DIAGNOSTIC ACCREDITATION PROGRAM

Accreditation Standards

Laboratory Medicine

Version 1.5 Revision Record

Effective February 1, 2021

ORGANIZATION

Standard or criterion number	Version 1.4	Version 1.5 revision
ORG1.1.7	The laboratory uses a risk management framework to identify and manage significant risks to quality and safety. *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.*	**Revised** The laboratory uses a risk management framework to identify and manage significant clinical and non-clinical risks to the organization. *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.*
ORG2.2.8	Laboratory directors establish an operational plan that is consistent with the strategic direction of the organization.	**Revised** Laboratory directors establish an operational plan that is consistent with the strategic direction of the organization and includes defined monitoring and measurement of the plan's progress.

Standard or criterion number	Version 1.4	Version 1.5 revision
ORG4.6.15	• sensitivity to cultural and religious diversity	**Revised** • sensitivity to cultural, religious and gender diversity

SAFETY

Standard or criterion number	Version 1.4	Version 1.5 revision
SAF2.1.2	**M** Safety inspections assess firefighting equipment and alarms. Alarm systems are tested at a defined frequency.	**M** **Revised** Laboratory management is responsible for ensuring that fire safety inspections are undertaken at a defined frequency. Fire safety inspections include the assessment of firefighting equipment and alarms.
SAF2.1.8		**M** **New** There is a policy for the use of personal electronic devices in the work area.
SAF2.1.9		**M** **New** Decorations are not attached to lights, light fixtures, work surfaces or technical instruments.
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	**M** **Revised** The Workplace Hazardous Materials Information System (WHMIS) training program is reviewed by the safety officer or designate, at least annually or more frequently if required by a change in work conditions or available hazard information.

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** Long-sleeved fluid-resistant protective clothing that are closed in the front, are worn when working with biological and chemical hazardous materials. *Guidance: The intent is to protect skin and street clothing.*
SAF3.2.13			**M**	**New** Protective clothing worn inside the laboratory shall be removed before entering non laboratory areas.
SAF3.5.1	**M**	Consolidated supplies for first aid are in a defined location in the laboratory. First aid services are available on site. Guidance: An emergency department typically has resources equivalent to a first aid room and a first aid kit. First aid attendants are still required to address non-ambulatory injuries.	**M**	**Revised** Basic first aid supplies are always readily accessible in a defined and labelled location within the laboratory. *Guidance: There is a procedure available for calling for medical assistance and prompt transfer to an emergency room or a hospital when required.*
SAF3.6.2	**M**	Emergency showers are available and conveniently located. Emergency showers are tested and flushed monthly. This is documented. *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.*	**M**	**Revised** Emergency showers are tested and flushed monthly. This is documented.
SAF3.6.3			**M**	**New** Facilities perform a risk assessment to determine if an emergency shower is appropriately located or required.
SAF3.7.4	**M**	There are procedures indicating the frequency and method of environmental cleaning and disinfection. This is documented.	**M**	**Revised** There is a record of the environmental cleaning.

Standard or criterion number	Version 1.4		Version 1.5 revision	
SAF3.7.8		Floor surfaces are slip resistant and easily cleanable.	**M**	**Revised to mandatory requirement**
SAF3.8.4	**M**	All laboratory personnel participate in an emergency evacuation drill (e.g. fire drill) at least once per year and a record of the drills must be kept.	**M**	**Revised** Laboratory personnel participate in an emergency evacuation drill (e.g. fire drill) at least once per year and a record of the attendance must be kept.
SAF5.1.9	**M**	Acids are stored in cabinets approved for acid storage and separate from alcohols.	**M**	**Revised** Acids are stored in dedicated cabinets for acid storage and separate from alcohols.
SAF5.2.2	**M**	Flammable liquids and gases are stored only in approved cabinets.	**M**	**Revised** Flammables are stored in an approved flammable liquid cabinet.
SAF5.2.5	**M**	Metal storage containers are grounded to avoid static charge. *Guidance: Safety cabinets may be grounded in addition to metal storage containers, but not instead of.*	**M**	**Revised** Metal storage containers and cabinets for bulk flammable liquids are grounded as per manufacturer instructions. *Guidance: Safety cabinets may be grounded in addition to metal storage containers, but not instead of.*
SAF10.4.2		Patients are informed of their rights.		**Revised** There are documented mechanisms in place to inform patients of their rights and responsibilities.

FACILITIES

Standard or criterion number	Version 1.4		Version 1.5 revision	
FAC1.3.11	**M**	Illumination provides for safe working conditions. Emergency lighting is available in the event of power failure.	**M**	**Revised** Illumination provides for safe working conditions. Emergency lighting, for example, a flashlight is available in the event of power failure.

QUALITY ASSURANCE

Standard or criterion number	Version 1.4		Version 1.5 revision	
QUA2.3.7	**M**	A record of corrective action for DAP-reportable tests is filed. *Guidance: DAP reportable criteria can be found in the DAP Laboratory Medicine PT Manual.*	**M**	**Revised** A record of corrective action for DAP-reportable tests is submitted to the DAP. *Guidance: DAP reportable criteria can be found in the DAP Laboratory Medicine PT Manual.*

PRE-EXAMINATION

Standard or criterion number	Version 1.4		Version 1.5 revision	
PRE1.1.19			**M**	**New** The organization or facility provides patient/users information on how to access laboratory services on their website or on their lab requisition.

POST-EXAMINATION

Standard or criterion number	Version 1.4		Version 1.5 revision	
POS3.1.8	**M**	• the name of the person receiving the result.	**M**	**Revised** • the unique identity of the person receiving the result.

SAMPLE COLLECTION

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** Indwelling intravenous lines containing heparin are cleared before drawing the required tubes. The laboratory shall specify the appropriate discard volume in the procedure and reference how it was determined.

ANATOMIC PATHOLOGY

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised reference** CLSI GP17-A3 9.1.4 CAP GEN.76720
ANP1.1.2	**M**	Xylene exposure levels are monitored initially and when there are changes likely to increase exposure levels.	**M**	**Revised reference** CLSI GP17-A3 9.1.4 CAP GEN.76720
ANP1.1.3	**M**	Ventilation in the gross room and in tissue storage areas ensures acceptable formaldehyde levels. This is monitored at a defined interval.	**M**	**Revised reference** CAP GEN.76720

Standard or criterion number	Version 1.4		Version 1.5 revision	
ANP1.1.4		Personnel at significant risk of exposure are identified and monitored.		**Revised reference** CAP GEN.76720
ANP1.1.5	**M**	Action limits for exposure are defined and consistent with WorkSafeBC guidelines. *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.*	**M**	**Revised** Action limits for exposure are defined and consistent with WorkSafeBC guidelines. *Guidance: Exposure limits are listed for eight-hour weighted average (TWA). The formaldehyde limit is 0.1 ppm TWA and xylene is 100 ppm TWA.*
ANP1.1.7	**M**	Corrective action occurs when exposure limits are exceeded.	**M**	**Revised reference** CAP GEN.76720
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.	**M**	**Revised reference** CAP GEN.76720
ANP2.1		There are guidelines for the collection of anatomic pathology samples.		**Revised** There are guidelines for the collection of anatomic pathology specimens.
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, samples containers, additives and fixatives.	**M**	**Revised** Collection instructions for locations that send specimens to anatomic pathology include information on the completion of the request form with relevant clinical information, specimen containers, additives and fixatives.
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).	**M**	**Revised** There are procedures where indicated, for the safe handling of tissues that may contain radioactive material (e.g. sentinel lymph nodes, breast biopsies, prostate seeds).

Standard or criterion number	Version 1.4		Version 1.5 revision	
ANP2.2.2	**M**	Laboratory personnel are notified prior to submission of samples from suspected or known cases of prion disease.	**M**	**Revised** Laboratory personnel are notified prior to submission of specimens from suspected or known cases of prion disease.
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.	**M**	**Revised** There are procedures that address the handling of tissue in suspected or known cases of prion disease. The procedure includes that the tissue is visibly identified and neuropathology tissues are treated with formic acid. If not treated with formic acid, all scraps of paraffin and unused sections are collected on a disposable sheet and placed into hazardous waste containment. 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.
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.	**M**	**Revised** All patient specimens are grossly examined by a pathologist who may delegate this task to qualified personnel or a resident trainee with the appropriate supervision.
ANP3.1.2	**M**	There is a list of samples that may be grossed by technologists or other non-pathologist laboratory personnel.	**M**	**Revised** There is a list of specimens that may be grossed by technologists or other non-pathologist laboratory personnel.
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.	**M**	**Revised** If specimens are grossed by technologists or other non-pathologist laboratory personnel, there is a dissection manual that includes instructions for each specimen type and specific indications when a pathologist is to be contacted for advice or assistance.

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** If specimens 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.
ANP3.2.2	**M**	All samples are assessed for the appropriate type and amount of fixative and nonconformities are documented.	**M**	**Revised** All specimens are assessed for the appropriate type and amount of fixative or preservative, and nonconformities are documented. **Revised reference** CAP ANP.10038
ANP3.2.3	**M**	A gross dissection and sample handling manual that includes all specialized diagnostic procedures is available.	**M**	**Revised** Gross dissection and specimen handling procedures are available. *Guidance: Reference text can supplement gross dissection and specimen handling procedures.*
ANP3.2.4	**M**	All instruments and work surfaces are cleaned between cases to prevent cross contamination.	**M**	**Revised** All instruments and work surfaces used during gross examination are cleaned between cases to prevent cross-contamination. **Revised reference** DAP15 v1.0 CAP ANP.21397
ANP3.2.5	**M**	Multiple sample containers on the same case are clearly differentiated in dictation.	**M**	**Revised** Multiple specimen containers on the same case are clearly differentiated in dictation.

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ANP3.2.7	**M**	Samples are inked prior to cutting into the sample when appropriate.	**M**	**Revised** Specimens are inked prior to cutting into the specimen when appropriate.
ANP3.3		There are procedures to maintain sample identity throughout all processes.		**Revised** There are procedures to maintain specimen identity throughout all processes.
ANP3.3.1	**M**	There are documented processes to reduce sample identification errors.	**M**	**Revised** There are documented processes to reduce specimen identification errors.
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.	**M**	**Revised** Multiple specimens 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.
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. 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.	**M**	**Revised** Specimens are fixed for a minimum of six hours prior to processing and there is a documented process to record inadequate fixation. *Guidance: If specimens arrive unfixed, the laboratory notes the time the specimen was fixed, particularly if a significant time has elapsed between specimen collection and fixation*. **Revised reference** DAP AC 2018 CAP ANP.22983

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** Flotation baths are kept clean and well maintained and there is a procedure for preventing cross-contamination. **Revised reference** CAP ANP.23350 CAP ANP.21397
ANP4.3.2		Microtomes are clean and well maintained.	**M**	**Revised** Microtomes are clean and well maintained and there is a procedure for preventing cross-contamination. **Revised to mandatory requirement**
ANP4.3.3	**M**	Microtome blades are stored safely to avoid injury.	**M**	**Revised** Microtome blades are stored and disposed of safely to avoid injury.
ANP4.3.6		Like or similar samples are not cut consecutively.		**Revised** Like or similar specimens are not cut consecutively.
ANP4.5.2	**M**	The review of slide quality is performed and documented by a supervisor or designate.	**M**	**Revised** The review of slide quality is performed and documented with defined criteria.
ANP4.6		There is space for the storage of samples.		**Revised** There is space for the storage of specimens.
ANP4.6.1		There is refrigerated storage room for large unfixed samples.		**Revised** There is refrigerated storage room for large unfixed specimens.

Standard or criterion number	Version 1.4		Version 1.5 revision	
ANP6.1.2	**M**	Pathology reports include the type, number, volume, size or weight of samples.	**M**	**Revised** Pathology reports include the type, number, volume, size or weight of specimens.
ANP6.2		Pathology reports use a structured format (e.g. synoptic reports).		**Revised** Pathology reports use a structured format.
ANP6.2.1	**M**	Reporting on cancer diagnoses meets or exceeds provincial cancer reporting guidelines as established by provincial synoptic reporting committees or groups.	**M**	**Revised** Reporting on cancer diagnoses uses the province-wide electronic synoptic pathology reporting tool recommended by the Provincial Electronic Synoptic Pathology Reporting Committee. **Revised reference** CAP ANP.12385
ANP6.2.2	**M**	Pathology results of major organ system malignancies are reported in a routine format including all of the appropriate prognostic variables.	**M**	**Revised** Pathology results of major organ system malignancies are reported in a synoptic format including all of the appropriate prognostic variables.
ANP8.1.3	**M**	A minimum of 20 positive and 20 negative tissues are examined for the validation or verification of predictive examinations. *Guidance: This applies only to estrogen receptor and progesterone receptor and to HER2.*	**M**	**Revised** A minimum of 20 positive and 20 negative tissues are examined for the validation or verification of predictive examinations.
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.	**M**	**Revised reference** CAP ANP.22570 CAP ANP.22750

Standard or criterion number		Version 1.4		Version 1.5 revision
ANP8.1.6		Markers with both predictive and non-predictive applications are validated or verified as a predictive marker if used as such.		**Revised reference** CAP ANP.22570 CAP ANP.22750
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).		**Revised** Results of validation or verification are recorded and compared to another valid examination (e.g. an existing examination method, specimen exchange with a laboratory performing the same type of examination using similar methodology). **Revised reference** CAP ANP.22570 CAP ANP.22750
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.		**Revised** 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 specimens or on decalcified tissues. **Revised reference** CAP ANP.22570 CAP ANP.22750
ANP8.1.9	**M**	Validation or verification studies achieve a minimum 95% concordance rate.	**M**	**Revised** Validation or verification studies achieve a minimum 90% concordance rate. **Revised reference** DAP AC 2018 CAP ANP.22750

Standard or criterion number	Version 1.4		Version 1.5 revision	
ANP8.1.11		Once optimized, panels of tissues are examined to determine the examination's sensitivity and specificity.	**M**	**Revised reference** CAP ANP.22550 **Revised to mandatory requirement**
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.	**M**	**Revised reference** CAP ANP.22750
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.	**M**	**Revised** Performance of IHC antibodies on specimens fixed in a medium other than 10% neutral buffered formalin are fully validated on tissues and slide controls fixed in that same medium. **Revised reference** CAP ANP.22300 CAP ANP.22983 CAP ANP.22985 DAP AC 2018
ANP8.3.1		The laboratory uses a bank of high and low expressor tissue as positive controls. *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.*		**Revised reference** CAP ANP.22750
ANP8.4.1	**M**	The laboratory has defined a minimum fixation time of eight hours for Class II prognostic markers (HER2, ER, PgR).	**M**	**Revised** The laboratory has defined a minimum fixation time of six hours for Class II prognostic markers.
ANP8.4.3		Immunohistochemistry examinations performed on B-Plus fixed tissues use B-Plus fixed controls.		**Deleted**

Standard or criterion number	Version 1.4		Version 1.5 revision	
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. *Guidance: HER2 and ER/PgR examination are not performed on decalcified tissue.*	**M**	**Revised** If decalcified tissues are used for examination, there is a documented process for fixation time prior to decalcification, the type of reagent, and length of time of decalcification. **Revised reference** DAP AC 2018
ANP8.4.6		The laboratory has defined scoring criteria for the interpretation of Class II prognostic markers.		**Deleted**
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.		**Deleted**
ANP9.3.2	**M**	Ultramicrotomes are clean and in good repair. Knives are sharp and free of nicks.	**M**	**Revised** Ultramicrotomes and knives are kept clean and well maintained.
ANP10.1.2	**M**	Non-pathologist personnel performing autopsy services have appropriate academic qualifications, training and experience as defined by the medical director.	**M**	**Revised** Non-pathologist personnel performing autopsy services have appropriate documented academic qualifications, training and experience. **Revised reference** CAP ANP.33050 CCCPA

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised reference** DAP15 v1.0 CCCPA
ANP10.2.8	**M**	There are guidelines for the use of PPE in the morgue.	**M**	**Revised** There are guidelines for the use of specialized personal protective equipment (PPE) in the morgue.
ANP10.3.1	**M**	Physical access to the morgue is restricted.	**M**	**Revised** Physical access to the morgue is restricted and documented.
ANP10.3.2	**M**	Crypts or walk-in fridges have temperature monitors.	**M**	**Revised** Crypts or walk-in fridges, under the direction of the laboratory have temperature monitors that read in the range of 1.1 to 4.4°C. This is documented.
ANP10.3.7	**M**	Instructions and sample containers for laboratory examinations are available (e.g. toxicology, microbiology).	**M**	**Revised** Instructions and specimen containers for laboratory examinations are available (e.g. toxicology, microbiology).
ANP10.4.7			**M**	**New** The identity of the patient is confirmed using two identifiers before the autopsy begins.
ANP10.4.8			**M**	**New** The anatomical site is recorded for specimens collected for ancillary testing, including toxicology.

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ANP10.5.9			**M**	**New** Final autopsy photographs and/or digital images are labeled and stored securely and to prevent system loss (e.g. backup electronic storage system).
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.	**M**	**Revised** There are documented processes to communicate unexpected autopsy results that require notification as per the BC *Coroner's Act*, results that may influence completion of the death certificate, finding a notifiable disease, or finding important information that was clinically unapparent. **Revised reference** CAP ANP.31100 GOBC PHA Part 1 CAP ANP.30100 DAP APAC2018 CAP ANP.30160 2018 BC APLM Best Practice Guidelines

CHEMISTRY

Standard or criterion number	Version 1.4		Version 1.5 revision	
CHE1.1		There are procedures for drug screening and TDM and reporting.		**Revised** There are procedures for testing and reporting of TDM and drug screening.
CHE1.1.3	**M**	TDM examination requests include the time of last medication dose.	**M**	**Revised** TDM examination requests ask for the date and time of last medication dose.

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** Sweat stimulation and collection is from the patient's lower arm or upper leg using a site that is free from diffuse inflammation, rash, tattooed skin and areas of dense hair.
CHE2.1.10	**M**	The incidence of insufficient sweat samples is routinely monitored. *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.*	**M**	**Revised** The incidence of insufficient sweat samples and the incidence of repeats per patient, are routinely monitored. *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.*
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. *Guidance: Sweat chloride concentrations greater than 160 mmol/L are not physiologically possible. Patients should be reexamined when results are greater than 160 mmol/L.*	**M**	**Revised** If quantitative examination of sweat chloride is performed, the upper limit of the reportable range is less than or equal to 160 mmol/L. *Guidance: Sweat chloride concentrations greater than 160 mmol/L are not physiologically possible. Patients should be reexamined when results are greater than 160 mmol/L.*
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.	**M**	**Revised reference** CLSI C34 CAP CHM.30600
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.	**M**	**Revised reference** CLSI C34 CAP CHM.30600

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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.	**M**	**Revised reference** CLSI C34 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.	**M**	**Revised reference** CLSI C34 CAP CHM.30700
CHE5.1.5	**M**	There are procedures for detection and evaluation of potential carry-over that includes reassessment of samples when necessary.	**M**	**Revised** There are procedures for detection and evaluation of potential carry-over that includes reassessment of samples when necessary according to predefined criteria.
CHE5.1.6	**M**	Calibrators are run with each examination batch.	**M**	**Revised** Calibration or calibration verification is performed with each examination batch.
CHE6.1.1	**M**	Spectrometers are tuned on each day of patient examination, or according to the manufacturer's recommendations. Tune records are maintained.	**M**	**Revised** Mass calibration and tuning are verified at minimum every six months, after major maintenance or according to manufacturer's recommendations. Mass calibration and tune records are documented and retained.
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.	**M**	**Revised** Acceptance limits for identification criteria are predefined, and the limits are supported by references from the literature or experimental data.
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.		**Deleted**

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CHE6.1.5	**M**	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.	**M**	**Revised to mandatory requirement**
CHE6.1.6	**M**	The procedure includes precautions to recognize ion suppression.	**M**	**Revised** There are procedures and documentation to evaluate matrix effect (ion suppression/enhancement) for each ion transition during method development and validation.
CHE6.1.7	**M**	There is recovery of the internal standard or records for alternative methods used.	**M**	**Revised** For each internal standard, there are procedures to monitor matrix effects (ion suppression/enhancement) for each ion transition(s), or records of alternative methods used.
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.	**M**	**Revised** For each internal standard, there are predefined acceptance limits to monitor ion transition(s) during analysis of patient samples.
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.		**Deleted**
CHE7.1.3	**M**	Criteria for the selection of isotopes and internal standards consider interferences (isobaric and polyatomic species) and relative abundances.	**M**	**Revised** Criteria for the selection of isotopes and internal standards consider interferences (isobaric and polyatomic species) and relative abundances during assay development.
CHE7.1.5	**M**	The peak width is optimized.	**M**	**Revised** The peak width is optimized during mass calibration.

Standard or criterion number	Version 1.4		Version 1.5 revision	
CHE7.1.7	**M**	The reaction or collision gases are optimized when a reaction or collision cell is utilized.	**M**	**Revised** The reaction or collision gases are optimized when a reaction or collision cell is utilized during assay development.
CHE7.1.11	**M**	All calibrators are verified.	**M**	**Revised** There are records of calibration and cross-calibration if a dual detector mode is used.
CHE9.1.3	**M**	Tolerance limits are set for controls where the electrophoretic bands are quantified.	**M**	**Revised** Acceptance limits are set for controls where the electrophoretic bands are quantified.
CHE10.2.3	**M**	There is a documented process to assess consistency among personnel performing urine sediment microscopy.	**M**	**Revised** There is a documented process to assess competency and consistency among personnel performing urine sediment microscopy.
CHE13.1.5				**New** The screening program should be operating with an organizational body that is collecting and monitoring the screen positive and screen negative rates.

CYTOGENETICS

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised reference** ISO15189 5.4.6 CAP COM.06200

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG1.1.2	**M**	The laboratory documents reagent lot numbers and media used.	**M**	**Revised** The laboratory documents lot numbers for all reagents used. **Revised reference** ISO 15189 5.3.2.7
CYG1.1.3		There is a method to mechanically and enzymatically disaggregate samples.	**M**	**Revised** There is a method to mechanically or enzymatically disaggregate solid tissue samples. **Revised to mandatory requirement**
CYG1.1.4	**M**	Multiple cultures are used for all sample types.	**M**	**Revised** Duplicate or multiple cultures are established for all sample types whenever possible. **Revised reference** CAP CYG.40100 DAP AC 2019
CYG1.1.5		Laboratory procedures specify a prioritization scheme when sample volume or cellularity is insufficient to set up all routine cultures.	**M**	**Revised** Laboratory procedures specify a prioritization process when sample volume or cellularity is insufficient to set up all routine cultures and/or nucleic acid extraction. **Revised reference** DAP AC 2019 **Revised to mandatory requirement**

Standard or criterion number	Version 1.4		Version 1.5 revision	
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).	**M**	**Revised** There are documented processes to verify changes in all reagents and consumables (e.g. lot number changes or changes in manufacturer). **Revised reference** DAP AC 2019 AGT TM CH5
CYG1.1.7	**M**	Media is labeled with the expiry date and not used after that date.	**M**	**Revised** All culture reagents are labeled with the expiry date and not used after that date. **Revised reference** DAP AC 2019 AGT TM CH5
CYG1.1.8	**M**	Appropriate culture media is used depending on sample tissue type.	**M**	**Revised reference** DAP AC 2019 AGT TM CH5
CYG1.1.9		No aliquot is returned to the original container.	**M**	**Revised reference** DAP AC 2019 AGT TM CH5 **Revised to mandatory requirement**
CYG1.1.10		Only one sample is set up at one time.	**M**	**Revised reference** DAP AC 2019 AGT TM CH5 **Revised to mandatory requirement**

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG1.1.11		Tubes, flasks and dishes are labeled prior to inoculation.	**M**	**Revised reference** DAP AC 2019 AGT TM CH5 **Revised to mandatory requirement**
CYG1.1.12	**M**	All samples and cell cultures are manipulated in a biological safety cabinet.	**M**	**Revised reference** DAP AC 2019 AGT TM CH5
CYG1.1.13			**M**	**New** Each shipment and/or new lot number of culture media reagents is checked onsite for sterility and the ability to support growth.
CYG1.2.2		Amniotic fluid and the cell pellet are viewed after centrifugation.	**M**	**Revised** Amniotic fluid and the cell pellet are viewed for evidence of maternal blood cell contamination after centrifugation. **Revised reference** DAP AC 2019 **Revised to mandatory requirement**
CYG1.2.5		Efforts are made to determine the tissue type selected for culture setup (e.g. products of conception, fetal organs).	**M**	**Revised** The identity and description of tissue type (e.g. products of conception, fetal organs), selected for culture setup is recorded when possible. **Revised reference** DAP AC 2019 ACMG E3.3.1.3 **Revised to mandatory requirement**

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG2.1.1	**M**	The laboratory has defined when multiple cultures are incubated separately (e.g. amniocentesis samples, chorionic villus).	**M**	**Revised reference** CAP CYG.40100
CYG2.1.2	**M**	Incubation times are established according to clinical indications and sample type.	**M**	**Revised reference** CAP CYG.30350
CYG2.1.3	**M**	The laboratory documents the culture conditions, the incubation times for all preparations and the number of cultures.	**M**	**Revised reference** CAP CYG.30350
CYG2.1.4	**M**	Temperatures of 37°C to 38°C are maintained, monitored and documented.	**M**	**Revised** Temperatures of 37°C to 38°C are maintained, monitored and documented on each day of use. **Revised reference** DAP AC 2019
CYG2.1.5	**M**	CO2 levels of 4–6% are maintained, monitored and documented.	**M**	**Revised** CO2 levels of 4–6% are maintained, monitored and documented on each day of use. **Revised reference** CAP CYG.33700
CYG2.1.6	**M**	O2 levels are maintained, monitored and documented in tri-gas incubators	**M**	**Revised** O2 levels are maintained, monitored and documented in tri-gas incubators on each day of use. **Revised reference** CAP CYG.33700

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG2.1.7	**M**	Humidity levels of 90–95% are maintained, monitored and documented where appropriate.	**M**	**Revised reference** CAP CYG.61400
CYG2.1.8	**M**	A minimum level of CO2 and N2 (tri-gas incubators only) has been defined and is maintained.	**M**	**Revised reference** CAP CYG.33700
CYG2.1.10	**M**	Incubators are on emergency backup power and have a monitored alarm system.	**M**	**Revised reference** CAP CYG.40000 ACMG D1.2.1, E4.1.1
CYG2.1.12			**M**	**New** There are records of corrective action taken when incubator values fall outside the acceptable range. **Reference** CAP CYG.33700
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).		**Revised reference** CAP CYG.49575
CYG3.2.1	**M**	Giemsa banding, centromere banding, and nuclear organizing region banding are performed.	**M**	**Revised** There are procedures for performing G banding, special stains, and FISH. **Revised reference** ACMG E3.1

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** Examination using G banding, special stains, and FISH are performed when indicated and at the discretion of the clinical cytogeneticist.
CYG3.2.3	**M**	An established method to assess the banding level of karyotypes is used and the bandwidth level resolution is documented.	**M**	**Revised** An established method to assess band level resolution is used and documented. *Guidance: Each laboratory should establish its own acceptable level of band resolution for each tissue type and indication.* **Revised reference** ACMG E3.1.5
CYG3.2.4		There are procedures to address suboptimal staining and banding results on a case by case basis.	**M**	**Revised reference** DAP AC 2019 **Revised to mandatory requirement**
CYG3.2.5	**M**	The quality of banding and resolution is sufficient to render the reported interpretation, at the discretion of the cytogeneticist.	**M**	**Revised** The quality of banding and resolution is sufficient to render the reported interpretation. **Revised reference** ACMG E3.1.5 CYG.42400B
CYG3.3.1	**M**	The controls for each examination are documented.	**M**	**Revised reference** CAP CYG.30360

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised reference** 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.	**M**	**Moved to CYG4.1.10 and revised**
CYG3.3.4	**M**	There are procedures for the examination of all cytogenetic sample types.	**M**	**Moved to CYG4.1.11 and revised**
CYG3.3.6	**M**	There are documented criteria for performance of abbreviated examinations.	**M**	**Moved to CYG4.1.14 and revised**
CYG3.3.7	**M**	Procedures specify that all karyotypes are checked by a second individual.	**M**	**Moved to CYG4.1.15 and revised**
CYG3.3.8	**M**	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.	**M**	**Moved to CYG4.1.16 and revised**
CYG4.0		EXAMINATION		**Revised** METAPHASE EXAMINATION
CYG4.1.1	**M**	The number of cells counted is documented.	**M**	**Revised reference** CAP CYG.32500
CYG4.1.2	**M**	The sex chromosome complement is documented.	**M**	**Revised reference** CAP CYG.40500

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG4.1.3	**M**	The number of cells examined microscopically is documented.	**M**	**Revised** The number of cells analyzed microscopically is documented. **Revised reference** CCMG 2016
CYG4.1.4	**M**	The electronically karyotyping of cells is documented.	**M**	**Revised** At least two electronic karyograms per cell line are done and documented. **Revised reference** CYG.41600
CYG4.1.5	**M**	The crossover(s) for each cell counted, examined, and karyotyped is documented.	**M**	**Revised** The crossover(s) for karyotyped cells analyzed is documented. **Revised reference** CCMG 2016
CYG4.1.6	**M**	The microscopic coordinates of each cell examined is documented.	**M**	**Revised** The microscope and microscopic coordinates of each cell examined is documented. **Revised reference** CCMG 2016
CYG4.1.8	**M**	Band by band comparison of each homologous chromosomal pair occurs in fully examined cells.		**Deleted**

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG4.1.10	**M**	Additional metaphases and interphases are examined from multiple cultures to detect or exclude clinically significant mosaicism in prenatal samples using a published method.	**M**	**Moved from CYG3.3.3** **Revised** Additional cells are examined from multiple cultures to detect or exclude clinically significant mosaicism in prenatal samples using a published method.
CYG4.1.11	**M**	There are procedures for the examination of all cytogenetic sample types.	**M**	**Moved from CYG3.3.4** **Revised** There are defined criteria and procedures for the number of cells to be counted/analyzed/karyotyped for all clinical indications and sample types during routine cytogenetic examination. **Revised reference** CCMG 2016 DAP AC 2019
CYG4.1.14	**M**	There are documented criteria for performance of abbreviated examinations.	**M**	**Moved from CYG3.3.6** **Revised** There are documented criteria when abbreviated examinations are performed. **Revised reference** CCMG 2016 DAP AC 2019

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG4.1.15	**M**	Procedures specify that all karyotypes are checked by a second individual.	**M**	**Moved from CYG3.3.7** **Revised** Procedures specify that all karyotypes are checked by a second individual. **Revised reference** CCMG 2016 DAP AC 2019
CYG4.1.16	**M**	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.	**M**	**Moved from CYG3.3.8** **Revised** The selection criteria for cells for examination should be defined (e.g. number of crossovers, banding quality, morphology). **Revised reference** CCMG 2016 DAP AC 2019
CYG4.2				**New** There are procedures for the cytogenetic analysis of specimens referred for a chromosomal instability syndrome.
CYG4.2.1			**M**	**New** There are procedures for the use of interstrand crosslink (ICL)-inducing agents to detect chromosomal aberrations in Fanconi Anemia syndrome **Reference** CCMG 2016

Standard or criterion number	Version 1.4		Version 1.5 revision	
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).	**M**	**Revised** There are policies, procedures and records of validation/verification of all (FISH) probes. **Revised reference** CAP CYG.42700 CAP COM.01520
CYG5.1.2	**M**	There are procedures for the verification of all FISH probes.	**M**	**Revised** Laboratory modified procedures have been validated. **Revised reference** CAP COM.01520
CYG5.1.3	**M**	The laboratory documents the probes used including lot number, expiry date.		**Deleted**
CYG5.1.4			**M**	**New** For interphase in situ hybridization (FISH), the laboratory establishes a normal cut-off value for abnormal results for each probe used, when applicable. **Reference** CAP CYG.47885 CAP COM.01520

Standard or criterion number	Version 1.4	Version 1.5 revision
CYG5.1.5		**M** **New** For FISH studies of plasma cell dyscrasias, plasma cells must be purified or specifically identified. **Reference** CCMG 2016 NCNN Multiple Myeloma V2 2020, PMID 22371180
CYG5.2	There are procedures for scoring FISH results and monitoring FISH performance.	**Revised** There are procedures for FISH analysis.
CYG5.2.1		**M** **New** The laboratory documents the probes, reagents and supplies used including lot number and expiry date. **Reference** CCMG 2016 CLSI MM07A2
CYG5.2.2		**M** **New** Temperature checks are made of a representative sample of the slide slots of a FISH hybridization system for temperature accuracy before the apparatus is placed in service and at least annually after that. **Reference** CAP CYG.33950

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG5.2.3			**M**	**New** Procedures specify the number of metaphases and/or interphase nuclei to be analyzed. **Reference** CCMG 2016 CLSI MM07A2
CYG5.2.4			**M**	**New** There are procedures in place to address the handling of any discrepant results, including the examination of additional cells if required. **Reference** CCMG 2016
CYG5.2.7		A known positive control is used for each interphase FISH examination when available and appropriate.		**Moved to CYG5.3.7 and revised**
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).		**Deleted**
CYG5.3				**Moved from CYG5.2 and revised** There are procedures for scoring FISH results and monitoring FISH performance.
CYG5.3.1	**M**	There are procedures for scoring all FISH results on different sample types and indications.	**M**	**Revised reference** CLSI MM07-A2 – 9.2 CAP CYG.43000 CCMG 2016

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG5.3.2	**M**	Interphase FISH results are scored by two different individuals.	**M**	**Revised reference** CLSI MM07-A2 – 9.3 CCMG 2016
CYG5.3.3	**M**	FISH results are scored as instructed by the manufacturer.	**M**	**Revised reference** DAP15 V1.0 CLSI MM07-A2 – 9.2
CYG5.3.4	**M**	There are defined criteria for the selection of FISH probes to ensure the probe used is for the intended target.	**M**	**Revised reference** CLSI MM07-A2 – 11.3 CCMG 2016
CYG5.3.5	**M**	Examination results and controls are monitored.	**M**	**Revised** Examination results and controls are monitored over time. **Revised reference** CAP CYG.42750 CLSI MM07-A2 – 9.2 CCMG 2016
CYG5.3.6	**M**	Each lot of FISH probes is checked for acceptable performance.	**M**	**Revised** Each shipment and new lot of FISH probes is checked for acceptable performance. **Revised reference** CAP CYG.42775 CLSI MM07-A2 – 9.2 CCMG 2016

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG5.3.7			**M**	**Moved from CYG5.2.7** A known positive control is used for each interphase FISH examination when available and appropriate. **Revised reference** CAP CYG.42900 CLSI MM07-A2 – 9.2 CCMG 2016 **Revised to mandatory requirement**
CYG5.3.8	**M**	At least one cell is documented for examinations with normal results, and at least two cells are documented for examinations with abnormal results.	**M**	**Revised reference** CCMG 2016 CLSI MM07-A2 – 9.2
CYG6.0		MICROARRAY		**Revised** CHROMOSOME MICROARRAY ANALYSIS (CMA)
CYG6.1.1	**M**	Microarray pre-examination components are verified and monitored (e.g. nuclear extraction, purification, quantitation and equipment).	**M**	**Revised** Pre-analytic standards are verified and monitored (e.g. evaluate DNA quality). **Revised reference** CCMG 2016
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).	**M**	**Revised** Analytic standards are verified and monitored (e.g. assess fragmentation of DNA by sonication/enzyme digestion if applicable). **Revised reference** CCMG 2016

Standard or criterion number	Version 1.4		Version 1.5 revision	
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).	**M**	**Revised** Post-analytic standards are verified and monitored over time (e.g. visual inspection of hybridized array images, evaluation of QC data calculated from analysis software, genomic gains and losses called by the microarray software algorithm). **Revised reference** CCMG 2016
CYG6.1.4	**M**	Corrective action is taken when components fail to meet established criteria. This is documented.	**M**	**Revised reference** CLSI MM12-A – 6.1 CAP COM.01700
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.	**M**	**Revised** An internal database is established to identify common copy number variations specific to the patient population and recurrent false positives associated with a particular microarray platform. **Revised reference** DAP AC 2019 **Revised to mandatory requirement**
CYG6.1.6			**M**	**New** Nucleic acids are extracted, isolated and purified by a validated DNA extraction method. **Reference** CAP CYG.49545

Standard or criterion number	Version 1.4	Version 1.5 revision
CYG6.1.7		**M** **New** Validation is performed for DNA-based copy number arrays for each sample type: • that can be affected by different pre-analytic variables • that require different processes for DNA extraction • those with potentially interfering substances **Reference** CAP CYG.49545
CYG6.1.8		**M** **New** There are procedures for performing the analytical wet bench process. **Reference** CAP CYG.49580
CYG6.1.9		**M** **New** There are procedures that describe the steps in recording the bioinformatics process used to analyze, interpret and report array findings. **Reference** CAP CYG.49585

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG6.1.10			**M**	**New** There is a policy for interpreting and reporting array findings according to published guidelines. **Reference** CAP CYG.49590
CYG7.1.1	**M**	When a histopathological or cytological interpretation is required, a qualified pathologist is involved.	**M**	**Revised** When a histopathological or cytological interpretation is required, a qualified pathologist is involved and documented. **Revised reference** CAP CYG.47866
CYG7.1.2	**M**	When a cytogenetic interpretation is required, a qualified cytogeneticist is involved.	**M**	**Revised** All cytogenetic interpretation is provided by a qualified clinical cytogeneticist. **Revised reference** CAP CYG.31880
CYG7.1.3		The medical review of cytogenetics examinations is performed in a manner that meets clinical needs.		**Deleted**
CYG7.1.4	**M**	All cytogenetics results (e.g. karyotypes, diagnostic findings) are reviewed by a cytogeneticist.	**M**	**Revised** All cytogenetic results (e.g. karyotypes, diagnostic findings) are reviewed and signed off by a clinical cytogeneticist. **Revised reference** CYG.31880 DAP AC 2019

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG7.1.5	**M**	Discrepant outcomes are investigated and documented.	**M**	**Moved to CYG9.1.1**
CYG8.1.1	**M**	Cytogenetics reports include the number of cells examined.	**M**	**Revised** Cytogenetic reports include: • name and address of testing laboratory • patient name • unique identifying number • patient date of birth • name of physician, or authorized person ordering test • sample source • date sample received in the laboratory • comment on adequacy of sample, if indicated • date of report • clinical indication(s) for the test • special banding if performed • examination summary • International System for Human Cytogenetic Nomenclature (ISCN) • a cytogeneticist signature or electronic equivalent **Revised reference** CCMG 2016 CAP CYG.31875

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG8.1.2	**M**	Cytogenetics reports include the band level resolution.	**M**	**Revised** Cytogenetic reports include the band-level resolution. In addition to CYG8.1.1, karyotype reports include: • number of cells counted, analyzed and karyograms prepared, as applicable • band resolution, as applicable • banding methods, as applicable • an examination summary **Revised reference** CAP CYG.31875 CCMG 2016
CYG8.1.3		Cytogenetics reports include special banding if performed.	**M**	**Revised** In addition to CYG8.1.1, cytogenetic reports include the source and identification of any FISH probe used. **Revised reference** CAP CYG.31875 **Revised to mandatory requirement**

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG8.1.4	**M**	Cytogenetics reports include an examination summary.	**M**	**Revised** In addition to CYG8.1.1, chromosome microarray reports include: • ISCN nomenclature describing the result of the analysis. • a written description of the results indicating clinical significance, gene content (e.g. number of known genes, list of OMIM Morbid Map genes), size and location of imbalance, and follow-up recommendations • a description of the array platform with information regarding probe coverage and the effective resolution of analysis across the genome; if the effective resolution in regions known to be clinically significant differs from the remainder of the genome, this information should be provided • the genome build used as the reference (e.g. GRCh37) • the software program used for analysis of the microarray data • information regarding control DNA or in silico control reference data set used in the microarray analysis • information regarding limitations of microarray testing (e.g. mosaicism, balanced rearrangements, etc.) **Revised reference** CCMG 2016 CCMG Guidelines for GMT

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYG8.1.5	**M**	Cytogenetics reports include clinical indications for examination.		**Deleted**
CYG8.1.6	**M**	Cytogenetics reports include the source and identification of any FISH probe used.		**Deleted**
CYG8.1.7	**M**	Cytogenetics reports include a cytogeneticist signature or electronic equivalent.		**Deleted**
CYG8.1.8		Cytogenetics reports include reference to genetic follow-up procedures (e.g. family studies, ultrasound, amniocentesis, family counselling).	**M**	**Revised** All cytogenetic reports include reference to genetic follow-up procedures (e.g. family studies, ultrasound, amniocentesis, family counselling). **Revised reference** CAP CYG.32250 **Revised to mandatory requirement**
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).	**M**	**Revised** Reports include identification of sample quality or integrity issues that may contribute to a compromised result (e.g. delays). **Revised reference** ISO 15189 5.8.2a-b CAP CYG.31875

Standard or criterion number	Version 1.4	Version 1.5 revision	
CYG8.1.10	Cytogenetics reports include clinical information correlated with the cytogenetics findings and relevant previous examinations.	**M**	**Revised** When appropriate, reports include clinical information correlated with the cytogenetics findings and relevant previous examinations. **Revised reference** CAP CYG.32071 **Revised to mandatory requirement**
CYG8.1.13	Cytogenetics reports include abnormal FISH results suggestive of mosaicism in conjunction with confirmatory cytogenetic examination.	**M**	**Revised** Confirmatory cytogenetic examinations are included when appropriate (e.g. mosaicism). **Revised reference** DAP AC 2019 **Revised to mandatory requirement**
CYG8.1.14	Cytogenetics reports include limitations of FISH examination, when appropriate.	**M**	**Revised reference** DAP AC 2019 **Revised to mandatory requirement**
CYG8.1.15	Cytogenetics reports include description of the chromosome result and any changes from previous cytogenetics examinations	**M**	**Revised reference** DAP AC 2019 **Revised to mandatory requirement**
CYG8.1.16	Cytogenetics reports include interpretive comments about possible diagnoses, prognosis or other clinical correlations.	**M**	**Revised reference** DAP AC 2019 **Revised to mandatory requirement**

Standard or criterion number	Version 1.4		Version 1.5 revision
CYG8.2	Turnaround times for cytogenetics examinations have been established.		**Deleted**
CYG8.2.1	There are established turnaround times (consistent with CCMG guidelines for interim and final reports.		**Moved to CYG9.1.4**
CYG8.2.2	Turnaround times are monitored and documented. Identified problems are addressed.		**Moved to CYG9.1.5**
CYG9.0			**New** Quality Indicators **Reference** DAP AC 2019
CYG9.1			**New** Quality indicators and turnaround times for cytogenetic examinations have been established. **Reference** DAP AC 2019
CYG9.1.1		**M**	**Moved from CYG7.1.5** Discrepant outcomes are investigated and documented.
CYG9.1.2		**M**	**New** The number or frequency of culture failures, hybridization failures, and/or suboptimal analyses is recorded, and there are records of corrective action when adverse trends occur. **Reference** CAP CYG.20800

Standard or criterion number	Version 1.4	Version 1.5 revision
CYG9.1.3		**M** **New** All errors that are identified in the final report are thoroughly investigated, and the results of each investigation are recorded **Reference** DAP AC 2019 CAP COM.04050
CYG9.1.4		**M** **Moved from CYG8.2.1** There are established turnaround times (consistent with CCMG guidelines) for interim and final reports.
CYG9.1.5		**M** **Moved from CYG8.2.2** Turnaround times are monitored and documented. Identified problems are addressed.
CYG9.1.6		**M** **New** Retention of cytogenetic and molecular samples and genetic records complies with CCMG guidelines. **Reference** CCMG 2016

CYTOLOGY

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYT2.1.1	**M**	There are documented criteria to assess cytology sample adequacy. *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).*	**M**	**Revised reference** CAP CYP.03850
CYT2.1.2		Samples with atypical cells are categorized as satisfactory.		**Revised reference** CAP CYP.07452
CYT2.1.4		Reports on unsatisfactory samples indicate whether the sample was rejected or evaluated.		**Revised reference** CAP CYP.07452
CYT2.1.5				**New** Multiple specimens 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.
CYT2.2		There are procedures for processing cytology samples.		**Revised** There are procedures for processing cytology specimens.
CYT2.3.2		A sequence is used to ensure that paucicellular samples are stained before highly cellular samples.		**Revised reference** CAP ANP.12096 CSC 5.5
CYT2.3.3	**M**	Stains are filtered or changed frequently enough to reduce the possibility of cross-contamination.	**M**	**Revised reference** CAP ANP.21397 CAP CYP.04100

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYT2.3.4	**M**	The date and number of times the stains are filtered or changed are recorded.	**M**	**Revised reference** CAP CYP.03925 CAP CYP.04100
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.		**Revised reference** CAP ANP.21397 CAP CYP.04150
CYT2.3.6	**M**	When cross-contamination is identified, resolution of the case is documented.	**M**	**Revised reference** CAP ANP.21397 CAP CYP.04150
CYT3.1.1	**M**	There is a documented process for the ongoing monitoring of automated slide screening.	**M**	**Revised reference** CAP CYP.05292
CYT3.1.2	**M**	Tolerance limits for determination of sample adequacy and for diagnostic accuracy are defined.	**M**	**Revised reference** CAP CYP.05292
CYT3.1.3	**M**	Automated slide examination data summaries are performed. This information is reviewed by the medical director.	**M**	**Revised reference** CAP CYP.05292
CYT3.2		Workload limits are defined and monitored.		**Revised** Gynecological cytology – Workload limits are defined and monitored.

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYT4.1.2		Cytopathology reports include the volume, color and consistency of the sample and an assessment of sample adequacy when appropriate.	**M**	**Revised** Cytopathology reports include the volume, color and consistency of the specimen, *the fixative or preservative* and an assessment of specimen adequacy when appropriate. **Revised reference** CAP CYP.05350 CSC 10.0 **Revised to mandatory requirement**
CYT4.1.3	**M**	Cytopathology reports include the number of slides received.	**M**	**Revised reference** CAP CYP.05300 CSC 10.0
CYT4.1.4	**M**	Cytopathology reports include any ancillary procedures performed (e.g. TB, flow cytometry).	**M**	**Revised** Cytopathology reports include any ancillary procedures performed.
CYT4.1.5	**M**	Each separately submitted sample is recognized in the diagnostic report.	**M**	**Revised** Multiple specimens received on the same case are identified in the diagnostic report. **Revised reference** CSC 10.0
CYT4.1.7	**M**	Reporting of cytology results is clear, concise, consistent and easily interpretable.		**Deleted**
CYT4.1.8	**M**	Reports include an interpretation of the morphological findings and standard descriptive terminology.		**Deleted**
CYT4.1.9		Reports state the interpretation representing the highest degree of abnormality.		**Deleted**

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYT4.1.11	**M**	Reports specify a reason when a definite diagnosis cannot be rendered (e.g. inconclusive, indeterminate or non-diagnostic).	**M**	**Revised** Reports specify a reason when a definite diagnosis cannot be rendered.
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).		**Revised** Follow-up recommendations are made in compliance with established guidelines when available.
CYT4.2.1	**M**	Pathologists sign off all cases reviewed by pathologists.	**M**	**Revised** Cytopathology reports are reviewed and signed by the pathologist, when applicable.
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.		**Deleted**
CYT5.2.1	**M**	Personnel screening or examining cytology slides have access to the patient history, including cytopathology and surgical pathology results.	**M**	**Revised reference** CAP CYP.07675
CYT5.3.3	**M**	There is a review of previous abnormal or negative cases with documentation.	**M**	**Revised reference** CAP CYP.07600 CAP CYP.07675
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.		**Revised reference** DAP AC 2019

Standard or criterion number	Version 1.4		Version 1.5 revision	
CYT6.3.1	**M**	Slide review ensures evaluation of every cytotechnologist. *Guidance: The review process is documented (e.g. a minimum of 10% of negative screens, a rapid review of 100% of negative screens).*	**M**	**Revised reference** CAP CYP.07478 CAP CYP.07480 CSC 13.2.1
CYT6.3.6	**M**	The rate of referral cases by each cytotechnologist to a pathologist is monitored.	**M**	**Revised reference** CAP CYP.07655
CYT6.3.7	**M**	There is a documented process to record, analyze and communicate sample adequacy data by submitting physician.	**M**	**Revised reference** CAP CYP.07655
CYT6.3.8		The relative rates of atypical squamous cells of undetermined significance to squamous intraepithelial lesions (ASCUS to SIL) are monitored.		**Revised reference** CAP CYP.07600
CYT6.3.9	**M**	The rate of low-grade squamous intraepithelial lesions to high-grade squamous intraepithelial lesions (LSIL to HSIL) is monitored.	**M**	**Revised reference** CAP CYP.07600
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).		**Revised reference** CAP CYP.07569
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.	**M**	**Revised reference** CAP CYP.01900 CAP CYP.07543

MICROBIOLOGY

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC2.1.2	**M**	There are containment measures where recovery of highly infectious agents is likely (e.g. *Brucella,* dimorphic fungi). *Guidance: This does not apply to facilities who incidentally recover risk group 3 or 4 pathogens from clinical samples.*	**M**	**Revised reference** MCM CH15 GOC CBSG 3.1-3.8
MIC2.1.4	**M**	There is a procedure for handling requests for the isolation or identification of potential bioterrorism agents.	**M**	**Revised reference** MCM CH15
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.	**M**	**Revised reference** MCM CH9 CAP MIC.63220
MIC2.1.9	**M**	Microbiology samples, isolates, contaminated materials and supplies are disposed of in accordance with biohazard containment requirements.	**M**	**Revised reference** MCM CH9
MIC2.1.10	**M**	All discarded microbiology laboratory samples, cultures and contaminated waste are made intrinsically biologically safe prior to leaving the facility. *Guidance: Biologically safe may result from processing by autoclave, or other approved technology, or by packaging in appropriate containers.*	**M**	**Revised reference** MCM CH9
MIC3.1.1	**M**	All QC of media is recorded.	**M**	**Revised reference** CLSI M22-A3 5.3.1-5 CAP MIC.21240
MIC3.1.2	**M**	The manufacturer's QC specifications for each type of media, and certification details for each lot number of exempt media are retained.	**M**	**Revised** The manufacturer's QC specifications for each type of media and certification details for each lot number of exempt media are readily available.

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** Prior to use, testing of exempt media used for fastidious organisms, specialty testing or reactions not tested by the manufacturer is performed and documented.
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.	**M**	**Revised** Prior to use, 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.
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.	**M**	**Revised** Prior to use, there is a record of assessment of the biochemical reactivity of non-exempt media using a standardized inoculum of the appropriate reference strain.
MIC3.1.6		Upon receipt, media is visually assessed, including sterility.		**Deleted**
MIC3.1.9	**M**	Media is visually assessed prior to use (e.g. expiry, surface contamination).	**M**	**Revised** All media is visually assessed for sterility (e.g. surface contamination), and expiry, prior to use.
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.	**M**	**Revised** There is a documented process to ensure consistency of staining, morphological observations and grading performance among all personnel examining Gram stains.
MIC3.5.2	**M**	CO_2 incubators and jars are checked for adequate CO_2 levels at least weekly. *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.*	**M**	**Revised** CO_2 incubators and jars are checked for adequate CO_2 levels daily. *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.*

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC4.1.1	**M**	Collection instructions include the use and availability of transport media and collection systems as required.	**M**	**Revised reference** MCM CH19, 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).	**M**	**Revised reference** MCM CH19 CAP MIC.13250, 75
MIC4.1.3	**M**	Collection instructions include details on storage or preservation of samples if processing is delayed.	**M**	**Revised reference** MCM CH19 CAP MIC.13250, 75
MIC4.4.7			**M**	**New** Blood culture transportation instructions include acceptable transport and storage times.
MIC4.5.1		Collection instructions provide guidance to distinguish deep wounds from superficial wounds and subsequent handling requirements.		**Revised reference** MCM CH19
MIC4.5.2	**M**	Specialized transport media is used to facilitate the recovery of anaerobes where indicated by clinical conditions.	**M**	**Revised reference** MCM CH19
MIC4.6.1	**M**	Mycobacteriology sample collection instructions include the number, timing and minimum volume of samples.	**M**	**Revised reference** MCM CH31 CAP MIC.31100
MIC4.6.2		Mycobacteriology sample collection instructions include collection in sealed, leak-proof containers and prompt transport to the laboratory.		**Revised reference** MCM CH31 CAP MIC.33050

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC4.6.3		Viral culture sample collection instructions include the use of viral transport media.		**Revised reference** MCM CH81 CAP MIC.13175
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).	**M**	**Revised reference** MCM CH19
MIC5.1.2	**M**	Sample specific procedures define when a direct Gram-stained smear is examined.	**M**	**Revised reference** MCM CH19
MIC5.1.3	**M**	Sample specific procedures define suitable media including enriched or selective media.	**M**	**Revised reference** MCM CH19
MIC5.1.4	**M**	Sample specific procedures define the appropriate environments, temperatures and times for incubation.	**M**	**Revised reference** MCM CH19
MIC5.1.5	**M**	Sample specific procedures define specific criteria for the evaluation and work up of each type of culture.	**M**	**Revised reference** MCM CH19
MIC5.1.6	**M**	Sample specific procedures define potential pathogens.	**M**	**Revised reference** MCM CH19
MIC5.1.7	**M**	Sample specific procedures define identification procedures.	**M**	**Revised reference** MCM CH19
MIC5.1.8	**M**	Sample specific procedures define criteria for antimicrobial susceptibility testing.	**M**	**Revised reference** MCM CH19

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC5.1.9	**M**	Sample specific procedures define requirements to send samples, isolates or products to a reference laboratory (e.g. confirmation, uncommon pathogen).	**M**	**Revised reference** MCM CH19
MIC5.1.10	**M**	Sample specific procedures define when interim reports are issued.	**M**	**Revised reference** MCM CH19
MIC6.1.2		Additional confirmatory examinations are performed on group A *Streptococcus* direct antigen negative throat samples.		**Revised reference** MCM CH19 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.	**M**	**Revised reference** MCM CH19, 51, 47
MIC6.1.4	**M**	There are criteria for acceptance of a nasal sample.	**M**	**Revised reference** MCM CH19
MIC6.2.1	**M**	There is a procedure for the detection, isolation and/or identification of *Neisseria gonorrhoeae* in neonates.	**M**	**Revised reference** MCM CH19
MIC6.2.2	**M**	There are procedures for the detection, isolation and/or identification of Actinomyces and fungi in ocular samples, if indicated.	**M**	**Revised reference** MCM CH19
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.	**M**	**Revised reference** MCM CH19, 34, 106
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).	**M**	**Revised reference** MCM CH19

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC6.4.1	**M**	Screening of vaginal samples for Candida is performed by microscopic evaluation.		**Deleted**
MIC6.4.6	**M**	There are procedures for the detection, isolation and identification of *Neisseria gonorrhoeae* and *Chlamydia trachomatis.*	**M**	**Revised** There are procedures for the detection and identification of *Neisseria gonorrhoeae* and *Chlamydia trachomatis.*
MIC6.4.7	**M**	There are procedures for susceptibility and epidemiological examination of *Neisseria gonorrhoeae* isolates.	**M**	**Revised reference** MCM CH19, 36
MIC6.4.8	**M**	All requests for *Lymphogranuloma venereum* examination are forwarded to the BC Centre for Disease Control or other acceptable referral laboratory.	**M**	**Revised reference** MCM CH19, 65
MIC6.5.1	**M**	Procedures include the use of selective enrichment and differential media to allow recovery of small numbers of enteric pathogens.	**M**	**Revised reference** MCM CH19
MIC6.5.2	**M**	Procedures include the referral of isolates for confirmation and epidemiological examination when appropriate.	**M**	**Revised reference** MCM CH19
MIC6.5.3	**M**	There is a procedure for the detection, culture or referral of *Clostridium difficile*.	**M**	**Revised** There is a procedure for the testing of *Clostridium difficile toxin/toxin gene.* **Revised reference** MCM CH55 CAP MIC.22440
MIC6.6.1	**M**	Procedures include examination of direct Gram stains on all CSF and sterile fluid samples.	**M**	**Revised reference** MCM CH19

Standard or criterion number	Version 1.4		Version 1.5 revision	
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).	**M**	**Revised reference** MCM CH19, 81
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.	**M**	**Revised reference** MCM CH19 CAP MIC.22495
MIC6.6.4	**M**	Procedures include criteria defining the use of cultures with available antigen detection systems.	**M**	**Revised reference** MCM CH19 CAP MIC.22550
MIC6.6.5	**M**	Procedures include handling positive CSF and other sterile fluid direct examination and cultures as critical results.	**M**	**Revised reference** CMPH CH2.1
MIC6.7.1	**M**	Blood culture systems are capable of detecting aerobic and anaerobic organisms.	**M**	**Revised reference** CAP MIC.22600 MCM CH4
MIC6.7.2	**M**	Procedures include the automated screening of blood cultures. *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.*	**M**	**Revised reference** MCM CH4 CAP MIC.22620
MIC6.7.3	**M**	Procedures include the subculture of suspected positive and positive blood cultures in a biological safety cabinet.	**M**	**Revised reference** MCM CH4

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC6.7.4	**M**	Procedures include handling positive blood cultures as critical results.	**M**	**Revised reference** MCM CH4
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.	**M**	**Revised reference** MCM CH4
MIC6.7.6	**M**	The contamination rate of blood cultures is documented and feedback is provided to sample collectors as appropriate.	**M**	**Revised reference** MCM CH4 CAP MIC.22630
MIC6.7.7	**M**	The laboratory has established other quality monitors for blood cultures (e.g. single bottle inoculations, positivity rate).	**M**	**Revised reference** MCM CH4 CAP MIC.22630
MIC6.7.8				**New** All positive blood culture bottles are sub-cultured to plated media to assess and examine growth.
MIC6.7.9				**New** AST and organism identification performed directly from positive blood culture broth are inoculated onto solid media to assess growth and examined for consistency.
MIC6.8.1		There are guidelines for the reporting of normal skin flora.		**Revised reference** MCM CH19
MIC6.8.2	**M**	Procedures include examination for aerobic pathogens and anaerobic pathogens when indicated.	**M**	**Revised reference** MCM CH19 CAP MIC.22700

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised reference** MCM CH19 CAP MIC.22700
MIC7.0		MALDI-TOF ~~-i~~dentification		**Revised** MALDI-TOF
MIC7.1.1	**M**	MALDI-TOF verification is performed using microorganisms expected to be encountered.	**M**	**Revised reference** CAP MIC.22840 CLSI M58
MIC7.1.3	**M**	MALDI-TOF controls are examined at defined intervals.	**M**	**Revised** MALDI-TOF controls, reagents and kits are examined at defined intervals.
MIC7.1.5			**M**	**New** There is a process to review and update the instrument database every 6 months if data are available.
MIC8.1.5	**M**	Antimicrobial cascades (the antimicrobials reported for organisms isolated from different sites of infection) are defined.	**M**	**Revised reference** CLSI M02 A11 CLSIM02
MIC8.1.6	**M**	AST procedures include when a specific susceptibility testing system or method is to be used.	**M**	**Revised reference** CLSI M02
MIC8.1.7	**M**	Procedures include criteria for AST of anaerobes.	**M**	**Revised reference** CLSI M100
MIC8.1.8	**M**	AST procedures include methods to detect important types of antibiotic resistance (e.g. MRSA, VRE).	**M**	**Revised reference** CLSI M02

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC8.1.10	**M**	Criteria for interpretation of the endpoint or zone size in AST systems are defined.	**M**	**Revised reference** CAP MIC.21930 CLS M02
MIC9.2.3	**M**	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.	**M**	**Revised** 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 for newly positive patients.
MIC9.3.1	**M**	A culture is performed on all requests for Mycobacteria tuberculosis regardless of the smear or molecular examination result.	**M**	**Revised reference** MCM CH31 CLSI M48
MIC9.3.2	**M**	Procedures include inoculation onto media that supports the optimal growth of the majority of clinically relevant Mycobacterium species.	**M**	**Revised reference** MCM CH31 CLSI M48
MIC9.3.5	**M**	Solid media is examined after one week of incubation and weekly thereafter until the end of the defined incubation period.	**M**	**Revised reference** MCM CH31 CLSI M48
MIC9.3.6	**M**	Commercial liquid media systems are examined according to the manufacturer's recommendations.	**M**	**Revised reference** MCM CH31 CLSI M48
MIC9.3.7	**M**	Suspected Mycobacterium growth and suspected contamination are confirmed by an acid-fast stain.	**M**	**Revised reference** MCM CH31 CLSI M48

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC9.3.8	**M**	There are differential examinations to accurately and rapidly identify and differentiate the different species of mycobacteria.	**M**	**Revised reference** MCM CH31 CAP MIC.32420 CLSI M48
MIC9.3.9	**M**	Samples with contamination are reprocessed, re-cultured and re-incubated.	**M**	**Revised reference** MCM CH31 CLSI M48
MIC9.3.10	**M**	Instrument negative tubes are visually checked prior to discard.	**M**	**Revised reference** MCM CH31 CLSI M48
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.		**Revised reference** CAP MIC.31680 CLSI M24-A2
MIC9.3.12	**M**	Storage conditions and retention times for positive cultures are defined.	**M**	**Revised reference** MCM CH31 CLSI M48
MIC9.4.1	**M**	The nucleic acid sequencing method has been verified using known strains of Mycobacterium expected to be encountered.	**M**	**Revised reference** CLSI MM18-A 5.4,5.5,5.6 CLSI MM19-A 11.4.7.6 CLSI M48

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC9.4.2	**M**	The purity of cultures used for nucleic acid sequencing is verified.	**M**	**Revised** The purity of cultures used for nucleic acid sequencing is verified when applicable. **Revised reference** CLSI MM18-A 5.4,5.5,5.6 CLSI MM19-A 11.4.7.6 CLSI M48
MIC9.4.3	**M**	The database used for nucleic acid sequences has been verified.	**M**	**Revised reference** CLSI MM18-A 5.4,5.5,5.6 CLSI MM19-A 11.4.7.6 CLSI M48
MIC9.4.4	**M**	Nucleic acid sequencing results are reviewed in conjunction with other laboratory data prior to reporting results.	**M**	**Revised reference** CLSI M48
MIC10.1.2	**M**	Direct examinations are performed when indicated. A direct stain is available for tissue and sterile body fluids.	**M**	**Revised reference** MCM CH117
MIC10.1.3	**M**	Suitable selective media and incubation temperatures are defined for the growth and isolation of clinically significant fungi.	**M**	**Revised reference** MCM CH117 CAP MIC.42050
MIC10.1.4	**M**	Safety precautions prevent the accidental opening of a plate (e.g. taping lid).	**M**	**Revised reference** MCM CH117 CAP MIC.43050
MIC10.1.5	**M**	Mycology slide cultures are not performed with dimorphic fungi.	**M**	**Revised reference** CMPH

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC10.1.7	**M**	Criteria for the identification of fungi are defined.	**M**	**Revised reference** MCM CH117 CAP MIC.42250
MIC10.1.8	**M**	Differential procedures (e.g. slide culture, differential agars) are performed where appropriate.	**M**	**Revised reference** MCM CH117 CAP MIC.42250
MIC10.1.10	**M**	Suspected dimorphic fungi are immediately referred for confirmatory examination.	**M**	**Revised reference** MCM CH117 CAP MIC.42550
MIC10.1.13	**M**	Positive and negative controls are used with mycology nucleic acid probes at a defined frequency.	**M**	**Revised reference** MCM CH117 CAP MIC.41270
MIC10.1.14			**M**	**New** Transfers of a colony exhibiting mycelial growth is performed within a biologic safety cabinet. **Reference** CAP MIC.43100 Clinical MIC Practical Handbook
MIC10.1.15			**M**	**New** Slide culture technique is limited to work with Risk Group 1 or 2 organisms (*Human Pathogens and Toxins Act,* 2009). **Reference** CAP MIC.43100

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC11.1.1	**M**	Procedures for the examination of unpreserved stools for intestinal parasites include a macroscopic examination and a wet preparation for motility.	**M**	**Revised reference** MCM CH137 CAP MIC.52100 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.	**M**	**Revised reference** MCM CH137 7 CAP MIC.52100
MIC12.1.4	**M**	Media and diluents are checked for sterility and pH.	**M**	**Revised reference** CLSI M41-A 5.3.1.1
MIC12.2.1		Laboratory algorithms define the examination of choice based upon sample type, diagnosis and suspected viruses.		**Revised reference** MCM CH81 CAP MIC.62500
MIC12.2.2	**M**	The incubation time for tube monolayer cultures is sufficient to recover the virus.	**M**	**Revised reference** MCM CH81 CAP MIC.61210
MIC12.2.4	**M**	The frequency of examination for cytopathic effect (CPE) is defined.	**M**	**Revised reference** MCM CH81 CLSI M41-A 7.4
MIC12.2.5		Procedures define further manipulation of cell cultures demonstrating unusual CPE.		**Revised reference** MCM CH81 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.	**M**	**Revised reference** MCM CH81 CAP MIC.61370

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC12.2.7	**M**	There are procedures for the confirmation of positive hepatitis and positive HIV serology.	**M**	**Moved to MIC14.2.5**
MIC12.2.8	**M**	Negative antigen detection examinations are confirmed by culture or molecular examination.		**Deleted**
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. *Guidance: Controls are processed through all steps of the examination.*	**M**	**Revised** In an open system, the adequacy of nucleic acid isolation or preparation is evaluated with each examination by use of positive and negative controls run in parallel with patient samples. *Guidance: Controls are processed through all steps of the examination.* **Revised reference** CLSI MM03-A2 15.1, 15.3 CLSI MM19-A
MIC13.1.2	**M**	The laboratory monitors and records the adequacy of DNA extraction, including failure rates.	**M**	**Revised** In an open system, the laboratory monitors and records the adequacy of nucleic acid extraction and failure rates. **Revised reference** CLSI MM03-A2 15.1, 15.3 CAP MIC.65260 CLSI MM19-A
MIC13.1.3		Acceptable inhibition rates are established or provided by the manufacturer.		**Revised reference** MCM CH4 CAP MIC.65250

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC13.1.4		There are processes to identify and investigate false positive results of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* examinations.	**M**	**Revised reference** MCM CH7,36 CAP MIC.63252 **Revised to mandatory requirement**
MIC13.1.6		Verification of rare organism or subtype examination is performed at least annually.		**Moved to MIC13.5.7**
MIC13.2.1	**M**	There are procedures to prevent sample degradation during collection, transport, and storage.	**M**	**Revised** There are procedures to prevent sample degradation during collection, processing, transport, and storage. **Revised reference** MCM CH4,7 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.	**M**	**Revised** Dedicated equipment and supplies and a separate assay setup area are maintained in the clean area used for handling samples and extracting DNA in open systems. **Revised reference** MCM CH4,7 CLSI MM19-A 8.1.1
MIC13.2.3	**M**	No aliquot is ever returned to the original container.	**M**	**Revised reference** MCM CH4, 7 CLSI MM19-A 7 MIC.63322

Standard or criterion number	Version 1.4		Version 1.5 revision	
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).	**M**	**Revised reference** MCM CH4, 7 CLSI MM19-A 8.1.1
MIC13.2.5	**M**	Gowns and gloves are frequently changed during processing and when moving between areas.	**M**	**Revised** Gowns and gloves are frequently changed during processing and when moving between areas in an open system. Gloves are frequently changed during processing and when moving between areas in a closed system. **Revised reference** MCM CH4, 7 CLSI MM19-A 8.1.1
MIC13.2.6		There are sticky mats at the entry and exit to each area.		**Revised** There are sticky mats at the entry and exit to each area of an open system. **Revised reference** MCM CH4, 7 CLSI MM19-A 8.1.1
MIC13.2.7	**M**	Dedicated pipettes (positive displacement type or with aerosol barrier tips) are used.	**M**	**Revised reference** MCM CH4, 7 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).	**M**	**Revised reference** MCM CH4, 7 CLSI MM19-A 8.1.1

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC13.2.10	**M**	Wipe tests of exposed surfaces and equipment is performed at defined intervals.	**M**	**Revised reference** MCM CH4, 7 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.	**M**	**Revised** In an open system, negative controls are dispensed to reflect the cumulative effects of manipulations. **Revised reference** DAP AC 2019 CLSI MM19-A
MIC13.2.12		Procedures for amplification-based exams on residual samples ensure the absence of cross-contamination and results are interpreted with caution.		**Revised** If residual samples are used for amplification-based exams, policies and procedures are in place to ensure the absence of cross-contamination of samples. *Guidance: An example of a residual sample is a chemistry sample that is tested post chemistry testing using an amplification exam.* **Revised reference** MCM CH4,7 CLSI MM19-A 8.1.2 CAP MIC.63324

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC13.2.13	**M**	Handling of post-amplification products and used materials is consolidated to a defined area.	**M**	**Revised** Post-amplification products and used materials are handled and disposed of in a defined area. **Revised reference** MCM CH4,7 CLSI MM19-A 8.1.1
MIC13.2.14	**M**	Samples and extracted nucleic acids are stored under conditions that encourage stability. *Guidance: Frost-free freezers are not used for storage. DNA is stored at -20°C. RNA is stored at -80°C.*	**M**	**Revised** In an open system, samples and extracted nucleic acids are stored under conditions that ensure stability. *Guidance: Frost-free freezers are not used for storage. DNA is stored at -20°C. RNA is stored at -80°C.* **Revised reference** MCM CH4,7 CLSI MM19-A 7 CAP MIC.63328
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. *Guidance: This does not apply to real time PCR instruments.*	**M**	**Revised** In an open system, individual wells (or a representative sample) of thermocyclers are checked for temperature accuracy prior to initial use and at least annually thereafter.
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.		**Deleted**

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC13.3.3	**M**	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	**M**	**Revised** In an open system, 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. **Revised reference** MCM CH4,7 CLSI MM09 8
MIC13.4.1		Temperatures for each step of the examination are monitored.		**Deleted**
MIC13.4.2	**M**	Criteria for the acceptability and interpretation of primary sequence data are established.	**M**	**Moved to MIC13.5.9**
MIC13.4.3		Negative molecular examinations for group B streptococci are followed by selective broth culture.		**Deleted**
MIC13.4.4	**M**	Interpretation of sequence data is based on current databases.	**M**	**Moved to MIC13.5.10**
MIC13.4.5	**M**	Narrow temperature ranges are defined and monitored for examinations that generate a result based on a melting temperature.	**M**	**Moved to MIC13.5.11**
MIC13.4.6	**M**	Calibrator results are within defined ranges for each run of quantitative real time PCR examinations (e.g. viral load monitoring).	**M**	**Revised** In an open system, calibrator results are within defined ranges for each run of quantitative real time PCR examinations (e.g. viral load monitoring).

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC13.4.7	**M**	The required resolution of images (e.g. auto radiographs, gel images) is defined.	**M**	**Moved to MIC13.5.12**
MIC13.4.9	**M**	Visual or fluorescent markers are used to determine the endpoint of gel electrophoresis.	**M**	**Revised reference** CLSI MM19-A 8.7 CAP MIC.65720
MIC13.5.1	**M**	Laboratory developed examinations are validated. This is documented.	**M**	**Revised reference** CLSI MM19-A 8.7 CAP MIC.64760 CAP MIC.64968
MIC13.5.2	**M**	Alternative sequence interpretative databases, used either alone or in conjunction with the manufacturer's software are validated.	**M**	**Revised reference** MCM CH4,7
MIC13.5.3		There is a record of all probes and primers used in examinations.	**M**	**Revised reference** CLSI MM19-A 8.7 CAP MIC.31670 **Revised to mandatory requirement**
MIC13.5.4	**M**	There are criteria for the acceptability and interpretation of primary sequencing data to ensure unequivocal sequence readout.	**M**	**Revised reference** CLSI MM19-A 8.7
MIC13.5.5		Sequence data is correlated with phenotypic data, when available.	**M**	**Revised reference** CLSI MM19-A 8.7 CAP MIC.66000 **Revised to mandatory requirement**

Standard or criterion number	Version 1.4	Version 1.5 revision
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).	**Revised reference** CLSI MM19-A 8.7 CAP MIC.65330
MIC13.5.7	Verification of rare organism or subtype examination is performed at least annually.	**Moved from MIC13.1.6** **Revised** Verification of rare organism or subtype examination is performed at a defined interval.
MIC13.5.8		**M** **Moved from 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. **Revised reference** MCM CH4,7 CLSI MM09 8
MIC13.5.9		**M** **Moved from MIC13.4.2** **Revised** Criteria for the acceptability and interpretation of primary sequence data are established. **Revised reference** MCM CH4,7 CLSI MM09 8

Standard or criterion number	Version 1.4	Version 1.5 revision	
MIC13.5.10		**M**	**Moved from MIC13.4.4** **Revised** Interpretation of sequence data is based on current databases. **Revised reference** MCM CH4,7
MIC13.5.11		**M**	**Moved from MIC13.4.5** **Revised** Narrow temperature ranges are defined and monitored for examinations that generate a result based on a melting temperature. **Revised reference** CLSI MM19-A 8.7 CAP MIC.65300
MIC13.5.12		**M**	**Moved from MIC13.4.7** The required resolution of images (e.g. auto radiographs, gel images) is defined. **Revised reference** CLSI MM19-A 8.7 CAP MIC.64938
MIC13.5.13		**M**	**New** Laboratory modified examinations are validated. This is documented. **Revised reference** CAP MIC.64770

Standard or criterion number	Version 1.4		Version 1.5 revision	
MIC13.6.1	**M**	The final report includes a summary of the examination method and information regarding clinical interpretation if appropriate.	**M**	**Revised reference** CLSI – MM19-A 8.8
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.		**Deleted**
MIC14.2.5	**M**	There are procedures for the confirmation of positive hepatitis and positive HIV serology.	**M**	**Moved from MIC12.2.7** **Revised** There are procedures for the confirmation of positive hepatitis A IgM, hepatitis Bs Antigen, hepatitis C antibody and positive HIV serology.

POINT-OF-CARE TESTING

Standard or criterion number	Version 1.4		Version 1.5 revision	
POC1.2.4	**M**	The multidisciplinary POCT management group reviews all proposals to introduce any POCT equipment. *Guidance: Proposals to introduce POCT consider:* • *coordination with existing laboratory services* • *analysis of the current service* • *a cost-benefit analysis of the proposed POCT analysis of the service required* • *alternative options*	**M**	**Revised reference** ISO 22870 4.1.2.5 ISO 22870 4.15.2
POC1.2.6		The laboratory director and the multidisciplinary POCT advisory management group identify opportunities for improvement in POCT activities.	**M**	**Revised to mandatory requirement**

Standard or criterion number	Version 1.4		Version 1.5 revision	
POC1.3.2		A training manager with theoretical knowledge and experience has been appointed to manage POCT training and competency assessment.		**Revised reference** ISO 22870 5.1.4 a
POC1.3.3	**M**	Training considers recommendations provided by the manufacturer.	**M**	**Revised reference** DAP AC 2019
POC1.3.4	**M**	Competency assessment is documented at a defined frequency. Retraining and continuing education is documented.	**M**	**Revised** The POCT multidisciplinary committee establishes a competency assessment program. The competency assessment is documented at a defined frequency. Retraining and continuing education are documented.
POC1.3.5	**M**	POCT is performed by personnel who have completed training and demonstrated competence.	**M**	**Revised reference** ISO 22870 5.1.4b
POC1.3.6		POCT operator performance is monitored for compliance with procedures.		**Revised reference** ISO 15189 5.1.6a ISO 22870 5.1.4e
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.	**M**	**Revised reference** ISO 15189 4.3 ISO 22870 4.3
POC2.1.9	**M**	All POCT policies, processes and procedures are reviewed every one to three years. This is documented.	**M**	**Revised reference** ISO 22870 4.3 ISO 15189 4.3
POC2.2.1	**M**	Internal audits of POCT are conducted. *Guidance: See QMS6.3.*	**M**	**Revised reference** ISO 15189 4.14.5 ISO 22870 4.14

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised reference** ISO 22870 4.14
POC2.2.3	**M**	Suggested modifications arising from audit analysis are incorporated into POCT processes and procedures.	**M**	**Revised reference** ISO 22870 4.14b
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.	**M**	**Revised reference** ISO 15189 4.15.2d, f, k, l
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.	**M**	**Revised reference** ISO 22870 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.	**M**	**Revised reference** ISO 22870 4.11
POC3.3.2	**M**	POCT equipment records include the date purchased, maintenance records and removal from service dates.	**M**	**Revised** POCT equipment records include the date received, maintenance records and removal from service dates.
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.	**M**	**Revised reference** ISO 22870 5.6.6d, e
POC4.1.2	**M**	QC procedures are defined for each POCT examination.	**M**	**Revised reference** ISO 15189 k ISO 5.6.2.1

Standard or criterion number	Version 1.4		Version 1.5 revision	
POC4.1.3	**M**	The frequency of internal QC is defined for each piece of POCT equipment.	**M**	**Revised reference** ISO 22870 5.6.6 c
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.	**M**	**Revised reference** ISO 22870 5.6.2 CAP POC.07300
POC4.1.9			**M**	**New** Quality control is performed by POCT operators.
POC4.2.1	**M**	All POCT is evaluated using an alternate means of assessment or by formal proficiency testing (PT) programs.	**M**	**Revised** All POCT is evaluated using a formal proficiency testing program or by an alternate means of assessment.
POC4.2.2	**M**	The alternative assessment is established by the laboratory medical director or designate.	**M**	**Revised reference** ISO 22870 5.6.4
POC4.2.3	**M**	POCT PT or alternative assessment occurs at least twice per year.	**M**	**Revised** Proficiency testing or alternate assessment occurs at least twice per year.
POC4.2.4	**M**	POCT PT or alternative assessment is examined by personnel who routinely examine patient samples.	**M**	**Revised** Proficiency testing or alternate assessment is performed by POCT operators.
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.	**M**	**Revised** Proficiency testing or alternate assessment results are monitored by the laboratory medical director or designate at a defined interval and discussed with relevant personnel.

Standard or criterion number	Version 1.4		Version 1.5 revision	
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.	**M**	**Revised** Unacceptable proficiency testing or alternate assessment results are investigated, and corrective action is implemented where indicated. This investigation and any corrective action are documented and retained.
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.	**M**	**Revised** The authority to withdraw equipment or discontinue a POCT examination in the event of serious proficiency testing or alternate assessment problems are defined.
POC5.1.2	**M**	Procedures for sample collection for POCT are communicated and available to personnel performing the POCT examinations.	**M**	**Revised reference** ISO 15189 5.4.4.2-3 ISO 22870 5.4.2, 5.4.3
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.	**M**	**Revised reference** ISO 22870 5.6.6h
POC6.1.2	**M**	Every examination requested is recorded.	**M**	**Revised reference** ISO 22870 5.8.3
POC6.1.3	**M**	POCT results are recorded as a POCT result and incorporated into the patient's permanent medical record.	**M**	**Revised reference** ISO 22870 5.8.3-4 CAP POC.04400
POC6.1.4	**M**	POCT results are clear and legible. Thermal printouts are not used to record results.	**M**	**Revised reference** ISO 15189 5.8.3a CLSI POCT04