation during collection, transport, and storage. | MCM CH4<br>CLSI MM19-A 7 | |
| MIC13.2.2 | **M** | Dedicated equipment and supplies and a separate assay setup area are maintained in the clean area used for handling samples and extracting DNA. | MCM CH4<br>CLSI MM19-A 8.1.1 | |
| MIC13.2.3 | **M** | No aliquot is ever returned to the original container. | MCM CH4<br>CLSI MM19-A 7 | |
| MIC13.2.4 | **M** | Airflow is controlled within and across work areas and traffic is limited in areas to prevent disruptive airflow (e.g. when a biological safety cabinet is in use). | MCM CH4<br>CLSI MM19-A 8.1.1 | |
| MIC13.2.5 | **M** | Gowns and gloves are frequently changed during processing and when moving between areas. | MCM CH4<br>CLSI MM19-A 8.1.1 | |
| MIC13.2.6 | | There are sticky mats at the entry and exit to each area. | MCM CH4<br>CLSI MM19-A 8.1.1 | |
| MIC13.2.7 | **M** | Dedicated pipettes (positive displacement type or with aerosol barrier tips) are used. | MCM CH4<br>CLSI MM19-A– 8.1.1 | |
| MIC13.2.8 | **M** | Careful manipulation and other mechanisms to prevent aerosols are used (e.g. uncapping tubes, the use of absorbent wipes). | MCM CH4<br>CLSI MM19-A 8.1.1 | |
| MIC13.2.9 | **M** | There are procedures to detect, investigate and resolve contamination. | CAP MIC.64850<br>CAP MIC.64855 | |
| MIC13.2.10 | **M** | Wipe tests of exposed surfaces and equipment is performed at defined intervals. | MCM CH4<br>CLSI MM19-A 8.1.1 | |
| MIC13.2.11 | **M** | Negative controls are dispensed according to the manufacturer's recommendations to reflect the cumulative effects of manipulations. | CAP MIC.64926 | |
| MIC13.2.12 | | Procedures for amplification-based exams on residual samples ensure the absence of cross-contamination and results are interpreted with caution. | MCM CH4<br>CLSI MM19-A 8.1.2 | |
| MIC13.2.13 | **M** | Handling of post-amplification products and used materials is consolidated to a defined area. | MCM CH4<br>CLSI MM19-A 8.1.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC13.2.14 | **M** | Samples and extracted nucleic acids are stored under conditions that encourage stability.<br>*Guidance: Frost-free freezers are not used for storage. DNA is stored at -20°C. RNA is stored at -80°C.* | MCM CH4<br>CLSI MM19-A 7 | |
| **MIC13.3** | **There are procedures for equipment, reagents and supplies used for molecular examinations.** | | | |
| MIC13.3.1 | **M** | Individual wells (or a representative sample) of thermocyclers are checked for temperature accuracy prior to use and at least annually thereafter.<br>*Guidance: This does not apply to real time PCR instruments.* | CLSI MM19-A 8.2<br>CAP MIC.64614 | |
| MIC13.3.2 | **M** | Slides other than those recommended by the manufacturer for microbial fluorescent in situ hybridization (FISH) examinations are validated prior to use. | CAP MIC.64730 | |
| MIC13.3.3 | | Criteria are established for the acceptability of PCR assays and reagents, including the target region, the length of the PCR product, probe sequence selection, hybridization stringency and probe and primer forms and purity. | MCM CH4<br>CLSI MM09 8 | |
| **MIC13.4** | **There are procedures for molecular examination.** | | | |
| MIC13.4.1 | | Temperatures for each step of the examination are monitored. | CAP MIC.64350 | |
| MIC13.4.2 | **M** | Criteria for the acceptability and interpretation of primary sequence data are established. | MCM CH4<br>CLSI MM09 8 | |
| MIC13.4.3 | | Negative molecular examinations for group B streptococci are followed by selective broth culture. | MCM CH16<br>CLSI MM19-A 11.4.7.2 | |
| MIC13.4.4 | **M** | Interpretation of sequence data is based on current databases. | MCM CH4<br>CAP MIC.64840 | |
| MIC13.4.5 | **M** | Narrow temperature ranges are defined and monitored for examinations that generate a result based on a melting temperature. | CLSI MM19-A 8.7<br>CAP MIC.64934 | |
| MIC13.4.6 | **M** | Calibrator results are within defined ranges for each run of quantitative real time PCR examinations (e.g. viral load monitoring). | CLSI MM19-A 8.7 | |
| MIC13.4.7 | **M** | The required resolution of images (e.g. auto radiographs, gel images) is defined. | CLSI MM19-A 8.7<br>CAP MIC.64938 | |
| MIC13.4.8 | **M** | Known molecular weight markers that span the range of expected bands are used for each electrophoretic run. | CLSI MM19-A 8.7 | |
| MIC13.4.9 | **M** | Visual or fluorescent markers are used to determine the endpoint of gel electrophoresis. | CLSI MM19-A 8.7<br>CAP MIC.64944 | |
| **MIC13.5** | **There are procedures for the validation of laboratory-developed or laboratory-modified molecular examinations.** | | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MIC13.5.1 | **M** | Laboratory developed examinations are validated. This is documented. | CLSI MM19-A 8.7<br>CAP MIC.64952, 64960, 64964, 64968, 64980 | |
| MIC13.5.2 | **M** | Alternative sequence interpretative databases, used either alone or in conjunction with the manufacturer's software are validated. | MCM CH4<br>CAP MIC.64845 | |
| MIC13.5.3 | | There is a record of all probes and primers used in examinations. | CLSI MM19-A 8.7<br>CAP MIC.64910 | |
| MIC13.5.4 | **M** | There are criteria for the acceptability and interpretation of primary sequencing data to ensure unequivocal sequence readout. | CLSI MM19-A 8.7<br>CAP MIC.64920 | |
| MIC13.5.5 | | Sequence data is correlated with phenotypic data, when available. | CLSI MM19-A 8.7<br>CAP MIC.64924 | |
| MIC13.5.6 | | There is a documented process to ensure primers and probes are compatible with current circulating microbial strains (e.g. dialogue with colleagues, other reference laboratories). | CLSI MM19-A 8.7 | |
| **MIC13.6** | **There are procedures for reporting molecular examination results.** | | | |
| MIC13.6.1 | **M** | The final report includes a summary of the examination method and information regarding clinical interpretation if appropriate. | CLSI – MM19-A 8.8<br>CAP MIC.63330 | |
| MIC13.6.2 | **M** | Reports for laboratory-developed examinations contain a method description and a statement that the examination was developed by the laboratory with examination performance characteristics available upon request. | CAP MIC.64984<br>CLSI – MM19-A 8.8 | |

## MIC14.0 IMMUNOLOGY AND SEROLOGY

| | | | | |
|---|---|---|---|---|
| **MIC14.1** | **There are procedures for serological examinations for *Treponema pallidum*.** | | | |
| MIC14.1.1 | | The volume of antigen delivery needles (e.g. used for rapid plasma reagin (RPR) and syphilis-related cardiolipin-based examinations) is checked each time a new needle is used, when the antigen drop does not fall cleanly from the tip and when control patterns cannot be reproduced. | CAP IMM.41100 | |
| MIC14.1.2 | | A negative control plus positive serum controls of a known titre are run on each day of patient examination. | CAP IMM.41300 | |
| MIC14.1.3 | | New reagent lots are checked to verify suitable reactivity. | CA IMM.41400 | |
| **MIC14.2** | **There are procedures for Western blot examinations.** | | | |

| No. | Standard<br>Criterion | Reference | Change |
|---|---|---|---|
| MIC14.2.1 | Known molecular weight markers are included and reviewed with each Western blot examination. | CAP IMM.41500 | |
| MIC14.2.2 | Western blot separations are satisfactory (e.g. low background, clear signal, absence of bubbles) to interpret band size easily. | CAP IMM.41600 | |
| MIC14.2.3 | QC materials used for Western blot examinations have defined acceptance criteria. | CAP IMM.41700 | |
| MIC14.2.4 | There are defined criteria for interpretation of Western blot examinations. | CAP IMM.41800 | |

# Accreditation Standards 2015

Laboratory Medicine

## MOLECULAR DIAGNOSTICS STANDARDS

The molecular diagnostics standards are used in conjunction with the general standards for each laboratory.

# MOLECULAR DIAGNOSTICS

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **MOL1.0** | | **PRE-EXAMINATION** | | |
| **MOL1.1** | | **There are procedures for the selection, evaluation, verification and validation of molecular diagnostics examinations.** | | |
| MOL1.1.1 | **M** | The laboratory selects examination procedures which have been validated for their intended use. | | NEW |
| MOL1.1.2 | **M** | The performance characteristics of commercially available kits or instruments are verified. Laboratory developed or modified procedures are validated. This is documented. | ISO 15189 5.5.1.2<br>CLSI MM01-A3 10<br>CAP MOL.32425<br>CCMG B.1, B.2 | NEW |
| MOL1.1.3 | **M** | Verification and validation of examination performance uses an adequate number, type and source of samples to ensure that the examination results can be interpreted for specific patient conditions, and that the limitations of examinations and results are known. | CLSI MM20-A 7.1.4 | NEW |
| MOL1.1.4 | **M** | Verification and validation procedures determine analytical performance specifications including:<br>• accuracy<br>• precision/reproducibility<br>• sensitivity/limit of detection<br>• specificity<br>• reportable range<br>• reference range | CLSI MM20-A 7.1.5 | NEW |
| MOL1.1.5 | **M** | • the intended use of the exam (e.g. carrier, prenatal, diagnostic, predictive) | CLSI MM20-A 5.2 | NEW |
| MOL1.1.6 | **M** | • target genes, sequences and variants | CLSI MM20-A 5.2 | NEW |
| MOL1.1.7 | **M** | • the expected patient population | CLSI MM20-A 5.2 | NEW |
| MOL1.1.8 | **M** | • sample types (e.g. bone marrow, peripheral blood, paraffin embedded tissue) | CLSI MM20-A 5.2 | NEW |
| MOL1.1.9 | **M** | • reference materials | CLSI MM20-A 5.2 | NEW |
| MOL1.1.10 | **M** | • examination limitations (e.g allele drop out, interfering variants) | CLSI MM20-A 5.2 | NEW |
| MOL1.1.11 | **M** | Steps in processing that deviate from procedures are documented and reviewed by the medical director. Any resulting corrective action is documented. | CAP MOL.34946 | NEW |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MOL1.1.12 | **M** | There are procedures for ongoing verification or validation of examination performance. | CLSI MM20-A 7.1.8 | NEW |
| MOL1.1.13 | **M** | There is a procedure for the verification of each reagent lot. | CAP MOL.35766 | NEW |
| MOL1.1.14 | **M** | All probe and primer sequences are checked and monitored against relevant databases. Actions are taken to reduce the possibility of null alleles or allele dropout. | ACMG G7.2 | NEW |
| **MOL1.2** | **The laboratory provides information and assistance on molecular diagnostics examinations to users.** | | | |
| MOL1.2.1 | **M** | Facilities performing genetic examinations provide information with primary references documenting the scientific data on which an examination is based. | ACMG statement | NEW |
| MOL1.2.2 | **M** | The laboratory has established arrangements for communicating with users on advising on the choice of examinations and use of laboratory services (e.g. the required sample type, clinical indications, limitations of examination procedures, the frequency of requesting the examination). | ISO 15189 4.7a<br>QMS4.1.2 | NEW |
| MOL1.2.3 | **M** | The laboratory has established arrangements for communicating with users on case specific inquiries, professional judgment on the interpretation of the results of examinations, promotion of the effective utilization of laboratory services and consulting on scientific and logistic matters (e.g. instances of failure of samples to meet acceptance criteria). | ISO 15189 4.7b-e<br>QMS4.1.3 | NEW |
| MOL1.2.4 | **M** | The laboratory has defined any examinations where pre-examination genetic counseling is indicated. | CLSI MM20-A 5.3.1 | NEW |
| MOL1.2.5 | **M** | There is information and mechanisms to assist users in ordering appropriate genetic examinations and examination strategy. | ACMG statement<br>CLSI MM20-A 7.2 | NEW |
| MOL1.2.6 | **M** | The clinical validity and clinical utility of each examination has been determined, (independently, or through published evidence).<br>*Guidance: The clinical validity refers to the examinations ability to identify the clinical condition of interest (usually a disease state) as well as to identify unaffected individuals. The clinical utility identifies the outcomes associated with specific examination results.* | CLSI MM20-A 7.1.2 | NEW |
| **MOL1.3** | **Request forms for non-invasive prenatal examinations include space for required information.** | | | |
| | | The request form or electronic equivalent has space for the inclusion of appropriate information including: | CAP MOL.32350<br>ACMG G1.1 | NEW |
| MOL1.3.1 | **M** | • estimated date of delivery (based on ultrasound measurements) | CAP MOL.34915 | NEW |
| MOL1.3.2 | **M** | • parentage information for examinations that use paternal genotypes for interpretation or whose interpretation may be influenced by IVF techniques | CAP MOL.34918 | NEW |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MOL1.3.3 | **M** | • clinical evidence of multiple gestations | CAP MOL.34919 | NEW |
| MOL1.3.4 | **M** | • maternal weight | CAP MOL.34917 | NEW |
| MOL1.3.5 | **M** | • patient or family history of chromosomal abnormality (e.g. translocation carrier, offspring with Down syndrome) | CAP MOL.34920 | NEW |
| MOL1.3.6 | **M** | • the inclusion of prior pregnancy risk for aneuploidies for examinations that report odds, risks, or probabilities of being euploid or trisomic | CAP MOL.34922 | NEW |
| MOL1.3.7 | | • prior pregnancies | | NEW |
| MOL1.3.8 | | • patient race and/or ethnicity | | NEW |
| MOL1.3.9 | | • relevant family history | | NEW |
| **MOL1.4** | **There are procedures to prevent cross contamination.** | | | |
| MOL1.4.1 | **M** | There are procedures to prevent and monitor contamination. | CAP MOL34385,35766<br>CLSI MM01-A3 8.2.1, MM03-A2 13<br>CMG G7.1 | NEW |
| MOL1.4.2 | **M** | Dedicated equipment and supplies (including pipettes and reagents) are used for all pre-PCR activities. | | NEW |
| MOL1.4.3 | **M** | Reagent preparation, nucleic acid extraction and PCR set-up are conducted in separate areas and physically removed from post-PCR manipulations. | CLSI MM03-A2 11.1.1 | NEW |
| MOL1.4.4 | **M** | Positive displacement pipettes and/or aerosol barrier tips are used to prevent contamination for all pre-PCR activities. | ACMG G7:1.2.2<br>CLSI MM01-A3 8.2.1<br>CLSI MM03-A2 11.1.2 | NEW |
| **MOL1.5** | **There are procedures for molecular diagnostics examinations.** | | | |
| MOL1.5.1 | **M** | There are procedures for the examination of samples with known or suspected maternal cell contamination.<br>*Guidance: This includes the rejection of samples when there is a risk of false positive or false negative examinations.* | | NEW |
| MOL1.5.2 | **M** | There are procedures for longitudinal monitoring of assay characteristics. | CAP MOL.34925 | NEW |
| MOL1.5.3 | **M** | The quantity of nucleic acid is measured, when appropriate. | CLSI MM01-A3 8.1.5<br>CAP MOL.32430<br>CCMG B.1, B.2 | NEW |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MOL1.5.4 | **M** | The integrity and purity of nucleic acid is assessed, when appropriate. | CLSI MM01-A3 8.1.5<br>CAP MOL.32435<br>CCMG B.1, B.2 | NEW |
| MOL1.5.5 | **M** | Ribonuclease-free conditions are maintained for all assays that detect RNA or use an RNA probe. | CAP MOL.32440<br>CCMG B.2 | NEW |
| MOL1.5.6 | **M** | Information is documented for all probes and primers used in examinations to permit interpretation and troubleshooting of results.<br>*Guidance: This may include:*<br>• *the type and origin of the probe or sequence*<br>• *a restriction enzyme map of the DNA*<br>• *the oligonucleotide sequence and complementary sequence or gene region recognized*<br>• *recombination frequencies and map positions for linkage analysis*<br>• *chromosomal location of the target*<br>• *known benign variants*<br>• *sites resistant to endonuclease digestion*<br>• *the labeling methods used and standards for adequacy of hybridization or amplification*<br>• *allele frequencies of the variants in various ethnic groups, and recombination frequencies* | CLSI MM01-A3 10.3, 10.4<br>CAP MOL.34188<br>CCMG B.5e, B.7 | NEW |
| MOL1.5.7 | **M** | A positive control near limiting dilution is included in each run for quantitative examinations. These controls are rotated to include all measurands. | CAP MOL.35766 | NEW |
| MOL1.5.8 | **M** | There are procedures to verify nucleic acid integrity and labeling.<br>*Guidance: This may include control features that address an endogenous positive target, controls that visualize material on electrophoretic gels and capillaries, or by detection of label.* | CLSI MM12-A –6.1<br>CAP MOL.35722<br>CCMG 5, 9, 12 | NEW |
| MOL1.5.9 | **M** | In examinations for acquired conditions, a histological assessment of neoplastic cell content is documented when DNA or RNA is extracted from paraffin-embedded tumor samples. | CLSI MM13-A 7.2.6<br>CAP MOL.32395 | NEW |
| MOL1.5.10 | **M** | The lower limit of detection of a molecular examination performed on mixed populations of cells is validated and documented. The limit of detection is included in the report when applicable. | CAP MOL.34610 | NEW |
| MOL1.5.11 | **M** | There are defined criteria for the percentage of tumor cells and the lower limit of detection in the interpretation of negative examination results. | CAP MOL.34630 | NEW |
| MOL1.5.12 | **M** | Examinations are optimized to minimize background noise and achieve high signal to noise ratios near the stated limit of detection of the assay. | CAP MOL.34910 | NEW |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **MOL2.0** | **RESTRICTION ENDONUCLEASE DIGESTION, NUCLEIC ACID SEQUENCING** | | | |
| **MOL2.1** | **There are procedures for restriction endonuclease (RE) examinations.** | | | |
| MOL2.1.1 | **M** | The completeness and accuracy of RE digestion are confirmed, when appropriate.<br>*Guidance: DNA treatment with RE is performed for an appropriate amount of time under defined reaction conditions.* | CLSI MM01-A3 13.4.3<br>CAP MOL.34580<br>ACMG G6.1.2 | NEW |
| MOL2.1.2 | **M** | The efficacy of RE digestion is established for each new lot of enzyme and in each run. | CLSI MM01-A3 13.4.3<br>CAP MOL.34580<br>ACMG G6.1.2 | NEW |
| **MOL2.2** | **There are procedures for Sanger sequencing and pyrosequencing** | | | |
| MOL2.2.1 | **M** | There are defined criteria for the acceptance and interpretation of primary sequencing data that include correct assignments for variant positions, definition of the sequencing region, criteria for peak intensity, baseline fluctuation and signal-to-noise ratio and peak shapes. | CAP MOL.34911<br>ACMG G10.2.1, G10.2.2, G10.6.1 | NEW |
| MOL2.2.2 | **M** | The lower limit of detection in mixed populations of cells is validated and documented. The limit of detection is included in the report when appropriate and applicable. | CAP MOL.34610 | NEW |
| MOL2.2.3 | **M** | Sequence analysis software is used for Sanger sequencing to compare data of the patient sample with that of the reference sequence.<br>*Guidance: Sole reliance on unassisted visual inspection of the sequence data is not acceptable due to the possibility of operator error, particularly for homozygous variations).* | ACMG G10.6.1, G10.6.3 | NEW |
| MOL2.2.4 | **M** | For Sanger sequencing, the laboratory confirms all novel sequence variants using a second, independent PCR and sequencing reaction. | ACMG G10.7.2<br>CMGS 2.3 | NEW |
| **MOL2.3** | **There are procedures for next generation sequencing.** | | | |
| MOL2.3.1 | **M** | There are procedures to minimize the risk of contamination and sample mix-up throughout all steps of next generation sequencing. | DAP MDAC 2016 | NEW |
| MOL2.3.2 | **M** | The lower limit of detection in mixed populations of cells is validated and documented. The limit of detection is included in the report when appropriate and applicable. | CAP MOL.34610 | NEW |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MOL2.3.3 | **M** | There are defined criteria for the acceptance and interpretation of next generation sequencing data that include relevant data quality indicators (e.g. base calling quality (Q) scores, cluster density, percentage polyclonal beads) and appropriate ranges for these | DAP MDAC 2016 | NEW |
| MOL2.3.4 | **M** | There are defined criteria for confirmatory examination of reported variants. | CAP MOL.34940 | NEW |

## MOL3.0 BIOINFORMATICS ANALYSIS

| | | | | |
|---|---|---|---|---|
| **MOL3.1** | **There are procedures for bioinformatics analysis.**<br>*Guidance: Validation is performed by personnel qualified in computational biology/informatics.* | | | |
| MOL3.1.1 | **M** | There are defined criteria for monitoring, documenting, and implementing upgrades, and other updates to informatics. Changes are verified. | CAP MOL.34964 | NEW |
| MOL3.1.2 | **M** | The specific version(s) of informatics used to generate data files are traceable for each examination report. | CAP MOL.34968 | NEW |
| MOL3.1.3 | **M** | When steps used in informatics analysis deviate from procedures, the deviation is documented and reviewed by the medical director. Any resulting corrective action is documented. | CAP MOL.34970 | NEW |
| MOL3.1.4 | **M** | Informatics data and analysis are validated prior to implementation. This is documented. | CLSI MM01-A3 13.2.4.4.5<br>CAP MOL.34960 | NEW |
| MOL3.1.5 | **M** | After modification, informatics data and analysis are revalidated, or the performance of the components is verified. This is documented. | CLSI MM01-A3 13.2.4.4.5<br>CAP MOL.34960 | NEW |
| MOL3.1.6 | **M** | Software functional testing is performed and documented. | CAP MOL.35766 | NEW |
| **MOL3.2** | **There are procedures for the interpretation and reporting of sequencing data.** | | | |
| MOL3.2.1 | **M** | There is a documented algorithm for the interpretation of the clinical significance of identified variants and guidelines for subsequent reporting. | CLSI MM01-A3 5.11<br>CAP MOL.34980 | NEW |
| MOL3.2.2 | **M** | There is a documented process for instances when incidental, unrelated genetic findings are reported. | CAP MOL.34985 | NEW |

## MOL4.0 ELECTROPHORESIS AND POLYMERASE CHAIN REACTION (PCR)

| | |
|---|---|
| **MOL4.1** | **There are procedures for molecular diagnostics using electrophoresis.** |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MOL4.1.1 | **M** | Known molecular weight markers that span the range of expected bands are used for each electrophoretic run. | CLSI MM01-A3 13.2.1<br>CAP MOL.35100<br>ACMG G6.1.4 | NEW |
| MOL4.1.2 | **M** | Visual or fluorescent markers are used to determine the endpoint of electrophoresis. | CAP MOL.35050 | NEW |
| MOL4.1.3 | **M** | There are defined criteria for interpreting autoradiographs or electrophoretic data. | CAP MOL.35150 | NEW |
| MOL4.1.4 | **M** | Autoradiographs and images have sufficient resolution and quality for interpretation. | CAP MOL.35175 | NEW |
| **MOL4.2** | **There are procedures for molecular diagnostics using nucleic acid amplification.** | | | |
| MOL4.2.1 | **M** | Controls are used to minimize the occurrence of false positive and false negative results for PCR techniques.<br>*Guidance: This includes internal controls to detect false negative reactions secondary to extraction failure or the presence of an inhibitor, when appropriate.* | CLSI MM01-A3 8<br>CAP MOL.35360 | NEW |
| MOL4.2.2 | **M** | Examination components are verified and monitored (e.g. fragmentation of DNA by sonification-enzyme digestion). | CAP CYG.49500<br>CAP CYG. 49550<br>CYG6.1.2 | NEW |

## MOL5.0 MICROARRAYS AND IN SITU HYBRIDIZATION

| | | | | |
|---|---|---|---|---|
| **MOL5.1** | **There are procedures for molecular diagnostics using microarrays.** | | | |
| MOL5.1.1 | **M** | Microarray post-examination components are verified and monitored (e.g. visual inspection of hybridized array images, evaluation of QC data calculated from examination software, gains and losses called by the microarray software algorithm). | CAP CYG. 49525<br>CAP CYG. 49575<br>CYG6.1.3 | NEW |
| **MOL5.2** | **There are procedures for fluorescence and non-fluorescence in situ hybridization (ISH).** | | | |
| MOL5.2.1 | **M** | There are procedures for scoring fluorescence in situ hybridization (FISH) results, including the number of cells scored. | CLSI MM07-A2 9.2, 9.3, 9.4, 9.5<br>CAP MOL.39004 | NEW |
| MOL5.2.2 | **M** | Control loci (internal or external) are used with and documented for each FISH examination. | CAP MOL.39146<br>ACMG G6.3 | NEW |
| MOL5.2.3 | **M** | Gene amplification procedures by in situ hybridization (e.g. HER2) include appropriate sample fixation time. | CAP MOL.39358 | NEW |
| MOL5.2.4 | **M** | There are defined criteria for interpretation of gene amplification by in situ hybridization (e.g. HER2) using defined scoring criteria or the manufacturer's instructions. | CAP MOL.39393 | NEW |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MOL5.2.5 | **M** | The interpretation and correlation of results is performed by a pathologist or delegate for in situ hybridization examinations. | CLSI MM01-A3 9.2.1<br>CLSI MM07-A2 10.1-2<br>CLSI MM19-A 8.8, 10.3 | NEW |
| MOL5.2.6 | **M** | Conditions for examination and tissue pretreatment are verified and documented for each sample using an appropriate positive control probe(s) against endogenous targets. | CAP MOL.39430 | NEW |

## MOL6.0 INTERPRETATION AND REPORTING

| MOL6.1 | There are procedures for the reporting of molecular examination results. | | | |
|---|---|---|---|---|
| MOL6.1.1 | **M** | Variant curation in internal and external databases is versioned and current. | CAP MOL. 49575 | NEW |
| MOL6.1.2 | **M** | Reports include a summary of methods, appropriate loci or variants the sample was examined for, examination information, clinical interpretation and appropriate references. | CAP MOL.39398<br>CAP MOL. 49570 | NEW |
| MOL6.1.3 | **M** | All reports containing interpretations indicate authorship and assurance that the contents of the report have been verified by the author. | CAP MOL. 49585 | NEW |
| MOL6.1.4 | **M** | Reports include a risk estimate of false negatives and false positives arising from recombination between the linked locus and the disease locus when linkage examination is performed. | CAP MOL. 49595 | NEW |
| MOL6.1.5 | **M** | Reports include correlation (where appropriate) with the morphological findings when assays are performed on histology and cytology samples. | CAP MOL. 49625 | NEW |
| MOL6.1.6 | **M** | Reports include (where appropriate) an estimate of the clinical sensitivity and residual risk of being a carrier for a variant not included in genetic examination for heritable disease genes with multiple possible variants, if known. | CLSI MM01-A3 9.2.1<br>CLSI MM19-A 8.8, 10.3<br>CCMG A.7, B.7 | NEW |
| MOL6.1.7 | **M** | Reports include limitations of the results and clinical implications of the detected variant (or negative result) for disorders with regard to recessive or dominant inheritance, recurrence risk, penetrance, severity and other aspects of genotype-phenotype correlation. | CAP MOL. 49615 | NEW |
| MOL6.1.8 | **M** | Reports include a recommendation for genetic counseling, when applicable. | CAP MOL. 49620 | NEW |
| MOL6.1.9 | **M** | Standard Human Genome Variation Society nomenclature is used to designate reported genes and variants. The reference transcript is included when appropriate and applicable. | CLSI MM01-A3 5<br>CAP MOL. 49630<br>CCMG A.8 | NEW |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| MOL6.1.10 | | The limitations and sensitivity of the molecular examination are available. Examinations with low utility in assessing health are labeled as such. | CCMG statement<br>CCMG Mol Gen Guidelines | NEW |
| MOL6.1.11 | | Genetic examinations that are not medically significant are accurately labeled as such. | CCMG statement | NEW |
| **MOL6.2** | **There are procedures for the interpretation and reporting of examinations for non-invasive prenatal examinations.** | | | |
| MOL6.2.1 | **M** | The percentage of patients with positive results for each targeted disorder, examination failure rates and inconclusive examination results are calculated and reviewed at a defined frequency. | CAP MOL.34926 | NEW |
| MOL6.2.2 | **M** | The report includes qualitative and quantitative examination results for each target (chromosome, genetic variant or other), reference ranges or cutoff values as appropriate, and a summary set of risks or categorical interpretations. | CAP MOL.34927 | NEW |
| | | The report includes the following as appropriate: | | |
| MOL6.2.3 | **M** | • a recommendation for follow-up diagnostic examination for all patients with a positive examination result | CAP MOL.34930 | NEW |
| MOL6.2.4 | **M** | • recommendations regarding next steps for patients with uninformative results and examination failures | CAP MOL.34930 | NEW |
| MOL6.2.5 | **M** | • a statement that the examination is not intended to identify prenatal cases at risk for open neural tube defects | CAP MOL.34930 | NEW |

# Accreditation Standards 2015

Laboratory Medicine

## POINT-OF-CARE TESTING STANDARDS

The point-of-care testing standards are used in conjunction with the general standards for each laboratory.

# POINT-OF-CARE TESTING (POCT)

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|
| **POC1.0** | | **POCT – ORGANIZATION** | | |
| **POC1.1** | | **The authority, responsibility and accountability for point-of-care testing (POCT) within the facility is defined.** | | |
| POC1.1.1 | **M** | The governing body of the facility is ultimately responsible for ensuring that appropriate measures are established to monitor the quality of POCT within the facility regardless of where the examinations are performed. | ISO 22870 4.1.1 | |
| POC1.1.2 | **M** | The laboratory is responsible for the planning and development of quality objectives and requirements for POCT. | ISO 22870 4.1.1a | |
| POC1.1.3 | **M** | The laboratory is responsible for the planning and development needed to establish processes and documents, and to provide resources specific to POCT. | ISO 22870 4.1.1b | |
| POC1.1.4 | **M** | The laboratory is responsible for the planning and development of required validation, verification and monitoring of activities specific to POCT. | ISO 22870 4.1.1c | |
| POC1.1.5 | **M** | The laboratory is responsible for the planning and development of records to provide evidence that POCT processes and procedures meet requirements. | ISO 22870 4.1.1d | |
| POC1.1.6 | **M** | A health professional group such as a medical advisory committee (in consultation with administration and the laboratory director or designate) is responsible to the governing body for defining the scope of POCT available.<br>*Guidance: This takes into consideration the clinical need, financial implications, technical feasibility and the ability of the organization to fulfill the POCT requirements.* | ISO 22870 4.1.2.1 | REVISED |
| POC1.1.7 | **M** | The accountability for ensuring that POCT equipment maintenance, QC and patient examination are appropriately performed and documented rests with the individual(s) who perform each of these functions. That individual is also accountable to their professional college, where applicable, for ensuring that they are competent. | CLSI POCT07-A 5.2 | |
| **POC1.2** | | **A multidisciplinary POCT management group has been established.** | | |
| POC1.2.1 | **M** | The laboratory director or designate is assigned responsibility for appointing a multidisciplinary POCT management group with representation from the laboratory, administration, and clinical programs including nursing, to advise on the provision of POCT. | ISO 22870 4.1.2.2<br>CLSI POCT07-A 5.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| POC1.2.2 | **M** | The multidisciplinary POCT management group defines authorities and responsibilities for POCT and communicates them within the organization. | ISO 22870 4.1.2.3 | |
| POC1.2.3 | **M** | The multidisciplinary POCT management group assists in evaluating and selecting POCT equipment. | ISO 22870 4.1.2.4<br>CLSI POCT09-A | |
| POC1.2.4 | **M** | The multidisciplinary POCT management group reviews all proposals to introduce any POCT equipment.<br>*Guidance: Proposals to introduce POCT consider:*<br>• *coordination with existing laboratory services*<br>• *analysis of the current service*<br>• *a cost-benefit analysis of the proposed POCT*<br>• *analysis of the service required*<br>• *alternative options* | ISO 22870 4.1.2.5 | |
| POC1.2.5 | **M** | The laboratory director and the multidisciplinary POCT advisory management group review the relative benefits of POCT, monitor test ordering patterns, carry out audits to verify records and review critical value reports, at a defined frequency. | ISO 15189 4.12<br>ISO 22870 4.12.2 | |
| POC1.2.6 | | The laboratory director and the multidisciplinary POCT advisory management group identify opportunities for improvement in POCT activities. | ISO 22870 4.15.2 | |
| POC1.2.7 | **M** | There are procedures for the resolution of complaints or other feedback regarding POCT. | ISO 15189 4.8<br>ISO 22870 4.8 | |
| **POC1.3** | **POCT training and competency assessment is provided at a frequency determined by the organization.** | | | |
| POC1.3.1 | **M** | An appropriate theoretical and practical training program has been developed for personnel performing POCT. | ISO 22870 5.1.5a<br>CLSI POCT04-A2 12 | |
| POC1.3.2 | | A training manager with theoretical knowledge and experience has been appointed to manage POCT training and competency assessment. | ISO 22870 5.1.5a | REVISED |
| POC1.3.3 | **M** | Training considers recommendations provided by the manufacturer. | ISO 22870 5.1.5c | |
| POC1.3.4 | **M** | Competency assessment is documented at a defined frequency. Retraining and continuing education is documented. | ISO 22870 5.1.5b,c,d | |
| POC1.3.5 | **M** | POCT is performed by personnel who have completed training and demonstrated competence. | ISO 22870 5.1.5b | |
| POC1.3.6 | | POCT operator performance is monitored for compliance with procedures. | ISO 15189 5.1.6a | |
| POC1.3.7 | **M** | There is a procedure for dealing with non-compliant POCT operators. | ISO 15189 5.1.6 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **POC2.0** | **POCT QUALITY MANAGEMENT SYSTEM (QMS)** | | | |
| **POC2.1** | **There is a quality management system and a quality manager for POCT.** | | | |
| POC2.1.1 | **M** | The overall laboratory QMS includes POCT, or a QMS has been implemented for POCT that meets the requirements of the DAP QMS accreditation standards.<br>*Guidance: See QMS1.0–QMS6.0.* | ISO 22870 4.2.2<br>CLSI POCT07-A 5 | |
| POC2.1.2 | **M** | The QMS includes quality policies, processes and procedures for POCT. | ISO 22870 4.2.2<br>CLSI POCT07-A 5 | |
| POC2.1.3 | **M** | A POCT quality manager (or otherwise titled) with specific training and experience has been appointed.<br>*Guidance: The laboratory quality manager may assume responsibility for POCT within the facility. See QMS1.3.* | ISO 22870 4.2.2.1g | REVISED |
| POC2.1.4 | **M** | The quality manager is responsible to the laboratory director for the quality of all POCT. | ISO 22870 4.2.2.1g | |
| POC2.1.5 | **M** | The quality manager is responsible for the design, implementation and operation of QC that ensures POCT conforms to the quality standards of the laboratory. | ISO 22870 5.6.2 | |
| POC2.1.6 | **M** | The relationship between values obtained in the laboratory and POCT are established and made available upon request. | ISO 22870 5.6.2 | |
| POC2.1.8 | **M** | The overall laboratory QMS includes POCT document control, or document controls as described in the DAP QMS accreditation standards have been established for POCT. | ISO 15189 4.3 | |
| POC2.1.9 | **M** | All POCT policies, processes and procedures are reviewed every one to three years. This is documented. | ISO 22870 4.3 | REVISED |
| **POC2.2** | **There are procedures for conducting internal audits and management review of POCT.** | | | |
| POC2.2.1 | **M** | Internal audits of POCT are conducted.<br>*Guidance: See QMS6.3.* | ISO 15189 14.4<br>ISO 22870 14.4 | |
| POC2.2.2 | **M** | Results of internal audits are analyzed by the laboratory medical director, designate or the quality manager and by the multidisciplinary POCT management group. | ISO 22870 14.4a | |
| POC2.2.3 | **M** | Suggested modifications arising from audit analysis are incorporated into POCT processes and procedures. | ISO 22870 14.4b | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| POC2.2.4 | **M** | A management review of POCT has been implemented that meets the requirements of the DAP QMS accreditation standards.<br>*Guidance: See QMS6.4.* | ISO 22870 4.15<br>ISO 15189 4.15 | |
| POC2.2.5 | **M** | The management review of POCT includes quality indicators, internal audits and investigation of nonconformities, corrective action procedures and records of actions to deal with nonconformities. | ISO 15189 4.15.2d,f,k | |
| POC2.2.6 | **M** | Based on the management review, appropriate changes to POCT policies, processes or procedures are made by the laboratory medical director or designate, the POCT quality manager and the multidisciplinary POCT management group. | ISO 22870 4.15.4 | |
| **POC2.3** | **There are processes for the management of unauthorized POCT.** | | | |
| POC2.3.1 | **M** | The controls and related responsibilities and authorities for dealing with unauthorized POCT are defined.<br>*Guidance: ISO 22870 uses the term nonconforming. The DAP standards use the term unauthorized.* | ISO 22870 4.9.2<br>ISO 15189 4.9 | |
| POC2.3.2 | **M** | The organization addresses unauthorized POCT by either eliminating unauthorized POCT or by incorporating it into the existing POCT program. | ISO 22870 4.9.2a, b, c | |
| POC2.3.3 | **M** | Records of unauthorized POCT and any subsequent actions taken are maintained. | ISO 22870 4.9.2<br>ISO 15189 4.9 | |
| **POC2.4** | **There are procedures to manage POCT nonconformities and potential nonconformities.** | | | |
| POC2.4.1 | **M** | There are documented processes to identify and manage nonconformities in POCT using procedures for investigation, corrective action, records of action and review. | ISO 22789 4.9.1, 4.10, | |
| POC2.4.2 | **M** | There are procedures to eliminate the causes of potential nonconformities in POCT by identifying potential nonconformities and determining preventive action. Records of action taken and review are documented. | ISO 22780 4.11 | |

## POC3.0 EQUIPMENT AND SUPPLIES

| | | | | |
|---|---|---|---|---|
| **POC3.1** | **There are procedures for the selection, and evaluation of POCT equipment.** | | | |
| POC3.1.1 | **M** | The laboratory medical director or designate is responsible for ensuring there is a documented process for the evaluation and selection of POCT equipment. | ISO 22870 5.1.2a | |
| POC3.1.2 | **M** | The quality goals for laboratory examinations (accuracy, precision, detection limits, interferences and ease of use) are defined and considered in the selection of POCT. | ISO 22870 5.1.2b | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| POC3.1.3 | **M** | POCT manufacturer's performance claims are verified prior to use. | ISO 22870 5.3.2b | |
| POC3.1.4 | **M** | POCT conditions conform to applicable regulations and manufacturer's recommendations. | ISO 22870 5.2.2<br>ISO 22870 5.2.3 | |
| **POC3.2** | **There are procedures for the management of POCT equipment and consumables.** | | | |
| POC3.2.1 | **M** | Responsibility for the control of POCT inventory is defined and access to POCT equipment is controlled. | ISO 22870 5.3.2 | |
| POC3.2.2 | **M** | Locations and performance records for each piece of POCT equipment are maintained. | ISO 22870 5.3.2a | |
| POC3.2.3 | **M** | POCT reagents are labeled with date of preparation or reconstitution, content, expiry date and storage requirements. | CAP COM.30300 | |
| POC3.2.4 | **M** | Lot numbers and expiration dates of materials and reagents used for POCT are recorded. | ISO 22870 5.3.2e | |
| **POC3.3** | **There are procedures for maintenance of POCT equipment.** | | | |
| POC3.3.1 | **M** | POCT equipment records include the serial number or other identifier and the manufacturer or supplier. | ISO 22870 5.3.2a | |
| POC3.3.2 | **M** | POCT equipment records include the date purchased, maintenance records and removal from service dates. | ISO 22870 5.3.2a | |
| POC3.3.3 | **M** | POCT equipment is maintained according to the manufacturer's recommendations. The maintenance and repair of POCT equipment is documented. | ISO 22870 5.3.2c<br>ISO 22870 5.3.2f | |
| POC3.3.4 | **M** | Resource and service personnel are defined and communicated to POCT users. | ISO 22870 5.3.2 | |
| POC3.3.5 | **M** | POCT equipment that is entering into service after repair is calibrated and verified, as appropriate. | ISO 15189 5.3.1.5 | |

## POC4.0 QUALITY ASSURANCE OF POCT

| | | | | |
|---|---|---|---|---|
| **POC4.1** | **Quality control procedures for POCT are defined.** | | | |
| POC4.1.1 | **M** | Procedures for POCT contain the specific activities needed to assess the quality of each examination including the actions to be followed when controls fall outside acceptable ranges. | ISO 22870 5.6.8d<br>ISO 22870 5.6.8e | |
| POC4.1.2 | **M** | QC procedures are defined for each POCT examination. | ISO 22870 5.5.3, .8f | |
| POC4.1.3 | **M** | The frequency of internal QC is defined for each piece of POCT equipment. | ISO 22870 5.6.8c | |
| POC4.1.4 | **M** | POCT using internal, procedural or electronic QC utilizes conventional (wet testing) QC measures at a frequency determined by the laboratory medical director. | ISO 22870 5.6.2 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| POC4.1.5 | **M** | There are documented processes to review and supplement manufacturer minimal QC recommendations as required. | ISO 22870 5.5.3 | |
| POC4.1.6 | **M** | Dates of all POCT and QC results are recorded to provide a link between the control and patient results. | ISO 22870 5.5.3 | |
| POC4.1.7 | **M** | The QC data for POCT examinations is documented in a way that monitors the accuracy and precision of examination performance over time. | ISO 22870 5.5.3 | |
| POC4.1.8 | **M** | POCT QC results are reviewed at a defined frequency by the quality manager or designate and the review is documented. | ISO 22870 5.6.3 | |
| **POC4.2** | **POCT is evaluated using a formal external proficiency testing program or alternative assessment.** | | | |
| POC4.2.1 | **M** | All POCT is evaluated using an alternate means of assessment or by formal proficiency testing (PT) programs. | ISO 15189 5.6.3<br>ISO 22870 5.6.5<br>CLSI POCT04-A2 21 | |
| POC4.2.2 | **M** | The alternative assessment is established by the laboratory medical director or designate. | ISO 22870 5.6.5 | REVISED |
| POC4.2.3 | **M** | POCT PT or alternative assessment occurs at least twice per year. | DAP ACR | |
| POC4.2.4 | **M** | POCT PT or alternative assessment is examined by personnel who routinely examine patient samples. | ISO 15189 5.6.3.3 | |
| POC4.2.5 | **M** | POCT PT or alternative assessment results are monitored by the laboratory medical director or designate at a defined interval and discussed with relevant personnel. | ISO 15189 5.6.3.4<br>ISO 22870 5.6.6 | REVISED |
| POC4.2.6 | **M** | Unacceptable POCT PT or alternative assessment results are investigated and corrective action is implemented where indicated. This investigation and any corrective action is documented and retained. | ISO 15189 5.6.3.4 | |
| POC4.2.7 | **M** | The authority to withdraw equipment or discontinue a POCT examination in the event of serious POCT PT or alternate assessment problems is defined. | DAP ACR | |

## POC5.0 POCT EXAMINATION

| | | | | |
|---|---|---|---|---|
| **POC5.1** | **There are procedures for the collection of samples for POCT.** | | | |
| POC5.1.1 | **M** | There are procedures for ordering POCT examinations. | ISO 15189 5.4.4.2 | |
| POC5.1.2 | **M** | Procedures for sample collection for POCT are communicated and available to personnel performing the POCT examinations. | ISO 15189 5.4.4.2-3 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| POC5.1.3 | **M** | For POCT requiring a capillary blood sample, only single-use puncture devices are used. | CSA Z316.7 7.3 | |
| POC5.1.4 | **M** | Procedures are available to decontaminate equipment after exposure to known or suspected cases of infectious disease (e.g. MRSA). | CAP POC.09190 | |
| **POC5.2** | **There are procedures for the performance of POCT.** | | | |
| POC5.2.1 | **M** | Procedures for POCT examinations are communicated and available to personnel.<br>*Guidance: Manufacturer's documentation is only used as a supplement to the POCT procedure. POCT equipment is operated according to the manufacturer's recommendations.* | ISO 22870 5.5.1<br>SO 22870 5.5.2 | |
| POC5.2.2 | **M** | Any condensed document format used at POCT sites (e.g. job aids) is subject to document control and corresponds to the full procedure. | ISO 15189 5.5.3 | |
| POC5.2.3 | **M** | There are procedures for the follow-up of results that fall outside of the reportable range for POCT equipment or for results that do not correlate with the clinical presentation.<br>*Guidance: This may include repeat examination, collecting a repeat sample or referring a sample to the central or referral laboratory.* | ISO 22870 5.7.2<br>ISO 15189 5.7.1 | |
| POC5.2.4 | **M** | If allowed, the accuracy and comparability of patient self-testing using POCT equipment is validated by the laboratory medical director to ensure comparability of results to the central laboratory. | ISO 22870 5.6.8h | |

## POC6.0 POST-EXAMINATION

| | | | | |
|---|---|---|---|---|
| **POC6.1** | **There are procedures for recording and reporting POCT results.** | | | |
| POC6.1.1 | **M** | There are procedures for recording and reporting POCT results. | ISO 15189 5.8<br>ISO 22870 5.8 | |
| POC6.1.2 | **M** | Every examination requested is recorded. | ISO 22870 5.8.2 | |
| POC6.1.3 | **M** | POCT results are recorded as a POCT result and incorporated into the patient's permanent medical record. | ISO 22870 5.8.3-4 | |
| POC6.1.4 | **M** | POCT results are clear and legible. Thermal printouts are not used to record results. | ISO 15189 5.8.3a | |
| POC6.1.5 | **M** | POCT results identify the user requesting, and the personnel performing POCT. | ISO 15189 5.8.3e, .3n | |
| POC6.1.6 | **M** | POCT results identify the date and time of examination. | ISO 15189 5.8.3f, .3o | |
| POC6.1.7 | **M** | Reference intervals are available for users and personnel performing POCT examinations. | ISO 15189 5.8.3j | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| **POC6.2** | **There are procedures for addressing POCT critical values.** | | | |
| POC6.2.1 | **M** | Critical values are established for POCT examinations. | ISO 15189 5.8.2c | |
| POC6.2.2 | **M** | POCT critical values are evaluated with clinical information. | ISO 15189 5.9.1 | |
| POC6.2.3 | **M** | There are procedures addressing the action to be taken when critical POCT values are obtained. | ISO 15189 5.9.1b | |
| POC6.2.4 | **M** | Any action taken as a result of POCT is noted in the patient's medical record. | ISO 15189 5.9.1b | |

# Accreditation Standards 2015

Laboratory Medicine

## TRANSFUSION MEDICINE STANDARDS

The transfusion medicine standards are used in conjunction with the general standards for each laboratory.

# TRANSFUSION MEDICINE

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **TRM1.0** | **ORGANIZATION** | | | |
| **TRM1.1** | **A medical director is appointed with assigned responsibilities for the transfusion service.** | | | |
| TRM1.1.1 | **M** | There is a medical director of the transfusion service with responsibility for all medically related transfusion service activities that affect transfusion practices. | CSTM 1.4<br>CSTM 2.2 | |
| TRM1.1.2 | **M** | The transfusion service medical director is responsible for any technical or clinical policies processes or procedures, which relate to the care and safety of the transfusion recipient. | Z902 4.3.6.1<br>CSTM 2.2 | |
| TRM1.1.3 | **M** | The transfusion service medical director is responsible for the transfusion service disaster plan and the blood shortages contingency plan. | CSTM 2.2 | |
| **TRM1.2** | **A technical specialist is appointed with assigned responsibility for technical activities within the transfusion service.** | | | |
| TRM1.2.1 | **M** | The transfusion service technical specialist has responsibility and provides consultation for technical activities within the transfusion service. | CSTM 2.3 | |
| TRM1.2.2 | **M** | The transfusion service technical specialist meets applicable requirements and has training and experience in transfusion medicine. | CSTM 2.3<br>Z902 4.3.1.7 | |
| **TRM1.3** | **Specific training for transfusion activities is provided.** | | | |
| TRM1.3.1 | **M** | There is a documented training program for all personnel involved in all transfusion activities. There are documented processes for initial and ongoing training. | Z902 4.3.2.1, 4.3.6.2<br>CSTM 2.12(c) | |
| TRM1.3.2 | **M** | Non-laboratory personnel collecting samples for transfusion medicine examinations are trained and competent in request and labeling requirements. | | |
| TRM1.3.3 | **M** | All personnel (laboratory or non-laboratory) who participate in the processing, storage or administration of blood components and products are trained and competent in the relevant procedures. | Z902 4.3.2.3, 14.4(b)<br>CSTM 2.12(b), 2.13 | |
| TRM1.3.4 | **M** | Personnel involved in the packing and transportation of blood components and products receive specific training. This is documented. | CSTM 5.6.1.2<br>Z902 9.5.1 | |
| **TRM1.4** | **The competency of personnel providing transfusion related activities is assessed.** | | | |
| TRM1.4.1 | **M** | There is a documented process for the development and maintenance of a competency assessment program for all personnel involved in any transfusion related activity. | CSTM 2.14 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM1.4.2 | **M** | There is an annual competency assessment for personnel who prepare blood components and products for administration (e.g. cell washing, irradiation, reconstitution). | Z902 14.4b | |
| **TRM1.5** | **There is an active transfusion committee.** | | | |
| TRM1.5.1 | **M** | An established facility or regional committee meets to discuss transfusion-related issues at least quarterly.<br>*Guidance: Although a transfusion committee is preferred, the use of an established group such as the medical advisory committee is acceptable. Transfusion Committee meetings may be conducted by teleconference or other venue.* | CSTM 1.8, 1.9<br>DAP15 ver1.0 | |
| TRM1.5.2 | **M** | The transfusion committee provides consultation, audit, review and oversight of transfusion practices. | DAP15 ver1.0 | |
| TRM1.5.3 | **M** | The transfusion service medical director attends all transfusion committee meetings or sends a physician delegate. | CSTM 1.4, 2.2 | |
| TRM1.5.4 | **M** | The transfusion committee membership includes key stakeholders including physicians, nurses, transfusion personnel, and hospital administration. | Z902 4.4 | |
| TRM1.5.5 | **M** | The transfusion committee provides transfusion medicine information and education. | Z902 4.4<br>CSTM 1.8 | |
| TRM1.5.6 | **M** | The transfusion committee identifies criteria for blood component and product utilization, identifies inappropriate use of blood components and products and facilitates corrective action. | Z902 4.4<br>CSTM 1.8 | |
| TRM1.5.7 | **M** | The transfusion committee ensures that audits of transfusion practices are performed every two years at a minimum. | GOC HC-BR 94(1)(j) | |
| TRM1.5.8 | **M** | The transfusion committee evaluates reports of adverse transfusion events and all transfusion errors in the facility, as well as relevant governmental reports on adverse transfusion events. | Z902 4.4<br>CSTM 1.8 | |

## TRM2.0 QUALITY MANAGEMENT SYSTEM

| TRM2.1 | **There are processes for the review of transfusion service documents.** | | | |
|---|---|---|---|---|
| TRM2.1.1 | **M** | All policies, processes and procedures are reviewed every two years by the transfusion service medical director or designate. | Z902 4.6.1.6<br>CSTM 6.1.3 | |
| TRM2.1.2 | **M** | The process for review ensures compliance with current regulatory requirements, standards and facility requirements and practice. | Z902 4.6.1.6<br>CSTM 6.1.3 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM2.1.3 | **M** | Procedures are reviewed in response to accidents, errors or adverse events, changes in regulatory requirements, nonconformity identified through internal or external audits or other conditions defined in facility policy. | Z902 4.6.1.6<br>CSTM 6.1.3 | |
| **TRM2.2** | **There are procedures for the copy, storage and maintenance of records.** | | | |
| TRM2.2.1 | **M** | The identity of personnel making entries in transfusion documents and records is recorded. | CSTM 6.3.7<br>Z902 20.1.4 | |
| TRM2.2.2 | **M** | The details of any records copied for storage are documented. Copied records are easily retrievable. | Z902 20.1.11<br>CSTM 6.3.10 | |
| TRM2.2.3 | **M** | Audits to ensure that copied records are legible, accurate and complete are performed. Original records are retained until all the copy documentation and audits are complete. | Z902 20.1.11<br>CSTM 6.3.10 | |
| TRM2.2.4 | **M** | When records are copied off-site, there is a contract detailing the specific requirements for transport, storage, documentation, audit and where necessary, destruction of the original documents. | Z902 20.1.11<br>CSTM 6.3.10 | |
| TRM2.2.5 | **M** | Retention of transfusion documents and records complies with CSTM and CSA Z902 Standards and with British Columbia's revised *Limitation Act* (see POS1.3.1). | CSTM 6.4, 6.1.2<br>Z902 20.1.11, 20.1.2 | |
| **TRM2.3** | **There are procedures to manage nonconformities.** | | | |
| TRM2.3.1 | **M** | There are procedures for the identification and control of nonconformities that could adversely affect the safety, efficacy, or quality of blood components and products, or the safety of donors, recipients and personnel. | CSTM 7.1.1<br>Z902 4.6.2 | |
| TRM2.3.2 | **M** | Any nonconformity that has or may have adversely affected patient care is reported to the Canadian Blood Services or Health Canada, as appropriate. | Z902 18.2.2-5<br>CSTM 7.1.3 | |

## TRM3.0 SAFETY

| TRM3.1 | **There are procedures that address the safety of transfusion services.** | | | |
|---|---|---|---|---|
| TRM3.1.1 | **M** | There are policies and procedures that relate to the safety, quality, efficacy and the supply of blood including the safety of donors, recipients, and personnel. | CSTM 1.5<br>Z902 4.2.1.1 | |
| TRM3.1.2 | **M** | The transfusion service is involved in developing and monitoring policies and procedures for transfusion activities in areas outside the laboratory. | CSTM 1.6 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM3.1.3 | **M** | The transfusion service is involved in developing and monitoring policies and procedures for activities related to disaster planning.<br>*Guidance: A disaster plan has been developed that is consistent with the emergency plan of the health-care facility, the provincial plan and the blood supplier's contingency plan.* | CSTM 1.7<br>Z902 4.2.1.6 | |
| **TRM3.2** | **The transfusion service is involved in the informed consent process. Patients are notified after transfusion.** | | | |
| TRM3.2.1 | **M** | The transfusion service communicates information related to current risks of transfusion, transfusion ordering and transfusion administration practice(s). | CSTM 1.10<br>Z902 11.2.3 | |
| TRM3.2.2 | **M** | The transfusion service medical director participates in the development of policies and procedures regarding informed consent for transfusion. | CSTM 4.3.6.1<br>Z902 11.2.1<br>DAP TMAC 2012 | |
| TRM3.2.3 | **M** | There is a policy for obtaining informed consent. | CSTM 1.11 | |
| TRM3.2.4 | **M** | The process of obtaining informed consent includes the opportunity for recipients to ask questions and receive satisfactory answers. | CSTM 1.11 | |
| TRM3.2.5 | **M** | Information is provided for the blood component or product and discussion of clinically appropriate alternatives to transfusion including benefits and risks. | CSTM 1.11<br>Z902 11.2.1 | |
| TRM3.2.6 | **M** | All recipients of blood components and products are notified in writing. | CSTM 6.1.1<br>Z902 10 -11.2.2 | |

## TRM4.0 FACILITIES

| | | | | |
|---|---|---|---|---|
| **TRM4.1** | **There are procedures for a transfusion service sanitation program.** | | | |
| TRM4.1.1 | **M** | There is a training program that includes sanitation, workplace safety, infection control and hygiene training, as related to transfusion activities. | Z902 4.3.2.2<br>CSTM 2.12(d) | |
| TRM4.1.2 | **M** | Procedures and schedules of any specific cleaning requirements of transfusion service areas are defined. | Z90210 22.3.1 -3<br>CSTM 10.22-3 | |
| TRM4.1.3 | **M** | Procedures for pest control do not affect the safety of blood components and products. | Z902 22.1.8<br>CSTM 10.24 | |

## TRM5.0 EQUIPMENT, REAGENTS AND SUPPLIES

| | | | | |
|---|---|---|---|---|
| **TRM5.1** | **There are procedures for transfusion service equipment and supplies.** | | | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM5.1.1 | **M** | Equipment in the transfusion service is used according to the manufacturer's recommendations or a validated process. Any deviation has been approved by the transfusion service medical director. | Z902 23.1.1,<br>23.1.2, 23.2.1<br>CSTM 3.1.1, 3.1.2 | |
| TRM5.1.2 | **M** | Reagents are stored according to the manufacturer's recommendations. | DAP15 ver1.0 | |
| TRM5.1.3 | **M** | Reagent storage is monitored by equipment that continuously checks and records the temperature, or by a daily documented record of temperature. | DAP15 ver1.0 | |
| **TRM5.2** | **Equipment used for blood component and product storage maintains required storage conditions.** | | | |
| TRM5.2.1 | **M** | Equipment used for blood component and product storage is connected to an emergency power supply. | Z902 22.1.7<br>CSTM 3.2.1.1 | |
| TRM5.2.2 | **M** | The emergency power supply is checked at defined intervals to ensure an immediate switch to emergency power. | CSTM 3.2.1.1 | |
| TRM5.2.3 | **M** | Refrigerators and freezers for blood component and product storage are verified to ensure a temperature within the defined temperature range is maintained throughout the storage area. | CSTM 3.2.2.1 | |
| TRM5.2.4 | **M** | The storage of blood components and products is monitored by equipment that continuously checks and records temperatures or by manually checking and recording the temperature at least every four hours. | CSTM 3.2.4.1, 3.2.4.2<br>Z902 9.4.4 | |
| TRM5.2.5 | | Blood component and product storage equipment is monitored with an additional separate independent thermometer in a fluid equal in heat transfer characteristics to the smallest volume of blood product or component in storage. | CAP TRM.42650 | |
| TRM5.2.6 | **M** | The blood storage refrigerator is large enough to meet the needs of the facility. | DAP15 ver1.0 | |
| TRM5.2.7 | **M** | Equipment used for blood component and product storage has an audible alarm with a backup power supply for the alarm. Any battery powered alarm backup is checked monthly. | CSTM 3.2.2.2<br>Z902 9.4.5 | |
| TRM5.2.8 | **M** | There is alternate storage when equipment for blood components and products, reagents and patient samples is defective or malfunctioning. | CSTM 3.1.9 | |
| TRM5.2.9 | **M** | There is a documented process to continuously monitor and record the temperature of room temperature storage areas.<br>*Guidance: If a continuous recorder is not available, the temperature is documented at least every four hours.* | CSTM 3.2.4.1-2<br>Z902 9.4.4 | |
| TRM5.2.10 | **M** | There are procedures for monitoring and documenting temperature data daily. | CAP TRM.42350 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM5.2.11 | **M** | Temperature monitoring data is reviewed at a defined frequency by the technical supervisor or designate and this review is documented. | DAP15 ver1.0 | |
| TRM5.2.12 | **M** | Equipment for platelet storage is verified to maintain a constant, gentle agitation. | CSTM 3.2.3.1 | |
| **TRM5.3** | **There are procedures for thawing devices.** | | | |
| TRM5.3.1 | **M** | Thawing devices are used according to the manufacturer's recommendations. | CSTM 3.3.1.1 | |
| TRM5.3.2 | **M** | The temperature of the thawing devices is checked with each use and documented daily. | CSTM 3.3.1.2<br>DAP TMAC | |
| TRM5.3.3 | **M** | Equipment for thawing blood components is not used for the incubation of examinations containing biological samples. | CSTM 3.3.1.3 | |
| **TRM5.4** | **There are procedures for the operation and maintenance of centrifuges and incubation equipment.** | | | |
| TRM5.4.1 | **M** | Equipment for blood component centrifugation is maintained according to the manufacturer's recommendations. | CSTM 3.3.2.1<br>CSTM 3.3.2.2 | |
| TRM5.4.2 | **M** | The temperature, speed and processing time for centrifugation is checked with each use and documented daily. | CSTM 3.3.2.2 | |
| TRM5.4.3 | **M** | Centrifugation equipment is maintained according to the manufacturer's recommendations including the speed of rotation and the timing device.<br>*Guidance: This may require the laboratory to define documentation listing daily, weekly, monthly and annual tasks to be performed, particularly when manufacturer's recommendations are not available or do not provide the level of detail necessary.* | Z902 23.4.1<br>Z902 23.4.2 | |
| TRM5.4.4 | **M** | Incubation equipment used for serological testing is used and maintained according to the manufacturer's instructions. | CSTM 3.4.2.1 | |
| TRM5.4.5 | **M** | The temperature of incubation equipment is checked with each use and documented daily. | CSTM 3.4.2.2 | |
| **TRM5.5** | **There are procedures for the use of sterile connecting devices.** | | | |
| TRM5.5.1 | **M** | Procedures for sterile connecting devices include instructions for use, approved uses, and a documented process for the approval for nonconforming uses. | CSTM 3341<br>Z902 7.3.1 | |
| TRM5.5.2 | **M** | Procedures for sterile connecting devices include documentation requirements for product tracking, tube weld QC and lot numbers of disposables (e.g. new needles and wafers). | CSTM 3342<br>Z902 7.3.1 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM5.5.3 | **M** | Procedures for sterile connecting devices include instructions for testing each sterile weld for integrity.<br>*Guidance: If weld integrity has been maintained, the component's expiry date is retained, if weld integrity has not been maintained the component is considered an open system and its expiry date is changed accordingly.* | CSTM 3.3.4.1, 3.3.4.3<br>Z902 7.3.2 | |
| **TRM5.6** | **There are procedures for the use of infusion devices and associated equipment.** | | | |
| TRM5.6.1 | **M** | There are procedures for the use of infusion devices and associated equipment. | CSTM 3.5.1<br>Z902 11.4.1 | |
| TRM5.6.2 | **M** | The use of all infusion devices and associated equipment follows the manufacturer's instructions and recommendations. | CSTM 3.5.3 | |
| TRM5.6.3 | **M** | All infusion devices used to warm blood components and products have a temperature-sensing device and an audible alarm system. | CSTM 3.5.4<br>Z902 11.5.2 | |

## TRM6.0 QUALITY ASSURANCE OF EXAMINATION PROCEDURES

| **TRM6.1** | **There are procedures for the QC of serological examinations.** | | | |
|---|---|---|---|---|
| TRM6.1.1 | **M** | QC procedures are documented and maintained. | DAP15 ver1.0 | |
| TRM6.1.2 | **M** | QC records document acceptable reactivity and specificity of antisera and reagent cells on each day of use. | DAP15 ver1.0 | |
| TRM6.1.3 | **M** | Current package inserts are available for materials used by the transfusion service (e.g. antisera). | DAP15 ver1.0 | |
| TRM6.1.4 | **M** | All antisera are controlled using red cells known to be positive and negative for the specific antigen(s). | CSTM 5.3.4.1 | |
| TRM6.1.5 | **M** | For anti-D testing, a control system appropriate to the anti-D reagent is used. | CSTM 5.3.3.2<br>Z902 10.4.5 | |
| TRM6.1.6 | **M** | Red cells with a single expression of the antigen being tested are used for positive controls. | CSTM 5.3.4.2 | |
| TRM6.1.7 | **M** | An auto control or a direct antiglobulin test is performed in conjunction with patient red cell phenotyping or antibody identification that requires an indirect antiglobulin test. | CSTM 5.3.4.3 | |
| TRM6.1.8 | **M** | All negative antiglobulin tube tests are controlled by the addition of IgG sensitized red cells. When using an examination system that does not allow for the use of IgG sensitized red cells, the manufacturer's instructions are followed. | CSTM 5.3.5.4<br>Z902 10.4.7 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM6.1.9 | **M** | QC data is reviewed at a defined frequency by a technical supervisor or designate. This review is documented. | DAP15 ver1.0 | |

## TRM7.0 BLOOD INVENTORY AND STORAGE

| | | | | |
|---|---|---|---|---|
| **TRM7.1** | **There are procedures for transfusion service inventory control.** | | | |
| TRM7.1.1 | **M** | An emergency supply of group O Rh negative red blood cells is available at all times for emergency release.<br>*Guidance: A system that allows immediate allocation may be a suitable substitute for a dedicated emergency supply.* | DAP15 ver1.0 | |
| TRM7.1.2 | **M** | The transfusion service has a defined list of critical inventory of blood components and products. | CSTM 4.4 | |
| TRM7.1.3 | **M** | The blood component and product inventory level is assessed at a defined interval. | DAP15 ver1.0 | |
| TRM7.1.4 | **M** | Policies and procedures for management of the blood component and product inventory are based on clinical needs and utilization guidelines. | DAP15 ver1.0 | |
| TRM7.1.5 | **M** | There are processes to minimize overstocking and wastage of blood components and products. | DAP15 ver1.0 | |
| TRM7.1.6 | **M** | There are policies and procedures for emergency and disaster planning which include the evaluation of inventory and provision of blood components and products in critical situations. | CSTM 4.3 | |
| TRM7.1.7 | **M** | Blood contingency plans are developed to address blood shortages.<br>*Guidance: The British Columbia Blood Contingency Plan provides guidelines including establishing a blood contingency plan at the health authority level, and activities to be followed during blood shortages.* | DAP15 ver1.0 | |
| TRM7.1.8 | **M** | The transfusion service has defined a list of critical supplies including minimal levels of reagents. | CSTM 4.4<br>CAP TRM.30882 | |
| TRM7.1.9 | | There is a list of current suppliers including contact information, and alternate suppliers. | CSTM 4.3 | |
| **TRM7.2** | **Blood components and products are inspected upon receipt.** | | | |
| TRM7.2.1 | **M** | All blood components and products are inspected for abnormal appearance upon receipt. This is documented. | CSTM 5.1.1.5<br>Z902 8.5 | |
| TRM7.2.2 | **M** | The inspection includes the expiry date of blood components and products. | CSTM 5.1.1.5 | |
| TRM7.2.3 | **M** | Blood components and products not passing inspection are quarantined until appropriate disposition is determined. This is documented and the shipper is notified. | CSTM 5.1.1.5<br>Z902 8.5 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **TRM7.3** | **Blood components and products are stored as recommended by the blood supplier or manufacturer.** | | | |
| TRM7.3.1 | **M** | Red cells are stored at 1°C to 6°C with an expiry date as assigned by the blood supplier. | CSTM 5.1.2.1, 5.1.2.5<br>Z902 7.5.1.4 | |
| TRM7.3.2 | **M** | Washed red cells, thawed frozen red cells and red cells modified in an open system are stored at 1°C to 6°C with an expiry of 24 hours after preparation. | CSTM 5.1.2.6-8<br>Z902 7.5.3.4 | |
| TRM7.3.3 | **M** | Red cells modified by the blood supplier are stored as indicated by the blood supplier. | CSTM 5.1.2.6-8<br>Z902 7.5.2.9 | |
| TRM7.3.4 | **M** | Frozen plasma is stored at -18°C or colder, with an expiry date as assigned by the blood supplier. | CSTM 5.1.2.10 | |
| TRM7.3.5 | **M** | Thawed plasma is stored at 1°C to 6°C and transfused within five days of thawing. | Z902 7.6.2.3 | |
| TRM7.3.6 | **M** | Frozen cryoprecipitate is stored at -18°C or colder with an expiry date as assigned by the blood supplier. | CSTM 5.1.2.12 | |
| TRM7.3.7 | **M** | Thawed cryoprecipitate is stored at 20°C to 24°C with an expiry of four hours after thawing. | CSTM 5.1.2.13<br>Z902 7.6.3.4 | |
| TRM7.3.8 | **M** | Platelets are stored under gentle agitation at 20°C to 24°C with an expiry date as assigned by the blood supplier. | CSTM 5.1.2.14<br>Z902 7.7.5 | |
| TRM7.3.9 | **M** | Platelets pooled using an open system are stored at 20°C to 24°C with an expiry of four hours after preparation. | CSTM 5.1.2.15<br>Z902 7.11.3 | |
| **TRM7.4** | **Blood components and products are segregated during storage.** | | | |
| TRM7.4.1 | **M** | Blood components and products are stored separately from samples, tissues and reagents.<br>*Guidance: This can be done through the use of clearly identified areas in the same storage equipment.* | CSTM 3.2.1.7, 5.1.2.3<br>Z902 3.2.1.7 | |
| TRM7.4.2 | | Blood components and products are arranged in refrigerators and freezers to facilitate location and separation. | DAP15 ver1.0 | |
| TRM7.4.3 | **M** | Blood storage equipment within the laboratory has a clearly identified segregated quarantine location for the storage of blood components and products that do not meet the necessary criteria for release. | CSTM 5.1.2.4<br>Z902 9.4.8 | |
| TRM7.4.4 | **M** | There is a documented process for the release of blood components and products from quarantine, including specifying the individual responsible for this release. | Z902 9.4.7 | |

| No. | | Standard<br>Criterion | Reference | Change |
|---|---|---|---|---|

## TRM8.0 REQUESTS, SAMPLE COLLECTION AND RECEIPT

| | | | | |
|---|---|---|---|---|
| **TRM8.1** | **Request forms for blood components and products include the required information.** | | | REVISED |
| TRM8.1.1 | **M** | Requests for blood components and products include the recipient's first and last name, identification number and location. | CSTM 5.2.1.2<br>Z902 10.2.1 | |
| TRM8.1.2 | **M** | Requests for blood components and products include the name of the blood component or product, the volume or dosage, and any special requirements when indicated. | CSTM 5.2.1.2<br>Z902 10.2.1 | |
| TRM8.1.3 | **M** | Requests for blood components and products include the clinical indication, date and time of request, and the date and time of intended transfusion if available. | CSTM 5.2.1.2 | |
| **TRM8.2** | **There are procedures for the collection of samples from recipients.** | | | |
| TRM8.2.1 | **M** | Unequivocal identification of the recipient is made prior to collecting blood samples including a check of the recipient's identification band or by using an alternative process approved by the transfusion service. | CSTM 5.2.2.1<br>Z902 10.2.3 | |
| TRM8.2.2 | **M** | If problems are found during the identification process, blood samples are not collected until the problem has been resolved. | CSTM 5.2.2.1<br>Z902 10.2.3 | |
| TRM8.2.3 | **M** | There are procedures for recipient identification where the recipient's identity and identification number are not available. | CSTM 5.2.2.2<br>Z902 10.2.2, 4 | |
| TRM8.2.4 | **M** | There are procedures for identification of outpatient and pre-admission recipients. | CSTM 5.2.2.3 | |
| TRM8.2.5 | **M** | Blood samples are labeled in the presence of the recipient at the time of collection with the recipient's first and last name and the recipient's identification number, at a minimum. | CSTM 5.2.3.1 | |
| TRM8.2.6 | **M** | Personnel collecting blood sample verify that the sample label information matches the recipient's identification. | Z902 10.3.2 | |
| TRM8.2.7 | **M** | Identification of personnel collecting the sample and the date and time of sample collection is recorded and retained. | CSTM 5.2.3.2<br>Z902 10.3.1 | |
| **TRM8.3** | **The timeframe for use of a recipient's sample in compatibility testing is defined.** | | | |
| TRM8.3.1 | **M** | Samples for compatibility testing are collected within 96 hours prior to transfusion for recipients who have been transfused with a blood component containing red cells, recipients who have been pregnant within the preceding three months, or if the history of transfusion or pregnancy is uncertain. | CSTM 5.2.3.3<br>Z902 10.4.2 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM8.3.2 | **M** | The 96-hour time frame is applied after first exposure to blood components containing red cells. | CSTM 5.2.3.3<br>Z902 10.4.3 | |
| TRM8.3.3 | **M** | Procedures define how long a sample can be used if the recipient has not been transfused or pregnant in the last three months. | CSTM 5.2.3.3<br>Z902 10.4.2 | |
| TRM8.3.4 | **M** | The length of time and storage conditions for samples used in compatibility testing after initial group and screen procedures is defined. | CSTM 5.2.3.4 | |
| **TRM8.4** | **There are procedures for checking the recipient sample and reviewing the recipient's history.** | | | |
| TRM8.4.1 | **M** | Information on the blood sample label and request are checked before any examination begins. Any problems are resolved or new samples are collected. | CSTM 5.2.4.1<br>Z902 10.3.3 | |
| TRM8.4.2 | **M** | Incomplete, incorrect or illegible requests are not processed and a new sample is collected if discrepancies or errors are not resolved. | DAP15 ver1.0 | |
| TRM8.4.3 | **M** | The recipient's record is reviewed for previous ABO and Rh grouping and any difficulties in blood typing. | CSTM 5.2.4.2<br>Z902 10.4.8 | |
| TRM8.4.4 | **M** | The recipient's record is reviewed for previous transfusions and any previously identified clinically significant red cell antibodies. | CSTM 5.2.4.2<br>Z902 10.4.8 | |
| TRM8.4.5 | **M** | The recipient's record is reviewed for adverse reactions to a previous transfusion and any special transfusion requirements. | CSTM 5.2.4.2<br>Z902 10.4.8 | |

## TRM9.0 RECIPIENT EXAMINATION INCLUDING CROSSMATCH

| | | | | |
|---|---|---|---|---|
| **TRM9.1** | **There are procedures for the documentation of transfusion service examinations and activities.** | | | |
| TRM9.1.1 | **M** | All observed examination reactions are documented. | CSTM 5.3.1.3 | |
| TRM9.1.2 | **M** | Criteria for grading agglutination and hemolysis are defined. | DAP15 ver1.0 | |
| TRM9.1.3 | **M** | Current examination results are compared with previous records to identify any discrepancies. | CSTM 5.3.1.4 | |
| TRM9.1.4 | **M** | All discrepancies are resolved prior to reporting. This is documented. | CSTM 5.3.1.5 | |
| TRM9.1.5 | **M** | Personnel performing each step in the processing, examination and distribution of blood components and products are identified and recorded. | DAP15 ver1.0 | |
| **TRM9.2** | **There are procedures for pre-transfusion ABO and Rh grouping.** | | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM9.2.1 | **M** | The recipient's red cells are phenotyped with anti-A and anti-B. | CSTM 5.3.2.1<br>Z902 10.4.4 | |
| TRM9.2.2 | **M** | The recipient's serum or plasma is examined for the presence of anti-A and anti-B (excluding neonates). | CSTM 5.3.2.1<br>Z902 10.4.4 | |
| TRM9.2.3 | **M** | The recipient's red cells are phenotyped with anti-D. | CSTM 5.3.3.1<br>Z902 10.4.5 | |
| TRM9.2.4 | **M** | ABO and Rh discrepancies are resolved. | Z902 10.4.6 | |
| **TRM9.3** | **There are procedures for the detection and identification of antibodies.** | | | |
| TRM9.3.1 | **M** | A minimum of two unpooled reagent red cells are used for antibody screening. | CSTM 5.3.5.1, 5.3.5.2<br>Z902 10.4.7 | |
| TRM9.3.2 | **M** | Red cells with a double expression of antigens are used, wherever possible. | CSTM 5.3.5.1<br>Z902 10.4.7 | |
| TRM9.3.3 | **M** | Antibody screening includes a 37°C incubation followed by an indirect antiglobulin test or equivalent.<br>*Guidance: An alternative examination method may be used provided the manufacturer's instructions are followed and the method sensitivity is documented.* | CSTM 5.3.5.3<br>Z902 10.4.7 | |
| TRM9.3.4 | **M** | Additional examinations are completed for all positive antibody screens to determine the clinical significance and specificity of the antibody. | CSTM 5.3.5.5 | |
| TRM9.3.5 | **M** | Examination of patients with previously identified antibodies includes processes to determine whether there is evidence of any new antibody. | CSTM 5.3.5.6 | |
| TRM9.3.6 | **M** | Antibody investigations are reviewed by the medical director or designate. | | |
| **TRM9.4** | **There are procedures for direct antiglobulin testing (DAT).** | | | |
| TRM9.4.1 | **M** | Antiglobulin reagent used for a direct antiglobulin test contains antibodies to IgG and the C3d component of complement.<br>*Guidance: The only exceptions are cord blood and neonate testing which may be performed with anti-IgG reagent*. | CSTM 5.3.6.1 | |
| TRM9.4.2 | **M** | When a DAT on a clotted sample identifies complement on the red cell surface, the result is verified using an EDTA sample.<br>*Guidance: It is not necessary to collect an EDTA sample to re-examine a positive DAT on a neonate.* | CSTM 5.3.6.2 | |
| **TRM9.5** | **There are procedures for compatibility testing.** | | | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM9.5.1 | **M** | Serological compatibility testing uses the recipient's serum or plasma and donor cells from an originally attached segment. | CSTM 5.3.7.2.1<br>Z902 10.6.2 | |
| TRM9.5.2 | **M** | An immediate spin crossmatch is only used when the antibody screen is negative and there is no history of a clinically significant antibody. | CSTM 5.3.7.2.2 | |
| TRM9.5.3 | **M** | When the antibody screen indicates the presence of a clinically significant antibody, or the recipient has a history of clinically significant antibodies, red cells lacking the corresponding antigen are crossmatched using an antiglobulin or comparable technique. | CSTM 5.3.7.2.3<br>Z902 10.7.4 | |
| TRM9.5.4 | **M** | Compatibility testing is completed before red cells are transfused. | CSTM 5.3.7.1<br>Z902 10.6.1.1 | |
| **TRM9.6** | **There are procedures for a computer crossmatch.** | | | |
| TRM9.6.1 | **M** | A computer crossmatch is only used for recipients without clinically significant antibodies or a history of antibodies. | CSTM 5.3.7.3.1 | |
| TRM9.6.2 | **M** | When using a computer crossmatch, the recipient's ABO group is determined twice.<br>*Guidance: This includes ABO grouping on the current sample and verification by a second independent test of the same sample, previous ABO grouping stored in the computer system, or examination of a second correctly identified and labeled sample.* | CSTM 5.3.7.3.3<br>Z902 10.6.3.2 | |
| TRM9.6.3 | **M** | The system used is approved or validated and in full compliance with the requirements for a computer crossmatch. | Z902 10.6.3.1 | |
| TRM9.6.4 | **M** | The system contains recipient ABO and D groups and alerts the user to discrepancies between the current blood group results and previous results. | CSTM 5.3.7.3.4<br>Z902 10.6.3.3 | |
| TRM9.6.5 | **M** | The system alerts the user to discrepancies between the recipient and donor ABO group. | CSTM 5.3.7.3.7<br>Z902 10.6.3.4 | |
| TRM9.6.6 | **M** | The system includes information on the donor unit to be crossmatched including the unit donor number, the blood component type and the expiry date. | CSTM 5.3.7.3.6<br>Z902 10.6.3.3 | |
| TRM9.6.7 | **M** | The system alerts the user to discrepancies between the labeled donor ABO group and ABO confirmatory examination interpretation. | CSTM 5.3.7.3.8<br>Z902 10.6.3.4 | |
| TRM9.6.8 | **M** | The system prevents the release of ABO incompatible blood components. | CSTM 5.3.7.2.2<br>Z902 10.6.6.1 | |
| TRM9.6.9 | **M** | The ABO group of donor red cells is confirmed using a segment of the blood component if a serological cross match is not performed. | CSTM 5.2.5.1<br>Z902 10.6.3.5 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM9.6.10 | **M** | The D grouping of donor red cells is confirmed for all Rh negative units. | CAP TRM.40450 | |
| TRM9.6.11 | **M** | If there is any discrepancy with the confirmatory grouping and the blood bag label, the discrepancy is investigated, resolved and documented. The supplier is notified and the donor unit is returned to the supplier if requested. Unresolved discrepancies are documented as a nonconformance. | CSTM 5.3.7.3.5 | |

## TRM10.0 PROVISION OF BLOOD COMPONENTS AND PRODUCTS

| | | | | |
|---|---|---|---|---|
| **TRM10.1** | **There are procedures for the selection of red cells, plasma and platelets for transfusion.** | | | |
| TRM10.1.1 | **M** | Recipients receive ABO compatible red cells. | CSTM 5.4.2.1<br>Z902 10.7.1 | |
| TRM10.1.2 | **M** | There are policies and procedures for issuing blood components containing D-positive red cells to Rh-negative patients. | CSTM 5.4.2.2<br>Z902 10.7.3 | REVISED |
| TRM10.1.3 | **M** | Recipients of frozen red cells are informed of the screening procedures performed on the unit at the time of donation and freezing, as well as any subsequent testing of the donor. | CSTM 5.4.2.4<br>Z902 7.5.2.6 | |
| TRM10.1.4 | **M** | Recipients are transfused with plasma that is ABO compatible with their own red cells. | CSTM 5.4.3.1<br>Z902 10.7.5 | |
| TRM10.1.5 | **M** | There is a policy for ABO group substitution when ABO compatible platelets are not available. | CSTM 5.4.3.3<br>Z902 10.7.7 | |
| **TRM10.2** | **There are procedures to meet special transfusion requirements.** | | | |
| TRM10.2.1 | **M** | There are procedures that define when irradiated cellular blood components are provided.<br>*Guidance: Current BC Transfusion Medicine Advisory Group (TMAG) guidelines are available.* | CSTM 5.4.4.1.1-2<br>Z902 7.12.1, 11.7.1-2 | |
| TRM10.2.2 | **M** | There are documented processes to ensure that recipients of irradiated blood components continue to receive irradiated components as long as clinically indicated. | CSTM 5.4.4.1.4<br>Z902 11.7.3 | |
| TRM10.2.3 | **M** | There are documented processes to ensure that patients receive cytomegalovirus (CMV) safe or CMV negative blood components when required. | CSTM 5.4.4.2.1<br>Z902 11.6 | |
| TRM10.2.4 | | There are procedures for the transfusion of blood components and products to recipients with anti-IgA, or with an IgA deficiency and a history of severe allergic reactions.<br>*Guidance: Recipients with anti-IgA, or with an IgA deficiency and a history of severe allergic reactions receive red cells or platelets from IgA-deficient donors or red cells and platelets have been washed.* | CSTM 5.4.4.3.1-2<br>Z902 7.5.4.1 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM10.2.5 | | Red cells for transfusion are negative for Hemoglobin S when indicated. | CSTM 5.4.4.4.1<br>Z902 10.9.1.9 | REVISED |
| **TRM10.3** | **There are procedures for washing, pooling, mixing and aliquoting blood components and products.** | | | |
| TRM10.3.1 | **M** | Modification of blood components and products is performed using aseptic techniques in an area that minimizes the risk of contamination. | Z902 22.2.3<br>Z902 7.1.3 | |
| TRM10.3.2 | **M** | When red cells are mixed with plasma, plasma alloantibodies are compatible with the red cells. | CSTM 5.5.6.1 | |
| TRM10.3.3 | **M** | When a portion of a blood component is removed from the original container, the component label is changed to indicate the new volume. | DAP15 ver1.0 | |
| TRM10.3.4 | **M** | When pooling plasma, only units of the same ABO group are included. | CSTM 5.5.6.2 | |
| TRM10.3.5 | **M** | Platelets modification is performed at 20°C to 24°C. | CSTM 5.5.5.1 | |
| TRM10.3.6 | **M** | A record is maintained by the preparing facility which includes the identification numbers and collecting facility of each component in the pool or mixture. | CSTM 5.5.6.4<br>Z902 10.8.4 | |
| TRM10.3.7 | **M** | Reconstitution of blood products adheres to the manufacturer's recommendations. | CSTM 5.5.6.5, 5.5.7.1<br>Z902 14.4 | |
| TRM10.3.8 | **M** | When pooling blood products, only products from the same manufacturer are combined. | CSTM 5.5.6.5 | |
| TRM10.3.9 | **M** | The process for the preparation of washed red cells ensures that almost all of the plasma is removed, that 75% of the original red cells remain and that the hematocrit is not greater than 0.80 L/L. | CSTM 5.5.2.1.1<br>Z902 7.5.3.2 | |
| **TRM10.4** | **There are procedures for labeling modified blood components and products.** | | | |
| TRM10.4.1 | **M** | A new or additional label with a unique identification number, the blood component or product name, the ABO and Rh grouping, the modification performed, the modifying facility and the expiry date is applied to modified blood components and products. | CSTM 5.5.1.1<br>Z902 10.8.2 | |
| TRM10.4.2 | **M** | A new or additional label with the number of units in pooled blood components or blood products is applied to modified blood components and products. | CSTM 5.5.1.1<br>Z902 10.8.2 | |
| TRM10.4.3 | **M** | A new or additional label with the new volume is applied to modified blood components and products. | CSTM 5.5.1.1<br>Z902 10.8.2 | |
| TRM10.4.4 | | The new or additional label applied to modified blood components and products indicates the storage temperature. | CSTM 5.5.1.1<br>Z902 10.8.2<br>DAP TMAC 2012 | |
| TRM10.4.5 | **M** | The new label is compared to the original supplier label to ensure there is no discrepancy. | CSTM 5.5.1.1 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM10.4.6 | **M** | The new label Is firmly attached to the blood component or product. | CSTM 5.5.1.2<br>Z902 8.6.1.2 | |
| TRM10.4.7 | **M** | The new label is clear and legible. | CSTM 5.5.1.2<br>Z902 8.6.1.2 | |
| TRM10.4.8 | **M** | The label manufacturer has confirmed that adhesives and inks are safe for use. | CSTM 5.5.1.2<br>Z902 8.6.1.2 | |
| TRM10.4.9 | **M** | When barcoded labels are used ISBT 128 is followed. | CSTM 5.5.1.4<br>Z902 8.6.1.5 | |
| TRM10.4.10 | | Handwritten additions or changes are applied only to the label and not to the bag itself. | Z902 8.6.1.2<br>DAP TMAC 2012 | |
| TRM10.4.11 | | Only permanent moisture proof ink that will not leach through the label is used. | CSTM 5.5.1.3<br>Z902 8.6.1.2<br>DAP TMAC 2012 | |
| TRM10.4.12 | | Procedures ensure that all additions and changes are done using a consistent format that is understandable to the personnel who will be handling the blood component or product. | Z902 8.6.1.2<br>DAP TMAC 2012 | |
| TRM10.4.13 | | Procedures outline the steps to be taken if a label or bag is marked accidentally. | Z902 8.6.1.2<br>DAP TMAC 2012 | |
| TRM10.4.14 | **M** | The blood component and product label applied by the blood supplier is not obscured, changed or removed. | CSTM 5.1.1.2<br>Z902 8.6.3.2 | |
| TRM10.4.15 | **M** | Blood components and products do not have more than two visible unique identification numbers, one applied by the supplier and the second that is applied by the intermediate shipping or transfusing facility. | CSTM 5.1.1.3<br>Z902 8.6.2.2 | |
| **TRM10.5** | **There are procedures for the operation and maintenance of irradiators.** | | | |
| TRM10.5.1 | **M** | The transfusion service has a licence to operate an irradiator as per the Canadian Nuclear Safety Commission. | CSTM 3.3.3.1 | |
| TRM10.5.2 | **M** | Verification of dose delivery is performed and documented according to the licence requirement. | CSTM 3.3.3.3<br>Z902 7.12.4 | |
| TRM10.5.3 | **M** | The mechanical function of the irradiator is monitored and documented as required by the manufacturer. | CSTM 3.3.3.4 | |
| TRM10.5.4 | **M** | Irradiation time is adjusted to account for radioactive decay of the radiation source. Time adjustments are documented. | CSTM 3.3.3.5 | |
| TRM10.5.5 | **M** | The irradiator is checked for evidence of radiation leakage at the interval defined in the licence. | CSTM 3.3.3.6 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| **TRM10.6** | **There are procedures for the irradiation of blood components.** | | | |
| TRM10.6.1 | **M** | Procedures ensure that the required dose of irradiation has been applied to the blood component. | CSTM 5.5.8.1 | |
| TRM10.6.2 | **M** | Indicators are used to verify that each blood component has been exposed to an acceptable level of ionizing radiation. | Z902 7.12.3 | |
| TRM10.6.3 | **M** | A record of exposure is maintained. | DAP15 ver1.0 | |
| TRM10.6.4 | **M** | The amount of gamma irradiation delivered is not less than 25 Gy targeted to the mid-plane of the canister when using a free standing irradiator. | CSTM 5.5.8.2<br>Z902 7.12.2 | |
| TRM10.6.5 | **M** | The minimum dose is 15 Gy, and the maximum dose does not exceed 50 Gy for all locations in the canister or field of irradiation. | CSTM 5.5.8.2<br>Z902 7.12.2 | |
| TRM10.6.6 | **M** | Irradiated red cells have an expiry of 28 days from the time of irradiation or retain the original expiry date if this is less than 28 days. | CSTM 5.5.8.3<br>Z902 7.12.6 | |
| TRM10.6.7 | | There is a policy that defines the expiry date for irradiated red cells designated for prenatal and neonatal recipients. | Z902 10.9.1.10 | |
| TRM10.6.8 | **M** | The irradiating facility maintains a record of the date of irradiation. | CSTM 5.5.8.5 | |
| TRM10.6.9 | | A permanent label is applied to irradiated blood components indicating that the blood component has been irradiated, the facility performing the irradiation and if applicable, the new expiry date. | CSTM 5.5.8.4-5<br>Z902 7.12.5, 2 8.6.5.2 | |

## TRM11.0 PRENATAL EXAMINATIONS AND NEONATAL TRANSFUSION

| TRM11.1 | There are procedures for determining eligibility for Rh Immune Globulin (RhIg) therapy. | | | |
|---|---|---|---|---|
| TRM11.1.1 | **M** | Prenatal testing includes D typing and an antibody screen. | CSTM 5.3.8.1<br>SOGC CPG | |
| TRM11.1.2 | **M** | There are procedures to ensure that all potential candidates for RhIg therapy have their D type and antibody screen determined. | CSTM 5.3.8.1<br>CSTM 5.4.5.1<br>SOGC CPG | |
| TRM11.1.3 | **M** | RhIg is administered to Rh negative women not known to be immunized to the D antigen at 28 weeks gestation and following a procedure or event known to be associated with increased risk of Rh immunization due to fetomaternal hemorrhage. | CSTM 5.4.5.3<br>Z902 11.9.4<br>SOGC CPG | |
| TRM11.1.4 | | RhIg is administered within 72 hours, but may be given up to 28 days after the immunizing event. | CSTM 5.4.5.4<br>Z902 11.9.5 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM11.1.5 | | When a weakly reactive anti-D is detected in a post-partum Rh negative woman, a determination is made as to whether she received RhIg during her pregnancy. | CSTM 5.4.5.5<br>Z902 11.9.4<br>SOGC CPG | |
| TRM11.1.6 | **M** | Examination for weak D is not performed except in the case of a Rh negative neonate of an Rh negative mother with no evidence of D alloimmunization. | CSTM 5.3.8.1<br>SOGC CPG | |
| TRM11.1.7 | | An examination is performed to determine the amount of fetomaternal hemorrhage in an eligible candidate. The examination includes procedures to determine the appropriate dose of RhIg. | CSTM 5.4.5.6<br>Z902 11.9.5 | |
| TRM11.1.8 | | There are procedures for RhIg administration to Rh negative patients receiving components containing D positive red cells. | CSTM 5.4.5.7<br>Z902 11.9.7 | |
| **TRM11.2** | **There are pre-examination procedures for neonatal transfusion.** | | | |
| TRM11.2.1 | **M** | An appropriate venous or capillary sample from the mother or neonate is used for pre-transfusion examinations.<br>*Guidance: Cord blood is not acceptable for neonatal transfusion examination.* | CSTM 5.9.2.1<br>GOBC PBCO MPM 8.1<br>Z902 10.9.1.1 | |
| TRM11.2.2 | **M** | The neonate's ABO and D groups are determined. | CSTM 5.9.2.2<br>GOBC PBCO MPM 8.1 | |
| TRM11.2.3 | **M** | Screening for clinically significant red cell antibodies uses a neonatal sample when available. | CSTM 5.9.2.2<br>GOBC PBCO MPM 8.1 | REVISED |
| TRM11.2.4 | **M** | If the neonate is to receive non-group O red cells, the neonate's plasma or serum is tested by antiglobulin test (or equivalent) for the presence of passively acquired maternal anti-A or anti-B. | CSTM 5.9.2.4<br>GOBC PBCO MPM 8.1 | |
| TRM11.2.5 | **M** | If a neonate's initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units selected for transfusion either do not contain the corresponding antigen, or are compatible by antiglobulin crossmatch until the antibody is no longer demonstrable. | CSTM 5.9.2.6.2<br>GOBC PBCO MPM 8.1<br>Z902 10.9.1.6 | |
| TRM11.2.6 | | During a neonate's current hospital admission, after the initial ABO and D grouping, and antibody screening has been performed, repeat examinations may be omitted until the neonate reaches the age of four months. | CSTM 5.9.2.3,5.9.2.6.1<br>GOBC PBCO MPM 8.1<br>Z902 10.6.1.2,<br>10.9.1.4, 10.9.1.7 | |
| TRM11.2.7 | **M** | ABO compatibility is confirmed until the age of four months. Compatibility testing for children older than four months is defined. | CSTM 5.9.2.5<br>GOBC PBCO MPM 8.1 | |
| **TRM11.3** | **There are procedures for the selection of blood components and products for neonates.** | | | |
| TRM11.3.1 | **M** | CMV-seronegative red cells are provided for intrauterine transfusions and neonates with a birth weight less than 1200 g. | GOBC PBCO MPM 8.1<br>GOBC PBCO TMAG | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM11.3.2 | **M** | CMV-safe red cells are provided for neonates with a birth weight greater than 1200 g. | GOBC PBCO MPM 8.1 | |
| TRM11.3.3 | **M** | Cellular blood components from a blood relative are irradiated for neonatal transfusion. | CSTM 5.9.3.3 | |
| TRM11.3.4 | **M** | The storage period for irradiated red cells prior to exchange transfusion or transfusion to a neonate is defined. | Z902 10.9.1.10 | |
| TRM11.3.5 | | Red cells negative for Hemoglobin S are transfused in the case of massive transfusion to a neonate including exchange transfusion. | CSTM 5.9.3.4<br>Z902 10.9.1.9 | |
| TRM11.3.6 | | Platelet concentrates are ABO and Rh compatible with the neonate. There is a policy to address when ABO and Rh compatible platelets are not available. | CSTM 5.9.3.5 | |
| TRM11.3.7 | **M** | ABO selection for neonates defines whether group specific or group O cells are used. | DAP TMAC | |
| TRM11.3.8 | **M** | There are procedures that address aliquoting the required volume of blood component in the laboratory or at the bedside. The procedures ensure that positive patient identification and connection to the component or product being transfused is maintained at all times. | DAP TMAC | |
| TRM11.3.9 | | Compatibility testing for exchange and intrauterine transfusion is performed with maternal plasma or serum. If maternal plasma or serum is not available, a sample collected from the neonate is used. | CSTM 5.9.4.1 | |
| TRM11.3.10 | **M** | Red cells selected for exchange transfusion are ABO and Rh compatible with the neonate and negative for antigens corresponding to any clinically significant maternal antibodies. | CSTM 5.9.4.2 | |
| TRM11.3.11 | | Red cells intended for exchange and intrauterine transfusion are processed prior to transfusion to remove storage media and plasma. | CSTM 5.9.4.3 | |
| TRM11.3.12 | | Cellular blood components for intrauterine transfusion are irradiated. | Z902 11.7.2 | |

## TRM12.0 COMPATIBILITY LABELING, ISSUE AND RETURN

| TRM12.1 | | There are procedures for the release of blood components prior to the completion of pre-transfusion examinations. | | |
|---|---|---|---|---|
| TRM12.1.1 | **M** | There are procedures that address abbreviation of examinations and compatibility testing and issuing blood in emergency situations including massive transfusion events. | CSTM 5.3.7.4.2 | |
| TRM12.1.2 | **M** | The medical director of the transfusion service authorizes any abbreviation of examinations or compatibility testing. | CSTM 5.3.7.2.4 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM12.1.3 | **M** | When there is insufficient time to complete ABO and Rh grouping or a sample cannot be obtained, group O red cells are issued. Group O Rh negative red cells are issued for women of childbearing potential and children. | CSTM 5.3.7.4.4<br>Z902 10.9.3.2 | |
| TRM12.1.4 | **M** | When red cells are issued before pre-transfusion compatibility testing is complete, a label is attached to the component indicating that testing is incomplete. Upon completion of compatibility testing, the transfusion service notifies the recipient's physician and the transfusion service medical director if the compatibility testing is subsequently found to be incompatible. | CSTM 5.3.7.4.2<br>Z902 10.9.3.6 | |
| TRM12.1.5 | | Group AB plasma, if required, is issued when there is insufficient time to complete ABO and Rh grouping or a sample cannot be obtained. | CSTM 5.3.7.4.4 | |
| TRM12.1.6 | **M** | When time allows, the ABO and Rh group of the recipient is determined and blood components of the appropriate group are issued.<br>*Guidance: The patient's ABO and Rh group cannot be established from previous records only.* | CSTM 5.3.7.4.5<br>Z902 10.9.3.3 | |
| **TRM12.2** | **There are procedures for the release of outdated, untested or incompletely tested blood components.** | | | |
| TRM12.2.1 | **M** | Blood components and products are not used after their expiry date unless approval has been obtained from the transfusion service medical director or designate in consultation with the ordering physician if necessary. This conversation and approval are documented. | CSTM 5.4.1.2<br>Z902 10.7.2, 14.6.1 | |
| TRM12.2.2 | **M** | There are procedures that address the release of untested or incompletely tested blood components prior to the completion of required testing by the blood supplier. | CSTM 5.7.6.1 | |
| TRM12.2.3 | **M** | Medical personnel are notified of any blood component on which any examination is incomplete and authorize the use of the blood component prior to issue. This is documented and includes the clinical situation. | CSTM 5.7.6.1 | |
| TRM12.2.4 | **M** | A label is attached to untested or incompletely tested blood components indicating that testing has not been completed by the blood supplier. | CSTM 5.7.6.1, 5.7.6.2<br>Z902 8.6.5.4 | |
| TRM12.2.5 | **M** | Upon completion of examinations and receipt of the results from the blood supplier, the transfusion service communicates all results to medical personnel and documents all results in the patient's chart and the transfusion service record. | CSTM 5.7.6.1<br>Z902 10.9.3.6 | |
| TRM12.2.6 | | Informed consent is obtained from the recipient, if possible, when issuing unexamined or incompletely examined blood components. | Z902 10.9.3.5<br>CSTM 5.7.6.2 | |
| **TRM12.3** | **A compatibility label is attached to all issued blood components and products.** | | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM12.3.1 | **M** | A compatibility label is attached to all issued blood components that identifies the recipient's first and last name, identification number, ABO and Rh group. | CSTM 5.7.2.1, 5.7.2.2<br>Z902 11.1.2.2 | |
| TRM12.3.2 | **M** | The compatibility label on blood components identifies the ABO group, the identification number and the type of blood component as well as the date and time of issue. | CSTM 5.7.2.1<br>Z902 11.1.2.2 | |
| TRM12.3.3 | **M** | The compatibility label on red cells and components that may contain red cells identifies the Rh group of the recipient, and the Rh group and the compatibility status of the blood component. | CSTM 5.7.2.2 | |
| TRM12.3.4 | **M** | The compatibility label on platelets identifies the Rh group of the recipient and the blood component. | CSTM 5.7.2.3 | |
| TRM12.3.5 | **M** | The compatibility label on pooled components includes the pooled unit identification number. | CSTM 5.7.2.4 | |
| TRM12.3.6 | **M** | A compatibility label is attached to all blood products issued that identifies the recipient's first name, last name and identification number. | CSTM 5.7.2.7<br>Z902 14.2 | |
| TRM12.3.7 | **M** | The compatibility label on blood products identifies the type of blood product, the lot number or unique identification number, and the volume or units of dosage. | CSTM 5.7.2.7<br>Z902 14.2 | |
| **TRM12.4** | **There are procedures for the issue of blood components and products.** | | | |
| TRM12.4.1 | **M** | There is a request form or electronic equivalent to ensure the accurate issue of a blood component or product for the intended recipient.<br>*Guidance: Although CSTM and CSA standards refer to an issue voucher, for the purpose of accreditation, the term request form is used since an issue voucher is received from the Canadian Blood Services with shipped blood components and products.* | DAP TMAC 2012 | |
| TRM12.4.2 | **M** | Information required on the request form or in the electronic equivalent includes the recipient's first name, last name and identification number as well as the type of blood component or product and amount if applicable. | CSTM 5.7.5.1 | |
| TRM12.4.3 | **M** | An alternative validated system for the request form is developed when a pneumatic tube system is used to transport blood components or products. | Z902 17.5, 9.5.3 | |
| TRM12.4.4 | **M** | All blood components and products are inspected for abnormal appearance immediately prior to issue and this inspection is documented. | CSTM 5.7.3.1<br>Z902 10.10.2 | |
| TRM12.4.5 | **M** | When an abnormality is detected the unit is not issued and quarantined until appropriate disposition is determined. The blood supplier is notified regarding the final disposition. This notification is documented. | CSTM 5.7.3.1<br>Z902 10.10.2 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM12.4.6 | **M** | There is a procedure to verify the identification of the recipient and the blood component or product. | CSTM 5.7.4.1<br>Z902 11.3.1 | |
| TRM12.4.7 | **M** | The information on the compatibility label is checked against the information on the blood component or product. | CSTM 5.7.4.2<br>Z902 11.3.1 | |
| TRM12.4.8 | **M** | When information does not agree the blood component or product is not issued for transfusion and the discrepancy is resolved. | CSTM 5.7.4.3<br>Z902 11.3.5 | |
| TRM12.4.9 | **M** | There are procedures for the issue of blood components and products during hours when laboratory personnel are not present. | CSTM 5.7.1.1 | |
| TRM12.4.10 | **M** | Non-laboratory personnel who obtain blood from the emergency supply or tagged cross-matched blood have appropriate training and competency assessment. | DAP15 ver1.0 | |
| TRM12.4.11 | | Information or a product insert for each blood component or product used at a facility is available for reference and for distribution, if needed.<br>*Guidance: The information provides direction on storage conditions, composition and properties, indications for use, contraindications, and possible adverse events.* | CSTM 5.7.1.2<br>Z902 10.10.4 | |
| TRM12.4.12 | **M** | Policies and procedures for issuing blood components containing D positive red cells to Rh negative patients are available. | CSTM 5.4.2.2, 3<br>Z902 10.7.3, 11.9.7 | |
| **TRM12.5** | **Records for issued blood components and products are maintained.** | | | |
| TRM12.5.1 | **M** | A copy of all information relating to the recipient and the transfused blood component or product forms a permanent transfusion record for the patient. | CSTM 5.7.5.4<br>Z902 10.10.3, 11.2.1 | |
| TRM12.5.2 | **M** | For issued blood components and products the record documents the recipient's first name, last name and identification number. | CSTM 5.7.5.2, 5.7.5.3<br>Z902 11.1.2.2-3, 14.5 | |
| TRM12.5.3 | **M** | For issued blood components and products the record documents the visual inspection, the date and time of issue, the identity of the person issuing the blood component or product and identity of the person transporting the blood component or product to the recipient's location. | CSTM 5.7.5.2-3<br>Z902 11.1.2.2-3, 14.5 | |
| TRM12.5.4 | **M** | For issued red cells and platelets the record documents the recipient's ABO and Rh group. | CSTM 5.7.5.2<br>Z902 11.1.2.2 | |
| TRM12.5.5 | | For issued blood components the record documents the blood component identification number and a verification of compatibility for red cells. | CSTM 5.7.5.2<br>Z902 11.1.2.2 | |
| TRM12.5.6 | | For blood products issued the record documents the blood product name, lot number, volume, potency, manufacturer and the dosage or vials issued. | CSTM 5.7.5.3<br>Z902 14.5 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| **TRM12.6** | **There are procedures for the return and disposal of blood components and products.** | | | |
| TRM12.6.1 | **M** | Blood components and products are returned to the transfusion service immediately if the decision is made not to transfuse. | CSTM 5.8.1.3 | |
| TRM12.6.2 | **M** | When blood components are returned to inventory a visual inspection confirms the component is acceptable and that the bag is intact with at least one attached, sealed segment. | CSTM 5.7.7.1<br>Z902 10.10.5, 14.6.2 | |
| TRM12.6.3 | **M** | When blood components are returned to inventory, a temperature-monitoring system indicates that the blood component has not reached an unacceptable temperature since being released, or in the absence of a temperature monitoring system, that the blood component has not been outside of a controlled environment for more than 30 minutes. | CSTM 5.7.7.2<br>Z902 10.10.5, 11.4.7, 14.6.2 | |
| TRM12.6.4 | **M** | When blood products are returned to inventory, a visual inspection confirms the product is acceptable, the container is intact and storage conditions of the blood product are within the manufacturer's recommendations. | CSTM 5.7.7.2<br>Z902 14.6.2 | |
| TRM12.6.5 | **M** | All blood components and products, containers and tubing are disposed of in accordance with hospital procedures and any applicable regulations. | CSTM 5.6.2.1, 5.8.3.13<br>Z902 9.4.9 | |

## TRM13.0 TRANSFUSION, PATIENT MONITORING AND ADVERSE EVENTS

| **TRM13.1** | **There are procedures for transfusion orders.** | | | |
|---|---|---|---|---|
| TRM13.1.1 | **M** | Transfusion of blood components and products is prescribed only by a physician or an alternate health-care provider that has been approved by a documented process. | CSTM 5.8.1.2<br>Z902 11.4.3 | |
| TRM13.1.2 | **M** | The transfusion order specifies the recipient's first and last name and identification number. | CSTM 5.8.1.2 | |
| TRM13.1.3 | **M** | The transfusion order specifies the clinical indication for transfusion, the number or dosage and the specific blood component or product required. | CSTM 5.8.1.2 | |
| TRM13.1.4 | | The transfusion order specifies the rate of infusion or duration, the date and time of the transfusion, if known, and the sequence in which multiple blood components and products are to be transfused, if known.<br>*Guidance: In urgent situations or massive transfusion, the sequence may depend on which components or products are delivered to the patient first.* | CSTM 5.8.1.2<br>Z902 11.4.4 | |
| TRM13.1.5 | | The transfusion order specifies any modification to the blood component or product, any special transfusion requirements, and the use of a blood warmer or rapid infusion device with the exception of clinical areas where there is an established hospital policy and procedure. | CSTM 5.8.1.2 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM13.1.6 | | The transfusion order specifies the use of a blood warmer or rapid infusion device with the exception of clinical areas where there is an established hospital policy and procedure. | CSTM 5.8.1.2 | |
| **TRM13.2** | **There are procedures for the unequivocal identification of the recipient prior to transfusion.** | | | |
| TRM13.2.1 | **M** | All transfusionists have received specialized training on the positive identification of recipients. | CSTM 5.8.2.1<br>Z902 12.4.3 | |
| TRM13.2.2 | **M** | Immediately before transfusion and in the presence of the recipient, the transfusionist confirms and documents that all identifying information linking the recipient and the blood component or product matches. This information includes the recipient's identification band, the compatibility label and the patient record. | CSTM 5.8.2.2, 5.8.2.3<br>Z902 11.3.1-3 | |
| TRM13.2.3 | **M** | Transfusion is not initiated if any discrepancy is found in identification information, until the discrepancy is resolved. | CSTM 5.8.2.4<br>Z902 11.3.5 | |
| TRM13.2.4 | **M** | The compatibility label remains attached to the blood component or product until completion of the transfusion. | CSTM 5.8.2.5<br>Z902 11.3.4 | |
| **TRM13.3** | **There are procedures for the use of transfusion devices, equipment and administration sets.** | | | |
| TRM13.3.1 | **M** | Blood components and products are transfused through a standard sterile, pyrogen-free administration set that has a filter designed to retain particles potentially harmful to the patient.<br>*Guidance: Refer to established hospital procedures for filter size or specific tubing sets and to the product insert for filter requirements for blood products.* | CSTM 5.8.3.1<br>Z902 11.4.8 | |
| TRM13.3.2 | **M** | Blood warmer or rapid infusion devices are only used with a physician's order, except In clinical areas where there is an established hospital policy and procedure. | CSTM 5.8.3.9 | |
| TRM13.3.3 | **M** | Only Health Canada-approved infusion devices and ancillary equipment are used for transfusion. | CSTM 5.8.3.3<br>Z902 11.4.2 | |
| TRM13.3.4 | **M** | All equipment is used according to the manufacturer's recommendations. | CSTM 3.5.1<br>Z902 11.5.2 | |
| TRM13.3.5 | **M** | Medications, including those intended for intravenous administration, are not added directly to a blood component or product or to the administration set. | CSTM 5.8.3.4<br>Z902 11.4.11 | |
| TRM13.3.6 | **M** | Only a 0.9% sodium chloride solution is used to prime the administration set if priming is required. When intravenous immune globulin (IVIG) is not compatible with 0.9% sodium chloride, D5W is used. | CSTM 5.8.3.6<br>Z902 11.4.9 | |
| TRM13.3.7 | **M** | All connections are secured and directly luer-locked to the IV insertion site. | CSTM 5.8.3.10 | |

| No. | Standard<br>Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM13.3.8 | | The needle gauge has a diameter large enough to allow appropriate flow rates and avoid cell damage. | CSTM 5.8.4.2 | |
| TRM13.3.9 | **M** | Administration sets are changed according to manufacturer's recommendations and immediately prior to the transfusion of platelets. | CSTM 5.8.3.8<br>Z902 11.4.12 | |
| TRM13.3.10 | | The administration set is changed at least once every 24 hours, after a maximum of four red cell units have been infused through the set, if the set becomes occluded or when changing to another type of blood component. | CSTM 5.8.3.8<br>Z902 11.4.12 | |
| TRM13.3.11 | **M** | The administration of red cells is completed within four hours from the time of removal from a temperature-controlled environment. | CSTM 5.8.4.1<br>Z902 11.4.6 | |
| TRM13.3.12 | **M** | A record of transfusion is entered into the recipient's medical chart that includes the type of blood component or product, the identification number, the start and finish date and time, the identity of the transfusionist and any transfusion reactions. | CSTM 5.8.5.1<br>Z902 11.1.2.3 | |
| **TRM13.4** | **There are procedures for monitoring transfusion recipients.** | | | |
| TRM13.4.1 | **M** | Recipient vital signs are recorded prior to, during, and after transfusion. | CSTM 5.8.3.11<br>Z902 11.4.13 | |
| TRM13.4.2 | **M** | The recipient is monitored by qualified personnel for suspected adverse reactions during and after transfusion. | CSTM 5.8.3.11<br>Z902 11.4.14 | |
| TRM13.4.3 | **M** | A list of common signs and symptoms of suspected adverse reactions is available to the transfusionist. | Z902 18.2.1 | |
| TRM13.4.4 | **M** | If direct monitoring is not possible after transfusion (e.g. the recipient is discharged), the recipient or a responsible caregiver are given instructions concerning possible adverse reactions. | CSTM 5.8.3.11<br>Z902 11.4.14 | |
| **TRM13.5** | **There are procedures for the documentation and reporting of adverse reactions.** | | | |
| TRM13.5.1 | **M** | There are procedures for the documentation, reporting, evaluation and follow-up of all suspected transfusion reactions. | CSTM 7.2.1.1<br>Z902 18.1.1 | |
| TRM13.5.2 | **M** | In the event that a patient exhibits signs of a transfusion reaction, the transfusionist follows established hospital procedures for management of a transfusion reaction. | CSTM 5.8.3.12 | |
| TRM13.5.3 | **M** | The laboratory has defined when a suspected adverse transfusion reaction is to be reported to the transfusion service. At a minimum, serious adverse transfusion reactions are reported. | CSTM 7.2.2.2<br>Z902 18.2.1 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM13.5.4 | **M** | The transfusion service investigates all reports of suspected adverse reactions. The investigation determines the probable cause and includes appropriate laboratory examinations. | CSTM 7.2.2.3<br>Z902 18.2.2 | |
| TRM13.5.5 | **M** | The transfusion service submits reports of adverse reactions to authorities as required by regulations. | CSTM 7.2.2.4<br>Z902 18.2.2 | |
| TRM13.5.6 | **M** | Any adverse reaction that can be attributed to the quality of a blood component or product is reported to the blood supplier or to the blood product manufacturer. | CSTM 7.2.2.5<br>Z902 18.2.4 | |
| TRM13.5.7 | **M** | All serious adverse reactions including fatalities related to blood transfusion are reported to the blood supplier or blood product manufacturer within 24 hours. | CSTM 7.2.2.6<br>Z902 18.2.5 | |
| TRM13.5.8 | **M** | A report of any adverse reaction investigation, including recommendations for management of future transfusions is placed in the recipient's medical record. The transfusion service obtains a copy, and the information is accessed if the recipient requires further transfusion. | CSTM 7.2.2.7<br>Z902 18.2.7 | |
| **TRM13.6** | **There are procedures for the management and investigation of suspected hemolytic transfusion reactions.** | | | |
| TRM13.6.1 | **M** | There are guidelines for clinical personnel to recognize and manage suspected hemolytic transfusion reactions. | CSTM 7.2.1.1<br>Z902 18.1.1 | |
| TRM13.6.2 | **M** | In cases of suspected hemolytic transfusion reactions, the transfusion is stopped and investigation begins immediately. The investigation is documented. | CSTM 7.2.3.1<br>Z902 18.3.1 | |
| TRM13.6.3 | **M** | The implicated blood component is returned to the transfusion service. | CSTM 7.2.3.1<br>Z902 18.3.1 | |
| TRM13.6.4 | **M** | A post-transfusion blood sample is collected and sent to the transfusion service with any accompanying documentation. | CSTM 7.2.3.3<br>Z902 18.3.3 | |
| TRM13.6.5 | **M** | All relevant documentation is compared and verified to exclude clerical errors. | Z902 18.3.2 | |
| TRM13.6.6 | **M** | The identification of the recipient and the recipient's pre-transfusion blood results are verified. | CSTM 7.2.3.2<br>Z902 18.3.2 | |
| TRM13.6.7 | **M** | At a minimum, investigation includes a visual hemolysis check and a direct antiglobulin test. All aspects of the investigation are documented. | CSTM 7.2.3.3<br>Z902 18.3.3 | |
| **TRM13.7** | **There are procedures for the management and investigation of transfusion-transmitted bacterial sepsis and disease.** | | | |
| TRM13.7.1 | **M** | There are guidelines for clinical personnel to recognize and manage the signs and symptoms of transfusion-transmitted bacterial sepsis. | DAP15 ver1.0 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM13.7.2 | **M** | In cases of suspected transfusion-transmitted bacterial sepsis the transfusion is stopped and investigation begins immediately. | CSTM 7.2.4.1 | |
| TRM13.7.3 | **M** | The implicated blood component or product is returned to the transfusion service. Care is taken to avoid further contamination. | CSTM 7.2.4.1 | |
| TRM13.7.4 | **M** | Recipient blood cultures are included in the investigation. All aspects of the investigation are documented. | CSTM 7.2.4.3 | |
| TRM13.7.5 | **M** | Microbiological investigation of the blood component or product is performed according to established guidelines.<br>*Guidance: Typically, segments are not used for culture but if the medical director believes that further investigation is warranted, segments may be cultured in addition to bags.* | CSTM 7.2.4.2<br>DAP TMAC 2013 | |
| TRM13.7.6 | **M** | Any bacteria isolated from the blood component and product or recipient blood cultures are retained for further typing as required. | CSTM 7.2.4.4 | |
| TRM13.7.7 | **M** | If bacterial contamination is suspected, the blood supplier is notified. | CSTM 7.2.4.5 | |
| TRM13.7.8 | **M** | All cases of suspected transfusion-transmitted diseases (e.g. malaria) are reported promptly to the transfusion service, the manufacturer, blood supplier or Public Health Services. | CSTM 7.2.5.1<br>Z902 18.5.1 | |
| TRM13.7.9 | **M** | When notified, the transfusion service participates in a traceback process of suspected transfusion-transmitted disease by submitting a list of transfused blood components and products to the blood supplier and Public Health Services. | CSTM 7.2.5.2<br>Z902 18.5.1 | |

## TRM14.0 LOOKBACK AND RECALL

| | | | | |
|---|---|---|---|---|
| **TRM14.1** | **There are procedures for lookback notifications.** | | | |
| TRM14.1.1 | **M** | The transfusion service acknowledges receipt of lookback notifications. | CSTM 7.2.6.2 | |
| TRM14.1.2 | **M** | Documents related to recipient notification become part of the recipient's record and are subject to confidentiality regulations. | CSTM 7.2.6.3<br>Z902 19.3.6 | |
| TRM14.1.3 | **M** | The transfusion service notifies the physician of a recipient (or the recipient directly if required), identified in a lookback notification within 30 days of notification from the blood supplier. | CSTM 7.2.6.1<br>Z902 19.3.6 | |
| **TRM14.2** | **There are procedures for the recall of blood components and products.** | | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM14.2.1 | **M** | There are procedures for the rapid recall of any released blood components or products at any time. | CSTM 7.2.7.1<br>Z902 19.4.1 | |
| TRM14.2.2 | **M** | The recall procedure identifies the individual(s) responsible for recall activities including initiation and coordination. | CSTM 7.2.7.1<br>Z902 19.4.1 | |
| TRM14.2.3 | **M** | Receipt of recall notification is acknowledged. | CSTM 7.2.7.2<br>Z902 19.4.6 | |
| TRM14.2.4 | **M** | Recalled blood components and products are quarantined until final disposition is determined. | CSTM 7.2.7.3<br>Z902 19.4.5 | |
| TRM14.2.5 | **M** | Recipients of recalled blood components and products are notified as required. | CSTM 7.2.7.1<br>Z902 19.4.2 | |
| **TRM14.3** | **There are procedures for the removal of unsafe blood components and products.** | | | |
| TRM14.3.1 | **M** | When post-donation information indicates a blood component or product may cause harm to a recipient, there is prompt retrieval and safe disposal of those blood components and products. | CSTM 7.2.9.1<br>Z902 19.1.1 | |
| TRM14.3.2 | **M** | Recipients are notified when post-donation information indicates a blood component or product may cause harm. | CSTM 7.2.9.1<br>Z902 19.1.2 | |
| TRM14.3.3 | **M** | Activity related to the receipt of post-donation information is documented. | CSTM 7.2.9.1<br>Z902 19.1.3 | |

## TRM15.0 TRANSPORTATION OF BLOOD COMPONENTS AND PRODUCTS

| | | | | |
|---|---|---|---|---|
| **TRM15.1** | **There are procedures for the transportation of blood components and products.** | | | |
| TRM15.1.1 | **M** | Blood components and products are transported in a manner that will ensure that optimal conditions are maintained at all times.<br>*Guidance: Transportation applies to the shipment of blood components and products from one facility to another, including shipments between affiliated sites, other buildings within a site, and returns to the blood supplier.* | CSTM 5.6.1.1<br>Z902 9.5.2-3 | |
| TRM15.1.2 | **M** | Blood components and products are transported in a validated container and there is documented evidence that acceptable storage conditions are maintained at all times.<br>*Guidance: After the container has been initially validated there should be some intermittent monitoring of the ability of the container to maintain an acceptable temperature range. It is not intended that the facility should constantly monitor validated containers. This also includes transport by pneumatic tube system.* | CSTM 5.6.1.5<br>Z902 9.5.2.1-3<br>CSTM 5.6.1.7 | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM15.1.3 | **M** | Transportation containers for blood components and products are constructed to resist damage and include a tamper evident seal. | CSTM 5.6.1.6 | |
| TRM15.1.4 | **M** | All blood components and products are inspected for abnormal appearance immediately before packing for transport, and this inspection is documented. | CSTM 5.6.1.3<br>Z902 9.5.2.5 | |
| TRM15.1.5 | **M** | Blood components and products not suitable for transfusion are clearly identified. If these are transported for investigation or disposal the container's outside label clearly indicates that the contents are not for transfusion. | CSTM 5.6.1.4<br>Z902 9.5.2.5 | |
| TRM15.1.6 | **M** | Transportation times for blood components and products do not exceed the limit of the validated transport container. | Z902 9.5.2.4 | |
| TRM15.1.7 | **M** | Discontinuation of platelet agitation during transportation does not exceed 24 hours. | CSTM 5.6.1.8 | |
| TRM15.1.8 | **M** | When blood components and products are transported within a single health-care facility site, procedures define who may receive and transport blood components and products from the transfusion service to the recipient's location, the maximum time for transport, and acceptable storage locations. | CSTM 5.6.1.13<br>Z902 9.5.3 | |
| TRM15.1.9 | **M** | Internal assessments are conducted to ensure compliance with established packing and transportation procedures. | CSTM 5.6.1.2<br>Z902 9.5.1 | |
| **TRM15.2** | **Labeling and documentation requirements for shipping blood components and products are defined.** | | | |
| TRM15.2.1 | **M** | An outer label that meets transport regulations is applied to all shipping containers that identifies the shipping facility, the receiving facility and confirms the contents are blood components and products. | CSTM 5.6.1.9<br>Z902 9.5.2.6 | |
| TRM15.2.2 | **M** | A packing slip with a unique serial number is included with each shipment that identifies the shipping facility and the receiving facility. | CSTM 5.6.1.10<br>Z902 9.5.2.7 | |
| TRM15.2.3 | **M** | The packing slip includes total number, identification numbers and types of blood components and products. | CSTM 5.6.1.10<br>Z902 9.5.2.7 | |
| TRM15.2.4 | **M** | The packing slip includes the dates and times of packing and shipping and the identity of the individual who packed the shipment. | CSTM 5.6.1.10<br>Z902 9.5.2.7 | |
| TRM15.2.5 | **M** | The packing slip includes the status of any quarantined blood components and products being transported. | CSTM 5.6.1.10<br>Z902 9.5.2.7 | |
| **TRM15.3** | **Recipient blood samples and donor segments are stored after examination or transfusion.** | | | |

| No. | Standard Criterion | | Reference | Change |
|---|---|---|---|---|
| TRM15.3.1 | **M** | Recipient blood samples are stored at 1°C to 6°C for at least seven days after transfusion. | CSTM 5.2.3.5<br>Z902 11.1.2.5 | |
| TRM15.3.2 | **M** | An identifiable segment from the donor unit of all transfused red cells is stored at 1°C to 6°C for at least seven days after transfusion. | CSTM 5.3.1.6 | |

## TRM16.0 HOSPITAL-BASED DONATIONS AND HOME TRANSFUSION

| TRM16.1 | | There are procedures for hospital based donations and home transfusion programs. | | |
|---|---|---|---|---|
| TRM16.1.1 | **M** | Policies and procedures for hospital-based donations comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed. | CSTM 2.12, 2.14, 5.10.1.1-2<br>Z902 12.1.1-2, 12.1.6 | |
| TRM16.1.2 | **M** | Policies, processes and procedures for preoperative autologous donations comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed. | CSTM 5.10.2.-4<br>Z902 12.1.1 | |
| TRM16.1.3 | **M** | Policies, processes and procedures for perioperative autologous donation programs comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed. | CSTM 5.10.4.1-6<br>Z902 12.5 | |
| TRM16.1.4 | **M** | Policies, processes and procedures for directed and designated donation programs comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed. | CSTM 5.10.5.1-6 | |
| TRM16.1.5 | **M** | Policies, processes and procedures for a home transfusion program comply with CSTM standards, CSA-Z902-10 standards and Health Canada Blood Regulations, if performed. | CSTM 5.11.1.2-5.11.3.1<br>Z902 17.6.1-5 | |

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