Accreditation Standards 2015

Laboratory Medicine

Version 1.3 Revision Record

Effective February 1, 2017

GLOSSARY

Standard or Criterion Number	2015 Original	Version 1.3 Revision
referral laboratory	An external laboratory to which a sample is submitted for examination. **Note1:** A referral laboratory is one to which the laboratory chooses to submit a sample for examination when routine examinations cannot be carried out. This differs from a laboratory that may include public health, forensics, tumor registry, or a central (parent) facility to which submission of samples is required by structure or regulation. **Note2:** The referring laboratory is not expected to assess the quality of the referral laboratory directly. The referring laboratory is required to maintain evidence from the referral laboratory that demonstrates competence such as certification or accreditation status. For the purpose of the standards, referral laboratories working in laboratories that are accredited by the DAP are exempt.	Revised An external laboratory where a sample is submitted for examination. *Note: Each external laboratory where a sample is submitted should be considered to be a referral laboratory.* Also see QMS3.1.1

ORGANIZATION

Standard or Criterion Number		2015 Original	Version 1.3 Revision
ORG1.1.2	**M**	The governing body/ownership ensures the availability of **adequate** resources to enable the proper conduct of pre-examination, examination and post-examination activities.	Revised The governing body/ownership ensures the availability of resources to enable the proper conduct of pre-examination, examination and post-examination activities.
ORG2.2.10	**M**	Laboratory directors relate and function effectively with accrediting and regulatory agencies, **appropriate** administrative officials, the health-care community and the patient population served, and providers of formal agreements, when required.	Revised Laboratory directors relate and function effectively with accrediting and regulatory agencies, administrative officials, the health-care community and the patient population served, and providers of formal agreements, when required.
ORG2.2.11	**M**	Laboratory directors ensure that there are **appropriate** numbers of personnel with the required education, training and competence to provide laboratory services that meet the needs and requirements of users.	Revised Laboratory directors ensure that there are personnel with the required education, training and competence to provide laboratory services that meet the needs and requirements of users.
ORG2.2.18	**M**	Laboratory directors plan and direct research and development, **where appropriate**.	Revised Laboratory directors plan and direct **diagnostic examination** research and development.

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Preamble before ORG3.3 NEW		**CREDENTIALING AND PRIVILEGING** Credentialing is a process that involves the collection, verification and assessment of information regarding the education, training, experience and ability of an individual physician to perform a requested privilege. In British Columbia physicians must have the requisite credentials as outlined in the Provincial Privileging Dictionaries (http://bcmqi.ca/privileging-dictionaries). Credentialing for physicians who hold privileges at any health authority facility is performed by the health authority, and includes assessing eligibility for MSP billings for restricted services. Many medical offices are owner-operated solo practices and the physician may not hold privileges with a health authority; therefore, the physician would not have proceeded through a credentialing process. In these instances the physician is licensed to their scope of practice through the College of Physicians and Surgeons of BC. For MSP billing purposes for a restricted diagnostic service, the College will review the associated credentials required to be eligible to bill for these services and will notify MSP of the eligibility. For further information please contact credentialing@cpsbc.ca. For community-based multi-physician facilities the medical director and ownership are responsible to ensure the physicians that practice in their facilities are appropriately credentialed, either through the health authority or by reviewing the credentials of the physician and ensuring that the physician has been deemed eligible to bill MSP for the services. There must be a formal process used for credentialing and privileging, and it is the expectation of these accreditation standards that the medical director and ownership can demonstrate these processes.	
ORG3.3.7	**M**	A record is maintained for each medical practitioner indicating the scope of service and procedures they are permitted to perform within the laboratory and this is communicated to the practitioner and the organization.	**Revised** A record is maintained for each medical practitioner indicating the scope of service and procedures (**including any MSP billing eligibility confirmation for restricted services**) they are permitted to perform within the laboratory and this is communicated to the practitioner and the organization.
ORG3.3.9	**M**	Physicians providing medical biochemistry services are licensed to practise medical biochemistry or general pathology by the College of Physicians and Surgeons of British Columbia.	**Revised** Physicians providing medical biochemistry services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries. *Guidance: Medical biochemistry services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform* medical biochemistry.

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ORG3.3.10	**M**	Physicians providing hematology services are licensed to practise hematological pathology or general pathology by the College of Physicians and Surgeons of British Columbia.	Revised Physicians providing hematology services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries. *Guidance: Hematology services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform hematology.*
ORG3.3.11	**M**	Physicians providing microbiology services are licensed to practise medical microbiology or general pathology by the College of Physicians and Surgeons of British Columbia.	Revised Physicians providing medical microbiology services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries. *Guidance: Medical microbiology services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform medical microbiology.*
ORG3.3.12	**M**	Physicians providing transfusion medicine services are licensed to practise hematological pathology or general pathology by the College of Physicians and Surgeons of British Columbia.	Revised Physicians providing transfusion medicine services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries. *Guidance: Transfusion medicine services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform transfusion medicine.*

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ORG3.3.13	**M**	Physicians providing anatomic pathology services are licensed to practise anatomical pathology or general pathology by the College of Physicians and Surgeons of British Columbia.	Revised Physicians providing anatomic pathology services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries. *Guidance: Anatomic pathology services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform anatomic pathology.*
ORG3.3.14	**M**	Physicians providing genetic and cytogenetic services are licensed to practise hematological pathology or general pathology by the College of Physicians and Surgeons of British Columbia, with additional training and Canadian College of Medical Geneticists certification in the appropriate field.	Revised Physicians providing genetic and cytogenetic services have the requisite credentials for privileges as outlined in the Provincial Privileging Dictionaries. *Guidance: Genetics and cytogentics services are considered core and non-core privileges depending on the relevant specialty and therefore may require further training, experience and demonstrated skill. Refer to http://bcmqi.ca/privileging-dictionaries/ for the requirements to perform genetics and cytogenetics.*
ORG4.1.1	**M**	There is a human resources plan to identify **adequate** personnel numbers and required competencies to meet the current and future needs of the laboratory.	Revised There is a human resources plan to identify personnel numbers and required competencies to meet the current and future needs of the laboratory.
ORG4.2.2	**M**	Personnel making judgments with reference to examinations have the education, training, theoretical and practical background, and qualifications **appropriate** to the job.	Revised Personnel making judgments with reference to examinations have the education, training, theoretical and practical background, and qualifications **relevant** to the job.
ORG4.4.3	**M**	There are processes to ensure that existing potential conflicts and competing interests are openly **and appropriately** declared.	Revised There are processes to ensure that existing potential conflicts and competing interests are openly declared.

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ORG4.4.5	**M**	Confidentiality of information is maintained.	Revised There are procedures to ensure that the confidentiality of patient information is maintained at all times.
ORG4.6.5	**M**	At a frequency determined by the facility, personnel receive orientation and training on the applicable laboratory information processes and systems	Deleted See IMI1.3.1-2
ORG4.6.3-19		At a frequency determined by the **facility**, personnel receive orientation and training on risk management as **appropriate** to their role	Revised At a frequency determined by the organization, personnel receive orientation and training on (*) as relevant to their role on:
ORG4.7.1	**M**	At a frequency determined by the facility, personnel receive health and safety orientation and training for infection prevention, control, and reporting (e.g. routine precautions, sharps handling, needle stick injury protocol, personal protective equipment).	Revised At a frequency determined by the organization Moved to SAF3.1.10
ORG4.7.2	**M**	At a frequency determined by the facility, personnel receive health and safety orientation and training for injury prevention and reporting personal injuries	Deleted See SAF3.1.1
ORG4.7.3	**M**	At a frequency determined by the facility, personnel receive health and safety orientation and training for workplace hazardous materials information system (WHMIS) and other safety requirements.	Revised At a frequency determined by the organization Moved to SAF3.1.11
ORG4.7.4	**M**	At a frequency determined by the facility, personnel receive health and safety orientation and training for fire safety	Deleted See SAF3.1.7
ORG4.7.5	**M**	At a frequency determined by the facility, personnel receive orientation and training on the management of aggressive behaviour	Revised At a frequency determined by the organization Moved to ORG4.6.16

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ORG4.7.6	**M**	At a frequency determined by the facility, personnel receive orientation and training on violence and harassment in the workplace	Revised At a frequency determined by the organization Moved to ORG4.6.17.
ORG4.7.7	**M**	At a frequency determined by the facility, personnel receive orientation and training on emergency responses or codes, **where applicable**	Revised At a frequency determined by the organization, personnel receive orientation and training on emergency responses or codes. Moved to ORG4.6.18
ORG4.7.8		At a frequency determined by the facility, personnel receive orientation and training on disaster response	Revised At a frequency determined by the organization Moved to ORG4.6.19
ORG4.7.9	**M**	The effectiveness of the training program is reviewed at a defined interval.	Moved to ORG4.6.20
ORG4.8.6	**M**	Existing personnel are assessed on the use of current technology and current procedures prior to performance appraisals.	Deleted
ORG4.8.7	**M**	Competency assessments are conducted and reviewed by individuals with appropriate education, experience and qualifications.	Revised The education, experience and qualifications of individuals performing competency assessment are defined.
ORG4.10.7	**M**	Human resources records are disposed of **appropriately** and in accordance with regulations.	Revised There is a documented process for human resource record disposal that is in accordance with regulations.
ORG5.0		NEW	Delegated Medical Acts
ORG5.1.1	**M**	NEW	Each delegated medical act is clearly defined and circumscribed.
ORG5.1.2	**M**	NEW	The degree of medical supervision required is identified. *Guidance: Medical supervision may be direct, with the physician in attendance, or through technology (video link, digital imaging, telephone), or according to a written protocol.*
ORG5.1.3	**M**	NEW	Competency requirements to perform the delegated medical act are clearly identified.

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ORG5.2.1	**M**	NEW	Approval from the governing body/ownership of the organization has been obtained prior to the delegated medical act being carried out in the organization.
ORG5.2.2	**M**	NEW	The delegation of the medical act has been accepted by the individual(s) who will perform the delegated medical act.
ORG5.2.3	**M**	NEW	The laboratory maintains a list of approved medical acts that may be delegated and the individuals authorized to conduct each delegated medical act.
ORG5.3.1	**M**	NEW	Additional training is provided to individuals performing the delegated medical act.
ORG5.3.2	**M**	NEW	Competency assessment to perform a specific delegated medical act is conducted by a physician or technical delegate. *Guidance: Competency assessment of the technical delegate is conducted by a physician with relevant expertise in the medical act.*
ORG5.3.3-6	**M**	NEW	There is a competency assessment record for each individual performing delegated medical acts. The competency assessment record includes:
ORG5.3.3	**M**	NEW	• the date of the assessment
ORG5.3.4	**M**	NEW	• the specific act(s) being assessed
ORG5.3.5	**M**	NEW	• the name of the physician or technical delegate conducting the assessment
ORG5.3.6	**M**	NEW	• the signature of the physician or technical delegate attesting to the competence of the individual performing the specific act(s)
ORG5.3.7	**M**	NEW	The competency of the individual performing the specific delegated medical act is reassessed annually by a physician or technical delegate. *Guidance: The record of assessment for each individual is updated annually following the reassessment.*

QUALITY MANAGEMENT SYSTEMS

Standard or Criterion Number		2015 Original	Version 1.3 Revision
QMS1.1.5	**M**	The quality policy is reviewed for continuing suitability and revised as **appropriate**.	Revised The quality policy is reviewed for continuing suitability and revised as **required.**
QMS2.1.1	**M**	There are defined authorities, procedures and processes for the maintenance and review of documents.	Revised There are defined authorities, procedures and processes for the maintenance and review of documents. *Guidance: The laboratory controls documents required by the QMS and ensures that unintended use of any obsolete document is prevented.*
QMS2.1.2	**M**	The laboratory controls documents required by the QMS and ensures that unintended use of any obsolete document is prevented.	Deleted See QMS2.1.1
QMS3.2.3	**M**	The laboratory has the capability and resources to meet the requirements	Revised The laboratory has the capability and resources to meet the requirements of agreements including personnel with the skills and experience necessary for the performance of the intended examinations.
QMS3.2.4	**M**	Laboratory personnel have the skills and expertise necessary for the performance of the intended examinations.	Deleted See QMS3.2.3
QMS3.3.1	**M**	There are procedures for the selection and purchase of external services, equipment, reagents and consumables that affect the quality of examinations	Deleted See ERS3.1.1
QMS3.3.2	**M**	The laboratory selects and approves suppliers using established criteria based on the suppliers' ability to provide external services, equipment, reagents and consumables in accordance with the laboratory's requirements.	Deleted See ERS1.1.2
QMS3.3.3	**M**	A list of selected and approved suppliers is maintained.	Deleted See ERS1.1.3

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QMS3.3.4	**M**	The requirements for products and services to be purchased are described and the laboratory monitors the performance of suppliers to ensure that purchased products and services consistently meet the stated criteria.	Deleted See ERS1.1.4
QMS4.1.1	**M**	There are **appropriate** advisory and interpretative services that meet the needs of patients, users and other parties.	Revised There are advisory and interpretative services that meet the needs of patients, users and other parties.
QMS4.1.5		The laboratory ensures that **appropriate** communication processes are established with its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and QMS.	Revised The laboratory ensures that communication processes are established with its stakeholders and that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination and post-examination processes and QMS.
QMS5.1.8	**M**	The results of any nonconforming examinations already released are recalled or appropriately identified **as** necessary.	Revised The results of any nonconforming examinations already released are amended **where** necessary.
QMS5.1.9	**M**	When reviews by external organizations indicate the laboratory has nonconformities the laboratory takes **appropriate** immediate and corrective action to ensure continuing compliance with the requirements of ISO 15189.	Revised When reviews by external organizations indicate the laboratory has nonconformities the laboratory takes immediate, corrective action to ensure continuing compliance with the requirements of ISO 15189.
QMS5.2.3	**M**	The results of any potentially nonconforming examinations already released are recalled **or appropriately identified,** as necessary.	Revised The results of any potentially nonconforming examinations already released are identified, as necessary.
QMS5.2.4	**M**	When reviews by external organizations indicate the laboratory has potential nonconformities, the laboratory takes **appropriate** preventive action to ensure continuing compliance with the requirements of ISO 15189.	Revised When reviews by external organizations indicate the laboratory has potential nonconformities, the laboratory takes preventive action to ensure continuing compliance with the requirements of ISO 15189.
QMS6.1.6	**M**	Quality indicators are reviewed at a defined interval **to ensure their continued appropriateness.**	Revised Quality indicators are reviewed at a defined interval.

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QMS 6.2.3	**M**	Action plans for improvement are developed, documented and implemented **as appropriate**.	Revised Action plans for improvement of identified risk are developed, documented and implemented.
QMS6.3.8	**M**	Personnel responsible for the area being audited ensure that **appropriate** action is promptly undertaken when nonconformities are identified.	Revised Personnel responsible for the area being audited ensure that action is promptly undertaken to eliminate the causes of identified nonconformities.
QMS6.4.7		The **quality and appropriateness of the** laboratory's contribution to patient care is also objectively evaluated (to the extent possible).	Revised The laboratory's contribution to patient care is objectively evaluated (to the extent possible).
QMS6.4.8	**M**	Findings and actions arising from management reviews are recorded and reported to laboratory personnel, and reported within the organization **as appropriate**.	Revised Findings and actions arising from management reviews are recorded and reported to laboratory personnel, and reported within the organization.

SAFETY

Standard or Criterion Number		2015 Original	Version 1.3 Revision
SAF1.1.3		An **appropriately** qualified laboratory safety officer has been designated with the authority to stop unsafe work activities.	Revised A qualified laboratory safety officer has been designated with the authority to stop unsafe work activities.
SAF1.1.6	**M**	The safety program includes the prompt investigation of safety incidents to determine action necessary to prevent recurrence.	Deleted See SAF2.2.1
SAF1.1.8	**M**	The safety program includes the requirement for laboratory personnel to wear personal protective equipment (PPE) to ensure worker safety.	Deleted See SAF3.2.2
SAF1.1.12	**M**	The safety program includes risk assessments and preventive action. *Guidance: Safety risk assessments may include a review of chemicals to determine if a safety shower is needed, and to determine the contents of a spill kit.*	Deleted See SAF3.6, SAF2.2, SAF5.4
SAF1.1.16	**M**	The safety program includes a safety-focused review and update of all laboratory procedures and practices at a defined frequency.	Deleted See SAF2.1.7
SAF1.1.17		The safety program includes an audit conducted at least annually.	Revised and moved to SAF2.1.7 The safety program includes an **overall** audit conducted at least annually.
SAF1.2.1	**M**	The safety manual is available in all work areas.	Revised Safety **procedures and** references are available in all work areas. ***Guidance: Safety procedures and references may be in the form of online documents or a hard copy manual.***
SAF1.2.2	**M**	The safety manual addresses incident and injury procedures.	Deleted See SAF3.1.1
SAF1.2.3	**M**	The safety manual addresses biological, chemical, fire, and electrical safety.	Deleted Addressed elsewhere in standards.

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SAF1.2.4	**M**	The safety manual addresses compressed gas safety, cryogenic hazards and if applicable, radiation safety.	Deleted Addressed elsewhere in standards.
SAF1.2.5	**M**	The safety manual addresses hazardous waste disposal. *Guidance: This includes biological and chemical waste disposal.*	Deleted See SAF9.0
SAF1.2.6	**M**	The safety manual addresses disaster plans, including workplace evacuations.	Deleted Addressed elsewhere in standards
SAF1.2.7	**M**	The contents of the safety manual are reviewed at defined intervals by the laboratory director or designate (e.g. the laboratory safety representative, safety committee).	Revised Safety **procedures** are reviewed at defined intervals by the laboratory director or designate (e.g. the laboratory safety representative, safety committee).
SAF1.2.8	**M**	Personnel review the safety manual when there are changes relevant to their scope of practice and at a defined frequency.	Revised Personnel review the relevant safety **procedures** when there are changes to their scope of practice and at a defined frequency.
SAF2.2	**M**	There are procedures to address safety hazards and investigate incidents.	Revised There are procedures to report, investigate and follow up on safety related incidents.
SAF2.2.1	**M**	There is a documented process to promptly investigate and report safety incidents, injury, accidents and occupational illness. Investigating personnel have received **appropriate** orientation and training.	Revised There is a documented process to promptly report and investigate safety incidents, injury, accidents and occupational illness. Investigating personnel have received **specific** orientation and training.
SAF2.2.9	**M**	Signage is posted indicating areas of hazard (e.g. biohazard, radioactivity). *Guidance: Signage may be subject to regulation (e.g. radioactive material). Internationally approved signage is preferred if available.*	Deleted See FAC4.1.1

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SAF3.1.1	**M**	Personnel have received orientation and training in injury prevention and the identification and reporting of safety incidents, injury, accidents and occupational illness.	Revised Personnel receive orientation and training on injury prevention, the identification and reporting of safety incidents, injury, accidents and occupational illness at a frequency determined by the organization.
SAF3.1.5	**M**	Personnel preparing samples for transport and transporting patient samples to another facility are certified, or are supervised by personnel certified, in accordance with Transport of Dangerous Goods Regulations.	Moved to PRE3.1.6
SAF3.1.7	**M**	Laboratory personnel are provided with instruction and training on the recognition and evaluation of fire hazards, reducing the risk of fire and actions to take when fires occur.	Revised Laboratory personnel are provided with instruction and training on the recognition and evaluation of fire hazards, reducing the risk of fire and actions to take when fires occur at a frequency determined by the organization.
SAF3.2.1	**M**	Adequate and appropriate personal protective equipment is available.	Revised Personal protective equipment **appropriate to the level of risk for the tasks performed is available**.
SAF3.2.13	**M**	Requirements for special footwear in specific laboratory areas have been defined where appropriate.	Deleted See. SAF3.2.12
SAF3.4.2	**M**	The laboratory ensures that personnel **and visitors (e.g. vendors, service personnel)** wash their hands prior to and after contact with each patient	Revised The laboratory ensures that personnel wash their hands prior to and after contact with each patient.
SAF3.4.3	**M**	The laboratory ensures that personnel **and visitors (e.g. vendors, service personnel)** wash their hands after contact or potential contact with blood, body fluids or other contaminated material	Revised The laboratory ensures that **personnel** wash their hands after contact or potential contact with blood, body fluids or other contaminated material.
SAF3.4.4	**M**	The laboratory ensures that personnel **and visitors (e.g. vendors, service personnel)** wash their hands immediately after removing gloves or prior to putting on gloves	Revised The laboratory ensures that **personnel** wash their hands immediately after removing gloves or prior to putting on gloves.

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SAF3.5.3	**M**	Personnel know how to access first aid in the workplace.	Revised Personnel know how to access first aid in the workplace. All injuries are reported to first aid.
SAF3.5.4	**M**	All injuries are reported to first aid.	Deleted See SAF3.5.3
SAF3.7.1	**M**	Laboratory areas are free of obstructions and potential tripping hazards.	Revised Laboratory areas are clean, well maintained and free of obstructions and potential tripping hazards.
SAF3.7.6	**M**	Laboratory work areas are clean and well maintained.	Deleted See SAF3.7.1
SAF4.1.3	**M**	Sharps containers are sealed and replaced when filled to the fill line and disposed **of appropriately**.	Revised Sharps containers are sealed and replaced when filled to the fill line and disposed of in accordance with current guidelines for waste management.
SAF4.2.3		BSCs are certified on installation, after changing the HEPA filter, after movement of the unit, after any repair or maintenance that could affect the seal of the HEPA filter, and recertified annually by **an individual with appropriate knowledge, training and experience**. These certification records are retained.	BSCs are certified on installation, after changing the HEPA filter, after movement of the unit, after any repair or maintenance that could affect the seal of the HEPA filter, and recertified annually. These certification records are retained.
SAF5.1.6	**M**	All controlled substances are labeled **appropriately.**	Revised All controlled substances are labeled in accordance with WHMIS information.
SAF5.2.3	**M**	Flammable gases and liquids are kept away from heat and sources of ignition.	Revised Flammable liquids and gases are kept away from heat and sources of ignition and used only in well ventilated areas.
SAF5.2.7	**M**	Portable safety containers are used for storing, transporting and dispensing flammable liquids.	Deleted See SAF5.1.10
SAF5.2.8	**M**	Decanting or transferring flammable liquids from stock drums to small containers is done in a storage room reserved for this purpose.	Deleted

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SAF5.2.9	**M**	Flammable gases and liquids are used only in well ventilated areas.	Deleted See SAF5.2.3
SAF6.4	**M**	There are procedures for the safe use of ultraviolet (UV) and laser light.	Deleted
SAF6.4.1	**M**	Eye protection is available and appropriate signage is used.	Deleted
SAF6.4.2	**M**	Personnel are trained on the safe use of equipment and light sources are used only for the intended purpose.	Deleted
SAF6.4.3	**M**	The housing for UV and laser light sources is only opened by qualified service personnel.	Deleted
SAF8.1.1	**M**	Sites that submit samples to the laboratory have been provided with instructions on the safe transport of samples.	Moved to PRE3.1.7
SAF8.1.2	**M**	Samples are transported in approved, leak-proof containers	Moved to PRE3.1.8
SAF8.1.3	**M**	There is a means of containment for samples being transported.	Moved to PRE3.1.9
SAF8.1.4	**M**	Packaging is labeled with any appropriate safety warnings.	Moved to PRE3.1.10.
SAF8.1.5	**M**	There are procedures addressing emergencies during transportation (e.g. spillage).	Moved to PRE3.1.11.
SAF8.1.6	**M**	Sample transport is in compliance with the *Transport of Dangerous Goods Act* and other relevant legislation.	Moved to: PRE3.1.12
SAF9.1.1	**M**	Waste disposal practices minimize hazards to personnel and harmful effects to the environment.	Revised Waste disposal practices are consistent with current recommendations for waste management and minimize hazards to personnel and harmful effects to the environment.
SAF9.1.2	**M**	Sample disposal is carried out according to current recommendations for waste management.	Deleted See SAF9.1.1
SAF9.1.6	**M**	Microbiology samples, isolates, contaminated materials and supplies are disposed of in accordance with biohazard containment requirements.	Moved to MIC2.1.9

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SAF9.1.7	**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.*	Moved to MIC2.1.10
SAF10.4.1		Personnel have been provided with training on and are aware of the rights of patients. *Guidance: Patient rights include privacy, dignity and respect, **confidentiality of information**, personal safety and security, consent and the right to refuse laboratory services.*	Revised Personnel have been provided with training on and are aware of the rights of patients. *Guidance: Patient rights include privacy, dignity and respect, personal safety and security, consent and the right to refuse laboratory services.* Also see ORG4.6.6

FACILITIES

Standard or Criterion Number		2015 Original	Version 1.3 Revision
FAC1.1.7		Air flow is monitored to ensure adequate ventilation.	Deleted
FAC1.2.1	**M**	Laboratory work is performed in areas that are designed to ensure the health and safety of laboratory personnel, patients and visitors as well as ensuring the quality, safety and efficacy of the laboratory services provided.	Revised All laboratory work is performed in areas that are designed to ensure the health and safety of laboratory personnel, patients and visitors as well as ensuring the quality, safety and efficacy of the laboratory services provided. This includes primary sample collection areas and locations other than the main laboratory premises.
FAC1.2.2	**M**	Where applicable, similar provisions are made for primary sample collection and examinations at sites other than the main laboratory premises.	Deleted See FAC1.2.1
FAC1.2.7	**M**	There is **sufficient** space to allow unobstructed movement and safe working conditions.	Revised There is space to allow unobstructed movement, safe working conditions, and access for maintenance and service personnel.
FAC1.2.8	**M**	There is adequate space surrounding large pieces of equipment to enable unobstructed access for maintenance personnel, and suitable space for repairs.	Deleted See FAC1.2.7
FAC1.2.9	**M**	Laboratory communication systems are **appropriate and adequate** for the efficient transfer of information.	Revised Laboratory communication systems **allow** for the efficient transfer of information.
FAC1.3.6	**M**	Laboratories working with viable biological agents have design characteristics appropriate to the containment of microorganisms of moderate to high risk.	Moved to MIC2.1.11
FAC1.3.7	**M**	Laboratories designed to work with organisms of risk group III or above include design characteristics for greater containment.	Moved toMIC2.1.12
FAC1.3.8	**M**	There are appropriate containment facilities where there is an increased probability of the isolation of a highly infectious agent requiring a higher level of biosafety practice.	Moved to MIC2.1.13

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FAC1.3.9	**M**	Level III biosafety containment facilities participate in annual self-testing with report submission to the Public Health Agency of Canada.	Moved to MIC2.1.14.
FAC2.1.5		Multi-lingual personnel, **appropriate for the population served**, are identified and available when required.	Revised Multi-lingual personnel **are** identified and **available** when required.
FAC2.1.11	**M**	Sample collection facilities have and maintain **appropriate** first aid materials for both patient and personnel needs	Revised Sample collection facilities maintain first aid materials for both patient and personnel needs. *Guidance: See SAF3.5.1*
FAC3.1.1-4	**M**	The laboratory monitors, records, and controls (as required by relevant specifications) environmental conditions that may influence the quality of the sample or examinations	Moved to FAC1.2.13
FAC3.1.5	**M**	A quiet work environment is provided where needed (e.g. cytopathology screening, data analysis of sequencing reactions).	Moved to FAC1.2.14
FAC4.2	**M**	There is **adequate**, controlled storage space	Revised There is controlled storage space.

EQUIPMENT, REAGENTS AND SUPPLIES

Standard or Criterion Number		2015 Original	Version 1.3 Revision
ERS1.1.2	**M**	Suppliers are selected and approved based on their ability to supply services, equipment, reagents and consumables in accordance with the laboratory's requirements.	Revised The laboratory selects and approves suppliers using established criteria based on the suppliers' ability to provide external services, equipment, reagents and consumables in accordance with the laboratory's requirements.
ERS1.1.3	**M**	There is a list of selected and approved suppliers of equipment, reagents and consumables	Revised A list of selected and approved suppliers is maintained.
ERS2.1.2	**M**	Water quality is tested at defined intervals. *Guidance: A manufacturer's certificate of quality is **sufficient** for purchased water.*	Revised Water quality is tested at defined intervals. *Guidance: A manufacturer's certificate of quality is acceptable for purchased water.*
ERS2.2.2	**M**	Where the laboratory is not the receiving facility, it has verified that the receiving location has **adequate** storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.	Revised Where the laboratory is not the receiving facility, it has verified that the receiving location has storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration.
ERS2.2.11	**M**	The temperature is monitored where reagents are stored at room temperature.	Revised The temperature is monitored where reagents are stored at room temperature. *Guidance: Temperature monitoring need not be performed in situations where an assessment has determined there is a low risk of the ambient temperature falling outside the manufacturer's suggested storage temperature range.*
ERS3.3.2	**M**	Acceptable temperature ranges are defined for instruments and equipment, **where appropriate**.	Revised Acceptable temperature ranges are defined for instruments and equipment.

INFORMATION MANAGEMENT AND INFORMATICS

Standard or Criterion Number		2015 Original	Version 1.3 Revision
IMI1.2.7	**M**	Information can be exchanged with other organizations **as appropriate**.	Revised Information can be exchanged with other organizations.
IMI1.3.3	**M**	IS documentation is readily available to authorized users.	Revised IS documentation at an understandable level and language is readily available to authorized users.
IMI1.3.4	**M**	IS documentation is available to all users at an understandable level and language.	Deleted See IMI1.3.3
IMI1.4.2	**M**	Confidential data is destroyed **appropriately**.	Revised Confidential data is **destroyed in accordance with accepted guidelines**.
IM2.3.1	**M**	The LIS is maintained in a manner that ensures the integrity of the data and information and includes recording system failures and **the appropriate** immediate and corrective actions.	Revised The LIS is maintained in a manner that ensures the integrity of the data and information and includes recording system failures and **any** immediate corrective actions.
IMI2.3.2	**M**	Data integrity is verified after backup or restoration of data files.	Deleted See IMI4.4.3
IMI2.4.1	**M**	Computer facilities are operated in an environment that complies with vendor specifications (e.g. temperature controlled).	Revised Computer facilities are clean, well-maintained and operated in an environment that complies with vendor specifications.
IMI2.4.3	**M**	Computer facilities are clean, well maintained, well ventilated and humidity controlled.	Deleted See IMI2.4.1
IMI3.0	**M**	System Validation and Maintenance	Revised Laboratory Information System Validation and Maintenance
IMI3.2	**M**	There are procedures for LIS maintenance.	Revised There are procedures for LIS **hardware** maintenance.

Standard or Criterion Number		2015 Original	Version 1.3 Revision
IMI4.1.6	**M**	There is a documented process for incorporating warning messages from the instruments into the automated selection and reporting criteria, **when appropriate.**	Revised There is a documented process for incorporating warning messages from the instruments into the automated selection and reporting criteria.
IMI6.1.1		The governing body of the facility or region is ultimately responsible for ensuring there are **appropriate** measures to monitor the quality of telepathology within the facility.	Revised The governing body of the facility or region is ultimately responsible for ensuring there are measures to monitor the quality of telepathology within the facility.
IMI6.3.5	**M**	Physical facilities and equipment provided for telepathology **are adequate** for safe and efficient operation including environmental controls, network infrastructure, physical space and utilities.	Revised Physical facilities and equipment provided for telepathology **allow** safe and efficient operation including environmental controls, network infrastructure, physical space and utilities.
IMI6.4.4		Pathologists involved in validation have been **adequately** trained to use the telepathology system.	Revised Pathologists involved in validation have been trained to use the telepathology system.
IMI6.5.2	**M**	The identity of images is maintained by unique identifiers at all times image capture, diagnostic interpretation, reporting, storage and retrieval.	Revised The identity of images is maintained by unique identifiers at all times **including** image capture, diagnostic interpretation, reporting, storage and retrieval.
IMI6.6.4	**M**	The sender ensures that the correct image is sent along **with the appropriate** metadata.	Revised The sender ensures that the correct image and metadata are sent.
IMI6.7.1	**M**	There are policies to ensure the confidentiality of patient data, including when mobile devices are used. *Guidance: Access to patient data stored on any device is adequately restricted, **requiring** a password or multi-factor authentication **before the device can be accessed** and a time-out function is used.*	Revised There are policies to ensure the confidentiality of patient data, including when mobile devices are used. *Guidance: Access to patient data stored on any device is restricted, **including** a password or multi-factor authentication and a time-out function*.

QUALITY ASSURANCE

Standard or Criterion Number		2015 Original	Version 1.3 Revision
QUA1.2.5	**M**	**Appropriate** controls are used for all qualitative and quantitative examinations.	Revised Controls are used for all qualitative and quantitative examinations.
QUA1.4.4	**M**	There is documentation of the method used to establish the moving average including the frequency of calculation, and a definition of the basis for selection of upper and lower limits. Control limits for moving averages are **appropriately** sensitive such that significant calibration alterations or systematic error are detected.	Revised There is documentation of the method used to establish the moving average including the frequency of calculation, and a definition of the basis for selection of upper and lower limits. Control limits for moving averages are sensitive enough to detect significant calibration alterations or systematic error.
QUA2.3.7	**M**	A record of corrective action is filed with the DAP within the required reporting time frame**, if appropriate.** This record is retained by the laboratory.	Revised A record of corrective action is filed with the DAP within the required reporting time frame, when required. This record is retained by the laboratory.
QUA2.3.8	**M**	NEW	The authority to withdraw equipment or discontinue an examination in the event of serious PT or alternate assessment problems is defined.

PRE-EXAMINATION

Standard or Criterion Number		2015 Original	Version 1.3 Revision
PRE4.1.1	**M**	There is a procedure for sample receipt.	Revised There is a procedure for sample receipt that includes the systematic review for acceptability by trained personnel.
PRE4.1.2	**M**	Upon receipt, requests and samples are systematically reviewed for acceptability by trained personnel.	Deleted See PRE4.1.1
PRE4.5.1	**M**	Blood samples are allowed to clot for an **appropriate** length of time prior to centrifugation.	Revised Blood samples are allowed to clot for a **specified** length of time prior to centrifugation.
PRE5.1.1	**M**	There are procedures and **appropriate** facilities for storing patient samples to avoid deterioration, loss or damage during pre-examination activities and storage	Revised There are procedures and facilities for storing patient samples to avoid deterioration, loss or damage during pre-examination activities and storage.
PRE5.2.2	**M**	The laboratory **adopts the most appropriate means** of reporting referral laboratory results taking into account turnaround times, measurement accuracy, transcription and interpretative skill requirements.	Revised The laboratory **establishes a process** to report referral laboratory results taking into account turnaround times, measurement accuracy, transcription and interpretative skill requirements.
PRE5.2.5	**M**	Records of samples sent to referral laboratories are maintained and include the patient name, the name of the referral laboratory, and the date sent.	Revised Records of samples sent to other laboratories are maintained and include the patient name, the name of the other laboratory, and the date sent. ***Guidance: This does not apply to facilities that simply receive a sample from one laboratory and forward it on to another laboratory.***

EXAMINATION

Standard or Criterion Number		2015 Original	Version 1.3 Revision
EXA1.1.2	**M**	All documents that are associated with the performance of examinations, including procedures, summary documents, and product instructions for use, are subject to document control.	Moved to QMS2.1.12
EXA1.1.3	**M**	There is a documented process to ensure that examination procedure documentation is reviewed every one to three years by qualified individuals.	Deleted See QMS2.1.4
EXA1.1.4	**M**	Examination procedures are available in all appropriate locations.	Deleted See QMS2.1.6
EXA1.1.5	**M**	Any condensed document format (e.g. job aides) is subject to document control and corresponds to the full procedure.	Deleted See QMS2.1.12
EXA2.2.7	**M**	When secondary verification occurs within a regional network the site performing secondary verification retains proof that **an appropriate level** of performance was achieved.	Revised When secondary verification occurs within a regional network the site performing secondary verification retains proof that **performance expectations** were achieved.
EXA2.4.3	**M**	Personnel with the **appropriate** knowledge, expertise and authority review the results. The review is documented.	Revised Personnel with the required knowledge, expertise and authority review the results. The review is documented.
EXA2.4.6-13	**M**	Where **appropriate,** validation and verification studies include documentation of:	Revised Where **required**, validation and verification studies include documentation of:
EXA2.4.7	**M**	measurement precision at **appropriate** clinical decision levels	Revised measurement precision at clinical decision levels.
EXA2.5.1	**M**	When changes are made to an examination procedure, the influence of such changes is documented, **and when appropriate** a new validation is performed.	Revised When changes are made to an examination procedure, the influence of such changes is documented, and a new validation is performed **when required**.

Standard or Criterion Number		2015 Original	Version 1.3 Revision
EXA3.1.2	**M**	In-house reference intervals are created with a statistically significant number of values to determine **appropriate** ranges for each reference population.	Revised In-house reference intervals are created with a statistically significant number of values to determine ranges for each reference population.
EXA3.1.3	**M**	Where manufacturer's recommended reference intervals are applied, appropriate verifications of the ranges exist.	Revised Manufacturer's recommended reference intervals are verified when they are used.
EXA3.1.6	**M**	When the laboratory changes pre-examination conditions or examination procedures, the associated reference intervals and clinical decision values are reviewed **as appropriate**.	Revised When the laboratory changes pre-examination conditions or examination procedures, the associated reference intervals and clinical decision values are reviewed.
EXA3.1.7	**M**	When a particular biological reference interval or decision value is no longer relevant for the population served, **appropriate** changes are made and communicated to users.	Revised When a particular biological reference interval or decision value is no longer relevant for the population served, changes are made and communicated to users.

POST-EXAMINATION

Standard or Criterion Number		2015 Original	Version 1.3 Revision
POS1.1.7	**M**	Interim reports are distributed when **appropriate**. Interim reports are clearly identified and always followed by a final report issued to the user.	Revised Interim reports are distributed when **required**. Interim reports are clearly identified and always followed by a final report issued to the user.
POS1.1.11	**M**	Results are legible, **without mistakes in transcription** and reported to persons authorized to receive and use the information.	Revised Results are reported to persons authorized to receive and use the information. Also see POS1.1.4
POS1.1.13	**M**	NEW	There are procedures for reporting results when examinations are performed in duplicate. Limits of agreement are defined.
POS1.2.1	**M**	There are procedures to ensure that the confidentiality of patient information is maintained at all times.	Deleted See ORG4.4.5
POS1.4.4	**M**	Final reports are provided within a timeframe defined by the service standard.	Deleted See POS1.5.3

SAMPLE COLLECTION

Standard or Criterion Number		2015 Original	Version 1.3 Revision
SCT4.1.1	**M**	Appropriate, leak-proof, in-date sample containers and kits are used.	Revised In-date sample containers and kits appropriate for the examination are used.
SCT4.1.12	**M**	A gauze pad or cotton ball is placed over the site and mild pressure is applied. After a **sufficient** time the sample collector observes the patient for excessive bleeding and development of a hematoma.	Revised A gauze pad or cotton ball is placed over the site and mild pressure is applied. After a **defined** time the sample collector observes the patient for excessive bleeding and development of a hematoma.

ANATOMIC PATHOLOGY

Standard or Criterion Number		2015 Original	Version 1.3 Revision
ANP1.1.3	**M**	Ventilation in the gross room and in tissue storage areas is **adequate and** monitored for formaldehyde levels when required.	Revised Ventilation in the gross room and tissue storage areas ensures formaldehyde levels are within specified guidelines. This is monitored at a defined interval.
ANP4.6	**M**	There is **sufficient and appropriate** space for the storage of samples.	Revised There is space for the storage of samples.
ANP7.1.1	**M**	There is sufficient space to allow unobstructed movement and safe working conditions in the frozen section area.	Revised There is space to allow for safe working conditions unobstructed movement, and the storage of supplies in the frozen section area.
ANP7.1.2	**M**	There is adequate space and supplies for gross dissection of samples in the frozen section area.	Deleted See ANP7.1.2
ANP7.1.3	**M**	There is adequate ventilation in the frozen section area.	Revised Ventilation in the frozen section areas ensures acceptable formaldehyde levels. This is monitored at a defined interval.
ANP8.2.4	**M**	Examination performance is verified with a **sufficient** number of cases (as determined by the medical director) when any of the following has changed: fixative type; antigen retrieval method; antigen detection system; tissue processing or examination equipment; environmental conditions (e.g. laboratory relocation); laboratory water supply.	Revised Examination performance is verified with a **defined** number of cases (as determined by the medical director) when any of the following has changed: fixative type; antigen retrieval method; antigen detection system; tissue processing or examination equipment; environmental conditions (e.g. laboratory relocation); laboratory water supply.
ANP9.1.2	**M**	A validation or verification series **of sufficient size (25 to 100 samples)** is performed to indicate the sensitivity and specificity of ISH antibodies and procedures.	Revised A validation or verification **series of 25 to 100 samples** is performed to indicate the sensitivity and specificity of ISH antibodies and procedures.
ANP9.3.7	**M**	Slides and electron photomicrographs are reviewed to determine if **they are of sufficient** quality for interpretation of ultra-structural changes.	Revised Slides and electron photomicrographs are reviewed to determine if **the required** quality for interpretation of ultra-structural changes has been achieved.

CHEMISTRY

Standard or Criterion Number		2015 Original	Version 1.3 Revision
CHE1.1.4	**M**	Ethanol specificity evaluation studies have been performed and documented or the manufacturer's stated specificity has been **verified**.	Revised Ethanol specificity evaluation studies have been performed and documented or the manufacturer's stated specificity has been **evaluated**.

CYTOGENETICS

Standard or Criterion Number		2015 Original	Version 1.3 Revision
CYG2.1.8	**M**	**Adequate supplies** of CO_2 and N_2 (tri-gas incubators only) are maintained.	Revised **A minimum level** of CO2 and N2 (tri-gas incubators only) **has been defined** and is maintained.
CYG5.1.1	**M**	Validation studies are performed on laboratory-modified examination methods prior to reporting patient results (e.g. changed methodology such as a decreased amount of probe used).	Revised Laboratory-modified examination methods are validated prior to reporting patient results (e.g. changed methodology such as a decreased amount of probe used).
CYG8.1.12	**M**	Cytogenetics reports include failure to achieve **sufficient** banding resolution or a **sufficient** number of metaphases when indicated.	Revised Cytogenetics reports include failure to achieve the required banding resolution or the required number of metaphases when indicated.

HEMATOLOGY

Standard or Criterion Number		2015 Original	Version 1.3 Revision
HEM3.1.5	**M**	If a coagulation examination cannot be performed within these timeframes, platelet poor plasma is removed from the cells and frozen at -20°C for up to two weeks or -70°C for up to six weeks.	Revised If a coagulation examination cannot be performed within these timeframes, platelet poor plasma is removed from the cells and frozen at -20°C for up to two weeks or -70°C for up to six **months.**

MOLECULAR GENETICS

The molecular genetics standards have been replaced by the molecular diagnostics standards below:

MOLECULAR DIAGNOSTICS

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL1.0	**PRE-EXAMINATION**		
MOL1.1	**There are procedures for the selection, evaluation, verification and validation of molecular diagnostics examinations.**		
MOL1.1.1	**M**	NEW	The laboratory selects examination procedures which have been validated for their intended use.
MOL1.1.2	**M**	NEW	The performance characteristics of commercially available kits or instruments are verified. Laboratory developed or modified procedures are validated. This is documented.
MOL1.1.3	**M**	NEW	Verification and validation of examination performance uses an adequate number, type and source of samples to ensure that the examination results can be interpreted for specific patient conditions, and that the limitations of examinations and results are known.
MOL1.1.4	**M**	NEW	Verification and validation procedures determine analytical performance specifications including: • accuracy precision • reproducibility • sensitivity / limit of detection specificity • reportable range • reference range
MOL1.1.5	**M**	NEW	Verification and validation procedures address the intended use of the exam (e.g. carrier, prenatal, diagnostic, predictive)
MOL1.1.6	**M**	NEW	Verification and validation procedures address target genes, sequences and variants

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL1.1.7	**M**	NEW	Verification and validation procedures address the expected patient population.
MOL1.1.8	**M**	NEW	Verification and validation procedures address sample types (e.g. bone marrow, peripheral blood, paraffin embedded tissue)
MOL1.1.9	**M**	NEW	Verification and validation procedures address reference materials
MOL1.1.10	**M**	NEW	Verification and validation procedures address examination limitations (e.g. allele drop out, interfering variants).
MOL1.1.11	**M**	NEW	Steps in processing that deviate from procedures are documented and reviewed by the medical director. Any resulting corrective action is documented.
MOL1.1.12	**M**	NEW	There are procedures for ongoing verification or validation of examination performance.
MOL1.1.13	**M**	NEW	There is a procedure for the verification of each reagent lot.
MOL1.1.14	**M**	NEW	All probe and primer sequences are checked and monitored against relevant databases. Actions are taken to reduce the possibility of null alleles or allele dropout.
MOL1.2	**The laboratory provides information and assistance on molecular diagnostics examinations to users.**		
MOL1.2.1	**M**	NEW	Facilities performing genetic examinations provide information with primary references documenting the scientific data on which an examination is based.
MOL1.2.2	**M**	NEW	The laboratory has established arrangements for communicating with users on advising on the choice of examinations and use of laboratory services (e.g. the required sample type, clinical indications, limitations of examination procedures, the frequency of requesting the examination).

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL1.2.3	**M**	NEW	The laboratory has established arrangements for communicating with users on case specific inquiries, professional judgment on the interpretation of the results of examinations, promotion of the effective utilization of laboratory services and consulting on scientific and logistic matters (e.g. instances of failure of samples to meet acceptance criteria).
MOL1.2.4	**M**	NEW	The laboratory has defined any examinations where pre-examination genetic counseling is indicated.
MOL1.2.5	**M**	NEW	There is information and mechanisms to assist users in ordering appropriate genetic examinations and examination strategy.
MOL1.2.6	**M**	NEW	The clinical validity and clinical utility of each examination has been determined, (independently, or through published evidence). *Guidance: The clinical validity refers to the examinations ability to identify the clinical condition of interest (usually a disease state) as well as to identify unaffected individuals. The clinical utility identifies the outcomes associated with specific examination results.*
MOL1.3	**Request forms for non-invasive prenatal examinations include space for required information**		
	The request form or electronic equivalent has space for the inclusion of appropriate information including:		
MOL1.3.1	**M**	NEW	• estimated date of delivery (based on ultrasound measurements)
MOL1.3.2	**M**	NEW	• parentage information for examinations that use paternal genotypes for interpretation or whose interpretation may be influenced by IVF techniques
MOL1.3.3	**M**	NEW	• clinical evidence of multiple gestations
MOL1.3.4	**M**	NEW	• maternal weight

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL1.3.5	**M**	NEW	• patient or family history of chromosomal abnormality (e.g. translocation carrier, offspring with Down syndrome)
MOL1.3.6	**M**	NEW	• the inclusion of prior pregnancy risk for aneuploidies for examinations that report odds, risks, or probabilities of being euploid or trisomic
MOL1.3.7		NEW	• prior pregnancies
MOL1.3.8		NEW	• patient race and/or ethnicity
MOL1.3.9		NEW	• relevant family history
MOL1.4	**There are procedures to prevent cross contamination**		
MOL1.4.1	**M**	NEW	There are procedures to prevent and monitor contamination.
MOL1.4.2	**M**	NEW	Dedicated equipment and supplies (including pipettes and reagents) are used for all pre-PCR activities.
MOL1.4.3	**M**	NEW	Reagent preparation, nucleic acid extraction and PCR set-up are conducted in separate areas and physically removed from post-PCR manipulations.
MOL1.4.4	**M**	NEW	Positive displacement pipettes and/or aerosol barrier tips are used to prevent contamination for all pre-PCR activities.
MOL1.5	**There are procedures for molecular diagnostics examinations.**		
MOL1.5.1	**M**	NEW	There are procedures for the examination of samples with known or suspected maternal cell contamination. *Guidance: This includes the rejection of samples when there is a risk of false positive or false negative examinations.*
MOL1.5.2	**M**	NEW	There are procedures for longitudinal monitoring of assay characteristics.
MOL1.5.3	**M**	NEW	The quantity of nucleic acid is measured, when appropriate.
MOL1.5.4	**M**	NEW	The integrity and purity of nucleic acid is assessed, when appropriate.

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL1.5.5	**M**	NEW	Ribonuclease-free conditions are maintained for all assays that detect RNA or use an RNA probe.
MOL1.5.6	**M**	NEW	Information is documented for all probes and primers used in examinations to permit interpretation and troubleshooting of results.
MOL1.5.7	**M**	NEW	A positive control near limiting dilution is included in each run for quantitative examinations. These controls are rotated to include all measurands.
MOL1.5.8	**M**	NEW	There are procedures to verify nucleic acid integrity and labeling. *Guidance: This may include control features that address an endogenous positive target, controls that visualize material on electrophoretic gels and capillaries, or by detection of label.*
MOL1.5.9	**M**	NEW	In examinations for acquired conditions, a histological assessment of neoplastic cell content is documented when DNA or RNA is extracted from paraffin-embedded tumor samples.
MOL1.5.10	**M**	NEW	The lower limit of detection of a molecular examination performed on mixed populations of cells is validated and documented. The limit of detection is included in the report when applicable.
MOL1.5.11	**M**	NEW	There are defined criteria for the percentage of tumor cells and the lower limit of detection in the interpretation of negative examination results.
MOL1.5.12	**M**	NEW	Examinations are optimized to minimize background noise and achieve high signal to noise ratios near the stated limit of detection of the assay.

MOL2.0 RESTRICTION ENDONUCLEASE DIGESTION, NUCLEIC ACID SEQUENCING

MOL2.1	**There are procedures for restriction endonuclease (RE) examinations.**

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL2.1.1	**M**	NEW	The completeness and accuracy of RE digestion are confirmed, when appropriate. *Guidance: DNA treatment with RE is performed for an appropriate amount of time under defined reaction conditions.*
MOL2.1.2	**M**	NEW	The efficacy of RE digestion is established for each new lot of enzyme and in each run.
MOL2.2	**There are procedures for Sanger sequencing and pyrosequencing.**		
MOL2.2.1	**M**	NEW	There are defined criteria for the acceptance and interpretation of primary sequencing data that include correct assignments for variant positions, definition of the sequencing region, criteria for peak intensity, baseline fluctuation and signal-to-noise ratio and peak shapes.
MOL2.2.2	**M**	NEW	The lower limit of detection in mixed populations of cells is validated and documented. The limit of detection is included in the report when appropriate and applicable.
MOL2.2.3	**M**	NEW	Sequence analysis software is used for Sanger sequencing to compare data of the patient sample with that of the reference sequence. *Guidance: Sole reliance on unassisted visual inspection of the sequence data is not acceptable due to the possibility of operator error, particularly for homozygous variations).*
MOL2.2.4	**M**	NEW	For Sanger sequencing, the laboratory confirms all novel sequence variants using a second, independent PCR and sequencing reaction.
MOL2.3	**There are procedures for next generation sequencing.**		
MOL2.3.1	**M**	NEW	There are procedures to minimize the risk of contamination and sample mix-up throughout all steps of next generation sequencing.
MOL2.3.2	**M**	NEW	The lower limit of detection in mixed populations of cells is validated and documented. The limit of detection is included in the report when appropriate and applicable.

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL2.3.3	**M**	NEW	There are defined criteria for the acceptance and interpretation of next generation sequencing data that include relevant data quality indicators (e.g. base calling quality (Q) scores, cluster density, percentage polyclonal beads) and appropriate ranges for these
MOL2.3.4	**M**	NEW	There are defined criteria for confirmatory examination of reported variants.

MOL3.0 BIOINFORMATICS

MOL3.1	**There are procedures for bioinformatics analysis.** *Guidance: Validation is performed by personnel qualified in computational biology/informatics.*		
MOL3.1.1	**M**	NEW	There are defined criteria for monitoring, documenting, and implementing upgrades, and other updates to informatics. Changes are verified.
MOL3.1.2	**M**	NEW	The specific version(s) of informatics used to generate data files are traceable for each examination report.
MOL3.1.3	**M**	NEW	When steps used in informatics analysis deviate from procedures, the deviation is documented and reviewed by the medical director. Any resulting corrective action is documented.
MOL3.1.4	**M**	NEW	Informatics data and analysis are validated prior to implementation. This is documented.
MOL3.1.5	**M**	NEW	After modification, informatics data and analysis are revalidated, or the performance of the components is verified. This is documented.
MOL3.1.6	**M**	NEW	Software functional testing is performed and documented.
MOL3.2	**There are procedures for the interpretation and reporting of sequencing data.**		
MOL3.2.1	**M**	NEW	There is a documented algorithm for the interpretation of the clinical significance of identified variants and guidelines for subsequent reporting.

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL3.2.2	**M**	NEW	There is a documented process for instances when incidental, unrelated genetic findings are reported.

MOL4.0 ELECTROPHORESIS AND POLYMERASE CHAIN REACTION (PCR)

MOL4.1	**There are procedures for molecular diagnostics using electrophoresis.**		
MOL4.1.1	**M**	NEW	Known molecular weight markers that span the range of expected bands are used for each electrophoretic run.
MOL4.1.2	**M**	NEW	Visual or fluorescent markers are used to determine the endpoint of electrophoresis.
MOL4.1.3	**M**	NEW	There are defined criteria for interpreting autoradiographs or electrophoretic data.
MOL4.1.4	**M**	NEW	Autoradiographs and images have sufficient resolution and quality for interpretation.
MOL4.2	**There are procedures for molecular diagnostics using nucleic acid amplification.**		
MOL4.2.1	**M**	NEW	Controls are used to minimize the occurrence of false positive and false negative results for PCR techniques *Guidance: This includes internal controls to detect false negative reactions secondary to extraction failure or the presence of an inhibitor, when appropriate.*
MOL4.2.2	**M**	NEW	Examination components are verified and monitored (e.g. fragmentation of DNA by sonification-enzyme digestion).

MOL5.0 MICROARRAYS AND IN SITU HYBRIDIZATION

MOL5.1	**There are procedures for molecular diagnostics using microarrays.**		
MOL5.1.1	**M**	NEW	Microarray post-examination components are verified and monitored (e.g. visual inspection of hybridized array images, evaluation of QC data calculated from examination software, gains and losses called by the microarray software algorithm).
MOL5.2	**There are procedures for fluorescence and non-fluorescence in situ hybridization (ISH).**		

Standard or Criterion Number		2015 Original	Version 1.3 Revision
MOL5.2.1	**M**	NEW	There are procedures for scoring fluorescence in situ hybridization (FISH) results, including the number of cells scored.
MOL5.2.2	**M**	NEW	Control loci (internal or external) are used with and documented for each FISH examination.
MOL5.2.3	**M**	NEW	Gene amplification procedures by in situ hybridization (e.g. HER2) include appropriate sample fixation time.
MOL5.2.4	**M**	NEW	There are defined criteria for interpretation of gene amplification by in situ hybridization (e.g. HER2) using defined scoring criteria or the manufacturer's instructions.
MOL5.2.5	**M**	NEW	The interpretation and correlation of results is performed by a pathologist or delegate for in situ hybridization examinations.
MOL5.2.6	**M**	NEW	Conditions for examination and tissue pretreatment are verified and documented for each sample using an appropriate positive control probe(s) against endogenous targets.

MOL6.0 INTERPRETATION AND REPORTING

MOL6.1		There are procedures for the reporting of molecular examination results.	
MOL6.1.1	**M**	NEW	Variant curation in internal and external databases is versioned and current.
MOL6.1.2	**M**	NEW	Reports include a summary of methods, appropriate loci or variants the sample was examined for, examination information, clinical interpretation and appropriate references.
MOL6.1.3	**M**	NEW	All reports containing interpretations indicate authorship and assurance that the contents of the report have been verified by the author.
MOL6.1.4	**M**	NEW	Reports include a risk estimate of false negatives and false positives arising from recombination between the linked locus and the disease locus when linkage examination is performed.

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MOL6.1.5	**M**	NEW	Reports include correlation (where appropriate) with the morphological findings when assays are performed on histology and cytology samples.
MOL6.1.6	**M**	NEW	Reports include (where appropriate) an estimate of the clinical sensitivity and residual risk of being a carrier for a variant not included in genetic examination for heritable disease genes with multiple possible variants, if known.
MOL6.1.7	**M**	NEW	Reports include limitations of the results and clinical implications of the detected variant (or negative result) for disorders with regard to recessive or dominant inheritance, recurrence risk, penetrance, severity and other aspects of genotype-phenotype correlation.
MOL6.1.8	**M**	NEW	Reports include a recommendation for genetic counseling, when applicable.
MOL6.1.9	**M**	NEW	Standard Human Genome Variation Society nomenclature is used to designate reported genes and variants. The reference transcript is included when appropriate and applicable.
MOL6.1.10		**NEW**	**The limitations and sensitivity of the molecular examination are available. Examinations with low utility in assessing health are labeled as such.**
MOL6.1.11		NEW	Genetic examinations that are not medically significant are accurately labeled as such.
MOL6.2	**There are procedures for the interpretation and reporting of examinations for non-invasive prenatal examinations.**		
MOL6.2.1	**M**	NEW	The percentage of patients with positive results for each targeted disorder, examination failure rates and inconclusive examination results are calculated and reviewed at a defined frequency.
MOL6.2.2	**M**	NEW	The report includes qualitative and quantitative examination results for each target (chromosome, genetic variant or other), reference ranges or cutoff values as appropriate, and a summary set of risks or categorical interpretations.

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		The report includes the following as appropriate:	
MOL6.2.3	**M**	NEW	• a recommendation for follow-up diagnostic examination for all patients with a positive examination result
MOL6.2.4	**M**	NEW	• recommendations regarding next steps for patients with uninformative results and examination failures
MOL6.2.5	**M**	NEW	• a statement that the examination is not intended to identify prenatal cases at risk for open neural tube defects

POINT-OF-CARE TESTING (POCT)

Standard or Criterion Number		2015 Original	Version 1.3 Revision
POC1.1.6	**M**	A health professional group such as **the** medical advisory committee (in consultation with administration and the laboratory director or designate) is responsible to the governing body for defining the scope of POCT available.	Revised A health professional group such as **a** medical advisory committee…
POC1.3.2		A training manager with **sufficient** theoretical knowledge and experience has been appointed to manage POCT training and competency assessment.	Revised A training manager with theoretical knowledge and experience has been appointed to manage POCT training and competency assessment.
POC2.1.3	**M**	The quality manager (or otherwise titled) for the laboratory QMS has responsibility for POCT within the facility, or a POCT quality manager with appropriate training and experience has been appointed.	Revised A POCT quality manager (or otherwise titled) with specific training and experience has been appointed. *Guidance: The laboratory quality manager (or otherwise titled) may assume responsibility for POCT within the facility.*
POC2.1.7	**M**	All QC results for POCT are reviewed at a defined frequency by the quality manager or designate.	Deleted See POC4.1.8 POCT QC results are reviewed at a defined frequency by the quality manager or designate and the review is documented.
POC2.1.9	**M**	All POCT policies, processes and procedures are reviewed **at** every one to three years. This is documented.	Revised All POCT policies, processes and procedures are reviewed every one to three years. This is documented.
POC4.2.2	**M**	The alternative assessment is established by the medical director or designate.	Revised The alternative assessment is established by the **laboratory** medical director or designate.
POC4.2.5		POCT PT or alternative assessment results are monitored by the medical director or designate at a defined interval and discussed with relevant personnel.	Revised POCT PT or alternative assessment results are monitored by the **laboratory** medical director or designate at a defined interval and discussed with relevant personnel.

TRANSFUSION MEDICINE

Standard or Criterion Number		2015 Original	Version 1.3 Revision
TRM8.1	**M**	Request forms for blood components and products include **sufficient** information	Revised Request forms for blood components and products include the **required** information.
TRM10.1.2	**M**	Rh negative recipients are transfused with D negative red cells when possible.	Revised There are policies and procedures for issuing blood components containing D positive red cells to Rh negative patients.
TRM10.2.5		**Red cells negative for Hemoglobin S are transfused in the case of massive transfusion to a neonate including exchange transfusion.**	**Changed to non-mandatory**
TRM11.2.3	**M**	Screening for clinically significant red cell antibodies uses a neonatal sample **if sufficient sample** is available.	Revised Screening for clinically significant red cell antibodies uses a neonatal sample **when** available.