هيئة الصحة - أبوظبي
HEALTH AUTHORITY - ABU DHABI

Health Policy and Regulation

Health Authority Abu Dhabi

Version 1.0

HAAD Clinical Laboratory Standards

Table of Contents

Chapter		Page
I	Direction of the Laboratory	6
II	Laboratory Personnel – Human Resources	8
III	Policies and Procedures	10
IV	Infrastructure and Equipment Resources	16
V	Safety	19
VI	Quality Control Assurance & Processes	22
A	Processes Common across Laboratory Specialties	22
B	Processes for Laboratory Specialties	26
	1. Surgical Pathology and Autopsy	26
	2. Cytopathology	27
	3. Clinical Chemistry, Hematology and Coagulation	28
	4. Microbiology	30
	5. Parasitology	31
	6. Virology	31
	7. Urinalysis and Clinical Microscopy	32
	8. Diagnostic Immunology & Serology	33
VII	Blood Bank and Transfusion Services	34
VIII	Histocompatibility	54
IX	Cytogenetics	57
X	Molecular Testing	59

FORWARD

Health Authority Abu Dhabi (HAAD) is pleased to present the HAAD Clinical Laboratory Standards. These Standards represent another milestone of achievement towards HAAD vision for and strategic priorities in support of a healthcare system where providers of health services deliver World-class quality care and outcomes in compliance with the highest international standards. Following pressure testing in the second half of 2010 these standards have been revised to include refinements to regulatory best practices and implementation practicalities for the healthcare sector.

HAAD have, in recent times undertaken a comprehensive review of the structure and regulation of the health system including all policies and standards within the emirate to ensure that all healthcare facilities and professionals achieve defined standards and strive for continuous improvement.

In the fulfillment of HAAD's mandate, the Clinical Laboratory standards were developed by HAAD in collaboration with Joint Commission (JCI), a world leader in health standards. These standards are consistent with international standards and are a further step towards the highest level of achievement in health care.

The Clinical Laboratory standards are based on the JCI standards and informed by the research processes and validation methodologies that were used in their development. The Standards have been adapted to ensure their alignment with the regulatory requirements of HAAD and the federal and emirate laws.

The standards emphasize customized International Patient Safety Goals, and focus on quality and safety giving priority to Identifying Patients Correctly, Improving Effective Communication, Ensuring Correct-Site, Correct-Procedure, Correct-Patient intervention, Safety of Medical Devices and Reducing the Risk of Health Care–Associated Infections.

The standards are intended to be used by HAAD for Regulatory Audit and Compliance purposes and must be met in order to satisfy the Licensing requirements for Clinical laboratories. They are to be used by clinical laboratories in developing their quality management systems and assessing their own competence to ensure compliance with HAAD regulatory requirements and the federal and emirate laws.

1. Purpose

1.1. The HAAD Clinical Laboratory Standards specify the requirements for quality and competence particular to clinical laboratories licensed by HAAD to provide clinical and medical testing, screening and diagnostic services in Abu Dhabi. They are to be used by clinical laboratories in developing their quality management systems and assessing their own competence to ensure compliance with HAAD regulatory requirements and the federal and emirate laws.

2. Scope

2.1. The standards, intent statements, and measurable elements detailed in the HAAD Clinical Laboratory Standards describe requirements for the following categories:

2.1.1. International Patient Safety Goals

2.1.2. Management and Leadership

2.1.3. Development and Control of Policies and Procedures

2.1.4. Resource Management and Management of the Laboratory Environment

2.1.5. Quality Control Processes, including for molecular testing

2.1.6. Diagnostic and testing protocols for specified agents.

2.2. These Standards apply to healthcare facilities and professionals licensed by HAAD to provide clinical laboratory services in the emirate of Abu Dhabi.

3. Duties for Healthcare Facilities and Professionals

3.1. HAAD licensed healthcare facilities and professionals providing clinical laboratory services must:

3.1.1. Report and submit data to HAAD via *e-claims* and in accordance with the HAAD *Reporting of Health Statistics Policy* and as set out in the HAAD Data Standards and Procedures (found online at www.haad.ae/datadictionary).

3.1.2. Provide patient treatment and care services in accordance with the specifications on authorization rules and regulations, healthcare professionals and staffing specifications and eligibility criteria stated in this document and in accordance with HAAD Policies and Standards and the laws and regulations of the Emirate of Abu Dhabi.

3.1.3. Comply with HAAD policies and standards on managing patient medical records, including requirements for patient confidentiality, patient records and information technology and data management.

4. Enforcement and Sanctions

4.1. Where a healthcare provider is in breach of a duty under this standard, HAAD may take any or all of the following actions:

4.1.1. Issue a warning to the healthcare provider;

4.1.2. Suspend the licence of the healthcare provider for a period of time that HAAD determines to be appropriate in the circumstances of the case,

4.1.3. Require re-evaluation of the health professional to practice as HAAD determines to be appropriate in the circumstances of the case,

4.1.4. Revoke the licence of the healthcare provider.

4.2. Healthcare providers and payers must comply with the terms and requirements of this Standard as specified under Section 3, the HAAD Standard Contract and HAAD Data Standards and Procedures. HAAD may impose sanctions in relation to any breach of duties under this standard in accordance with the [HAAD Policy on Inspections, Complaints, Appeals & Sanctions].

International Patient Safety Goals

1. Improve the accuracy of patient identification
2. Improve the effectiveness of communication among care givers and care recipients
3. Improve the safety of using medications and medical devices
4. Reducing the risk of healthcare associated infections
5. Ensuring correct site, correct procedure, correct patient for all procedures
6. Accurately and completely reconcile medications across the continuum of care
7. Encourage patients active involvement in their own care as a patient safety strategy
8. Improve recognition and response to changes in a patient's condition
9. Reducing risk of patient harm resulting from falls
10. Reduce the risk of hospital fires

I
Direction of the Laboratory

	ROLES AND RESPONSIBILITIES	M	NM	N/A
	The laboratory director is ultimately responsible for every task required to assure accurate, reliable, timely, and relevant test results. This includes pre-analytic, analytic, and post-analytic processes. Therefore, the director must implement processes to assure consistent performance of testing activities. In addition, processes to monitor for test variances and provide timely corrective action, when required, must be in place. This section of standards specifies requirements that must be in place if the director is fulfilling his/her duties.			
	Standards	M	NM	N/A
DR1	The director of the laboratory is a professional licensed pathologist with appropriate training, education, and experience to direct the laboratory services provided by the laboratory.			
DR2	The responsibilities of the laboratory director are defined in writing, and include at least the following:			
DR.2.1	When the laboratory providing services for a health-care organization, such as a hospital, the director assures that the laboratory provides for the type and scope of services to meet the needs of ordering clinicians and the patient population served.			
DR.2.2	The laboratory provides for required services either directly or through referral to another laboratory.			
DR.2.3	The director assures the consistent performance of reference and contract laboratory services in accordance with HAAD laboratory standards, when they are used.			
DR.2.4	All reference and/or contract laboratory's used meets applicable laws and regulation.			
DR.2.5	The director plans and provides adequate resources for the provision of laboratory services. These resources include:			
	a. A budget and fiscal resources for operating the laboratory;			
	b. Required personnel in numbers and qualifications to meet the goals of the laboratory;			
	c. Physical structure and spaces to facilitate efficient, effective, and safe delivery of laboratory services;			
	d. Necessary equipment;			
	e. Accessibility of services and provisions for specimen collection, storage, and transport; and			
	f. Safe use, maintenance, and supervision of space, equipment, and other Environmental elements, such as required utilities.			
DR.2.6	The director requires practices that respect the needs of patients, including providing for privacy, security, and confidentiality of information.			
DR.2.7	The director provides for consultation to those who request tests about the choice of tests, the use of the laboratory's services, and the interpretation of test results.			
DR.2.8	The director is responsible for developing, implementing, and maintaining policies and procedures that guide and support the provision of services. This includes			

	policies and procedures for the pre-analytic, analytic, and post-analytic phases of testing. These procedures include:			
	• Specimen collection procedures provided to all those who collect specimens to be sent to the laboratory;			
	• All procedures related to performing laboratory tests; and			
	• Procedures for the review and reporting of laboratory test results.			
DR.2.9	The director is responsible for defining and maintaining necessary quality control programs.			
DR.2.10	The director is responsible for determining and defining in writing, the qualifications and competence of staff required to meet the laboratory's goals.			
DR.2.11	The director provides an adequate number of qualified, competent staff.			
DR.2.12	The director requires new employees to be oriented to all job responsibilities, and to be assessed as competent before performing these responsibilities independently.			
DR.2.13	The director provides ongoing, in-service training and education when required to update staff on new procedures or instrumentation or to maintain staff competence in current procedures.			
DR.3	The laboratory director assures ongoing monitoring of quality control and other processes to ensure the efficient provision of consistently reliable quality services. These monitoring activities are to be documented and include:			
DR.3.1	Day to day review of internal quality control results and at least monthly review of cumulative quality control results.			
DR.3.2	Monthly review of analytical equipment problems to determine if there are any recurring problems.			
DR.3.3	Review of customer complaints as they occur, along with a response to the customer, or if part of a larger health-care organization, in accordance with the organization's policy.			
DR.3.4	Prompt review of external quality control reports to determine if actions need to be taken.			
DR.3.5	Periodic (at least quarterly) review of data for unacceptable requests and specimens to identify trends from specific areas or clinicians, and the need to communicate with that area or clinician in order to improve the services provided.			
DR.3.6	Periodic monitoring and review of turn-around-times for laboratory tests.			
DR.3.7	Annual review of the above parameters to allow planning for the following year.			
DR.3.8	Annual review of customer satisfaction through a customer-satisfaction survey, in conjunction with a cumulative review of the year's customer complaints to identify any problematic trends. If the laboratory is part of a larger health-care organization, this should be done as part of the organization's customer satisfaction process.			

Laboratory Personnel

	ROLES AND RESPONSIBILITIES	M	N	N/A
LP.1	Laboratory leaders other than the director, such as supervisory and management staff are qualified by training, education, and experience to meet the requirements of their positions.			
L.P.1.1	Supervisor and management staff qualifications are documented and meet applicable regulatory requirements.			
LP.2	The laboratory has an adequate number of qualified technical and support staff appropriate for the services provided by the laboratory and all required related functions.			
L.P.3	Laboratory staff are licensed according to the requirements of law and regulation.			
LP.4	The laboratory has a defined, written job description for each laboratory employee that includes the education, training, and licensure requirements for the job, as well as an overview of job duties.			
LP.5	The laboratory maintains an employment record for each laboratory employee which includes the following:			
	a) A summary of education and training relevant to duties when hired			
	b) History of related work experience, including references from previous employers, if available			
	c) Verification of HA-AD licensure;			
	d) Current job description			
	f) Records of initial orientation and any retraining required			
	g) Records of any additional training for new job responsibilities			
	h) Records of continuing education and achievement			
	i) Records of performance evaluations and periodic assessments of competence			
	j) Records of the status of required immunizations;			
	k) Records of monitoring for exposure to hazardous chemicals, when such chemicals are used			
	l) Records of untoward incident or accident reports, such as accidental needle sticks			
LP.6	There is an orientation and induction program for new employees and current employees being trained to new duties. The orientation program is defined in a written policy.			
LP.6.1	Each new employee is provided with job-specific orientation that includes the following:			
	a) An introduction to the organization's/laboratory's goals, reporting structure, and personnel policies.			
	b) The organization/laboratory safety policies, procedures, and activities;			
	c) The employee's safety responsibilities;			
	d) The employee's job description, duties, and lines of authority;			
	e) A competence verification/training period during which supervisory staff provide instruction and observe the employee's abilities to			

	perform each job requirement including:			
	• Each analytical instrument and other equipment;			
	• Each technique used; and			
	• All related functions, such as specimen collection and identification, quality control and calibration, reporting of results, and notification of the supervisor when problems arise.			
LP.6.2	Participation in the orientation program is documented. This includes			
	a) verification that the individual has been successfully oriented and is now competent to perform assigned tasks;			
	b) written approval by the laboratory director or an appropriate supervisor, authorizing the employee to perform the duties for which he/she was hired; and			
	c) Any exceptions to testing authorization are indicated in the documentation.			
	d) The competence of employees is confirmed before they are allowed to perform tasks.			
LP.7	The laboratory provides for in-service or other education and training to maintain and improve staff competence. Participation is documented for each employee.			
LP.8	The laboratory director and supervisory staff are responsible for assuring that employees who perform testing or other work are deemed competent to perform the specific requirements of their work.			
LP.8.1	Competence is assessed and documented for each laboratory employee following orientation and annually thereafter.			
LP.8.2	The competence assessment process is defined in a written policy.			

III
Policies and Procedures

	ROLES AND RESPONSIBILITIES	M	NM	N/A
PP.1	The laboratory director has defined the basic requirements for written policies and procedures.			
PP.1.1	The requirements include at least the following:			
	a) An initial review and approval of all policies and procedures is performed and documented by the director of the laboratory. Policies and procedures are not distributed for use until the approval process is completed.			
	b) Periodic review of all policies and procedures is performed and documented at a frequency defined by the director, but at least every two years. This review is performed by the director, an appropriate supervisor, or another knowledgeable individual.			
	c) The director or supervisor approves, in writing, all changes in policies and procedures.			
	d) All policies and procedures are clearly and legibly written.			
PP.2	If manufacturers' manuals or package inserts are used for technical procedures, they are:			
	• Comprehensive, clear and simple to follow; and			
	• Enhanced to include specific operational policies (for example, detailed quality control protocols, calibration procedures, and other laboratory-specific procedures).			
PP.2.1	For discontinued policies and procedures, the following are defined and implemented:			
	a) The laboratory defines how long discontinued policies and procedures are to be retained. This time of retention is at least for two years.			
	b) The dates of implementation and discontinuance are available for all policies and procedures.			
	c) Discontinued documents are segregated to prevent accidental use while being retained for reference, if needed.			
PP.3	Control of policies and procedures includes the following:			
	a) There is a method to identify and track all policies and procedures in current use, including the dates of implementation and all changes and review information.			
	b) There is a process for informing staff about the content of policies and procedures as they are initially implemented and/or changed.			
	c) All policies and procedures, including those required for other chapters in this manual comply with the requirements in these standards.			

	Pre-analytic Policies and Procedures	M	NM	N/A
PP.4	The laboratory director assures that procedures for ordering tests are defined in writing, and available to those who order tests. These procedures include information about:			
	a) the use of correct request forms;			
	b) the process for identifying patients;			
	c) information required on orders or request forms, to include at least the following:			
	• Patient's name			
	• Patient's gender			
	• Patient's age or date of birth			
	• Authorized requesting individual, including, as applicable, a contact person to enable the reporting of imminently life-threatening laboratory results			
	• The specimen source, when appropriate			
	• Test(s) or examination(s) requested			
	• Date and, when relevant, time of specimen collection			
	• Additional information required to select appropriate tests and to ensure accurate test interpretation and reporting of results (for example, race/ethnicity, family history, pedigree)			
	d) the processes for confirming oral or telephonic requests; and			
	e) The process for ordering tests on an emergency or STAT basis.			
PP.5	Requests are made by a licensed physician or other qualified individual as authorized in Health Authority policy.			
PP.6	Written policies for ordering tests are implemented and enforced.			
PP.7	The director assures that written policies and procedures are developed to provide specimen collection protocols for each type of specimen submitted to the laboratory.			
PP.8	These procedures include a protocol to improve accuracy of patient and specimen identification, including the following:			
PP.8.1	Policies and procedures require the use of a minimum of two specified patient identifiers, not including the use of the patient's room number or location.			
PP.8.2	Policies and procedures require that patients are identified before taking blood and other specimens for clinical testing.			
PP.8.3	Patients are identified before administering medications, blood, or blood products.			
PP.8.4	Written policies and procedures for specimen collection include a list of available tests and any consent forms used.			
PP.9	Specimen collection procedures			
	a) are comprehensive and current and include a step-by-step guide for collecting specimens;			
	b) include instructions for any specimen collection procedure used and all types of specimens sent to the laboratory;			

PP.9.1	Specimen collection procedures relate to the following:			
	a)Medical indications for the test			
	b) Standard and special methods for preparing patients for specimen collection.			
	c) Precautions to be taken for special procedures			
	d)Proper storage, preservation, and transportation of specimens			
PP.9.2	Specimen collection procedures			
	a) apply to anyone collecting procedures for laboratory tests;			
	b) are made available to all individuals collecting specimens;			
	c) are followed by those who collect specimens;			
	d) include a means of identifying the individual who collected a specimen; and			
	e) Include instructions for specimens sent to reference or contract laboratories (may be obtained from the reference laboratory and need not be rewritten).			
PP.9.3	The laboratory has a written policy and process to maintain a record of daily specimen accession that allows convenient and timely retrieval by			
	date, or patient name or other identifiers, of the following:			
	a) Patient's name and other identifiers of the patient and specimen			
	b) Patient's gender			
	c) Patient's age or date of birth			
	d) Authorized requesting individual, including, as applicable, a contact person to enable the reporting of STAT or critical test results			
	e) The specimen source, when appropriate			
	f) Tests or examinations requested and reported			
	g) Date and, when relevant, time of specimen collections			
	h) Date and time of specimen receipt by the laboratory			
	i) Condition of any unsatisfactory specimen			
	j) Additional information required to select appropriate tests and to ensure accurate test interpretation and reporting (for example, race/ethnicity, family history, pedigree).			
PP.9.4	Policies and procedures include written directions for specimen processing and defined criteria for specimen rejection.			
10	**Analytic Policies and Procedures**			
	(**Note:** If assistance is needed in determining a format for technical procedures, an acceptable reference is NCCLS CLSI publication GP2-A3, *Clinical Laboratory Technical Procedures Manual, Third Edition*, *Approved Guideline*)			
PP.10.1	The laboratory director requires current written descriptions and instructions for performing test methods and procedures. Each procedure includes the following elements:			
	a) A complete description of reagents and equipment used			
	b) Any equipment function verification required before testing is performed			
	c) Specific instructions for verifying method validity through controls or calibrators, including a definition			
	of acceptable control values and actions to take when control results			

	are not acceptable			
	d) The reportable range for patient test results			
	e) Limitations in methodologies, including interfering substances			
	f) A step-by-step description of each phase of patient testing			
	g) Reference ranges, when applicable			
	h) Instructions for reporting results			
	i) Literature references			
PP.10.2	The laboratory's technical procedures are consistently followed.			
11	**Post-analytic Policies and Procedures**			
PP.11.1	The laboratory director develops policies, procedures, and controls for the post-examination processes, including the following:			
	a) There is a means of identifying each individual who performed tests, as well as the individual who reviewed and approved results.			
	b) The report includes the following:			
	• The name and other identifiers of the patient and the specimen			
	• The name of the ordering clinician			
	• The tests performed, test results, and units of measurement			
	• Date and, when relevant, time of specimen collection			
	• The condition of any unsatisfactory specimen			
	• Reference values for the tests performed			
	• Date and time the result is reported			
	• The identity of the laboratory that performed the test			
	c) The above elements are also included in reports from reference or contract laboratories.			
	d) Reports from reference or contract laboratories are not modified in any way that would change their meaning.			
	e) A report includes the identity of the laboratory that performed a test, including reference or contract laboratories.			
	f) When an interpretation of test results is included, the interpretation is validated by the person who performed it.			
PP.11.2	The director has defined in writing, a procedure for immediate notification of the responsible clinician when specific critical results indicate that the patient's situation is life-threatening. The defined process includes the following elements:			
	a) The laboratory director has defined the laboratory's critical values for specific tests, which in the critical range may be life-threatening.			
	b) These critical results are reported immediately, according to the laboratory's policy, to the authorized individual responsible for the patient.			
	c) The means of notifying the clinician of these critical values is defined. For inpatients, the process might be notifying a responsible nurse who calls the physician. For outpatients, the response may be to directly notify the physician.			
	d) The notification is documented, including time and date called, and the identification of the individual called. This individual should write down and read back the result to ensure that it has been understood			

	accurately.			
PP.11.3	The laboratory has a written, defined process for correcting reported results, including the following:			
	a) When an incorrect result is reported, the corrected report is generated as promptly as possible.			
	b) In such cases, the laboratory communicates directly with the ordering clinician or other authorized qualified individual who can take action to avert maltreatment of the patient.			
	c) The process includes maintenance of both the original and corrected reports, with identification of each on all copies of the report.			
PP.11.4	The director defines in a written policy requirements for giving or receiving verbal and telephone orders or test results. These include requirements that:			
	a) The complete verbal or telephone order or test result shall be written down legibly and signed by the receiver of the order or test result.			
	b) The complete verbal and telephone order or test result shall be read back by the receiver of the order or test result.			
	c) gave the order or test result, and the complete process is documented.			
12	**Procedures for Storage and Maintenance Requirements**			
PP.12.1	A written protocol defines the storage and maintenance requirements for records, including retained specimens, slides, tissues, and blocks. The following issues are addressed in the written protocol:			
	a) Stored records are maintained in an organized condition.			
	b) Records are chronologically and alphabetically or numerically identified for easy retrieval.			
	c) Identity and legibility are maintained.			
	d) Storage is under acceptable environmental conditions to maintain record or specimen integrity.			
	e) The length of time each type of record or specimen will be stored is specified.			
PP.12.2	Minimum required storage includes the following:			
	a) The following records should be stored for at least two years:			
	• Records of quality management and improvement process activities			
	• Records of quality control results, including remedial actions			
	• Patient testing activities and results			
	• Proficiency testing (external quality control) results			
	• Results of equipment performance testing and calibrations			
	b) Equipment maintenance and repair records are retained for the life of the instrument.			
	c) Blood bank records, including quality control records for blood banking, are retained for at least five years.			
	d) It is important that records and specimens are retained at least as long as required by applicable law and regulation.			
	e) The laboratory must comply with storage and maintenance requirements for records, as defined in the protocol, and practices are			

	monitored for noncompliance. Actions are taken when noncompliance issues are identified.			
	(**Note:** If assistance is needed in determining a format for technical procedures, an acceptable reference is NCCLS publication GP2-A3, *Clinical Laboratory Technical Procedures Manual, Third Edition*, *Approved Guideline*.)			

IV
Infrastructure and Equipment

	ROLES AND RESPONSIBILITIES	M	NM	N/A
IE.1	The building in which the laboratory is located is structurally safe and appropriate for the services provided.			
IE.2	Appropriate safety features (such as fire prevention and control equipment) are provided.			
IE.3	There is sufficient and appropriate space for all areas under control and/or authority of the laboratory.			
IE.4	Areas where sample handling, processing, and testing are performed are appropriate and adequate to ensure the efficiency of processes, and the safety of staff members.			
IE.5	Spaces where specimens are collected are adequately designed to allow patient privacy, confidentiality, and safety, and specimen integrity.			
IE.6	Storage areas have adequate and appropriate space, including temperature and humidity control where required.			
IE.7	There is a means to provide adequate housekeeping for all laboratory areas.			
IE.8	Necessary utilities are provided and maintained. These include:			
	a) Humidity and temperature control;			
	b) Appropriate ventilation systems;			
	c) Necessary communications equipment;			
	d) Stable electrical power and grounded outlets;			
	e) Emergency power, when required*;			
	f) Biological safety cabinets and chemical fume hoods, when indicated; and			
	g) Other utility features, as required.			
IE.9	Critical components for utility systems are periodically tested. This includes:			
	a) Periodically testing the emergency generator;			
	b) Checking for polarity and ground on electrical outlet circuits at least every twelve months;			
	c) Checking and maintaining the biological safety cabinet at least every twelve months.			
	d) Checking the chemical fume hood for adequate function at least every twelve months.			
	e) When environmental conditions are unacceptable, there are records of the remedial actions taken, and the results of the actions.			
	* Emergency power is required to supply electricity to critical areas when the normal power supply is interrupted. Such Areas include blood, bone, and tissue storage units; essential refrigeration and heating; and essential equipment that might be required for STAT testing in an emergency situation. If emergency electrical power is not provided for these services, there should be a			

	defined plan for transfer of blood, bone, and tissue, as well as specimens and tests, to another specified laboratory and an agreement that the receiving laboratory will accept what is sent and perform required testing.			
IE.10	Laboratory leaders ensure that analytic and other equipment, as well as other material resources required for the provision of services, are adequate, appropriate, and available.			
IE.11	There are processes for ensuring the initial and continued acceptability of reagents and other supplies.			
IE.12	Laboratory equipment is maintained, tested, and inspected, including:			
IE.12.1	A program to regularly monitor and demonstrate proper calibration and function of instruments, reagents, and analytical systems. (Refer to the quality control section for specific calibration and other requirements for analytical systems.)			
IE.12.2	Equipment assessed through periodic inspections and performance testing. The following are performed and documented:			
	a) Daily monitoring of temperature-controlled spaces and equipment, such as water baths, heating blocks, refrigerators, and freezers			
	b) Periodic evaluation of automated and manual volumetric equipment			
	c) Periodic checking of mechanical timers for accuracy			
	d) Periodic cleaning, maintenance, and checking of optical alignment for microscopes			
	e) Checking of thermometers against an appropriately standardized thermometer prior to use			
	f) Periodic checking of centrifuges for essential operating characteristics			
	g) Checking of sterilizers for proper performance			
IE.12.3	Preventive maintenance for each piece of equipment.			
IE.12.4	All inspections, testing, repair, and maintenance of equipment is documented.			
IE.13	A historical record is maintained for each analytical instrument and piece of equipment.			
IE.13.1	The historical record identifies the equipment with			
	a) the name of the manufacturer;			
	b) equipment type; and			
	c) a serial number or another unique identifier.			
IE.13.2	The record includes			
	a) all validation, performance testing, and maintenance performed;			
	b) major repairs or modifications made to the equipment;			
	c) contact information for any outside individual or organization that maintains or repairs the equipment; and			
	d) manufacturers' instructions or guidelines, when possible.			
IE.13.3	Records are retained as follows:			
	a) Detailed records identifying daily, weekly, or monthly performance tests and function checks are retained for at least two years, unless there are more stringent requirements to meet applicable law and regulation.			
	b) Records of major repairs, parts replacement, and semiannual or annual			

	calibration checks and preventive maintenance are retained for the life of an instrument.			
	c) Each entry is dated (including the date the equipment was obtained and placed into service and the date retired) and includes the identity of the person who performed work on the equipment.			
IE.14	Maintenance and inspection ensure that equipment is safe.			
IE.14.1	Safety evaluation of equipment, including checks for electrical safety and for working emergency stop devices;			
IE.14.1.1	Safety evaluation of equipment is performed by an individual(s) who is competent to perform that function.			
IE.14.2	When maintaining and inspecting equipment, manufacturers' instructions are followed.			
IE.14.3	Unsafe equipment is removed from use.			
IE.14.4	If equipment is repaired onsite, appropriate space and personal protective equipment is provided for this work.			
IE.15	When computers or electronic testing equipment are used for any of the laboratory's processes, there is validation of the computer software prior to use.			
IE.15.1	The laboratory provides environmental conditions required for electronic systems and the maintenance of data integrity.			
IE.15.2	Procedures are developed for the use of computers and routine maintenance.			
IE.15.3	There are defined procedures to protect data and information against loss, destruction, tampering, and unauthorized access or use.			
IE.15.4	There is a defined backup procedure to follow when a computer is not functioning so that laboratory results continue to be reported in a timely manner and data during this time are not lost.			
IE.16	The laboratory has and follows written guidelines for the periodic evaluation of all reagents, including water, to provide for accurate and precise test results.			
IE.17	Laboratory reagents are properly labeled with the following:			
	a) Identity;			
	b) Strength or concentration;			
	c) Storage requirements;			
	d) Cautionary and accessory information;			
	e) Date prepared or received, date opened. and			
	f) Expiration date.			
IE.18	The laboratory does not use materials or reagents of substandard reactivity or outdated or deteriorated materials.			

V
Safety

	ROLES AND RESPONSIBILITIES	M	NM	N/A
	Security			
SF.1	Security measures are in place, as required for the laboratory services provided. These include safeguards for specimens, resources, laboratory spaces, and information against unauthorized access.			
SF.1.2	Laboratory staff are able to accurately describe security measures.			
SF.1.3	Security measures are consistently followed.			
	Hazardous Materials and Waste			
SF.2	The laboratory maintains a current inventory of hazardous materials and waste.			
SF.2.1	The laboratory has written procedures for			
	a) Handling, storage, and use of hazardous materials;			
	b) Reporting and investigating spills, exposures, and other incidents;			
	c) Proper disposal of hazardous waste;			
	d) Proper protective equipment and procedures during use, spill, or exposure;			
	e) Required documentation, including required permits, licenses, or other regulatory requirements.			
	f) Proper labeling of hazardous materials and wastes.			
SF.2.2	The written procedures are consistently followed.			
SF.3	Safety policies and practices are defined in writing and followed for biohazardous or infectious materials and waste, including sharps.			
SF.3.1	As applicable, practices controlling the following biosafety hazards and practices are followed:			
	a) Exposures to aerosols and droplets are controlled.			
	b) Exposures to needlestick and other sharps are minimized and addressed.			
	c) Practices include the use of laboratory coats, gowns, or uniforms to protect street clothes and prevent contamination.			
	d) Gloves are required for all personnel when handling potentially infectious specimens, cultures, or tissues.			
	e) Training is provided on the proper use of personal protective equipment.			
	f) Biosafety cabinets are used, when required.			
	g) Rules govern how to handle laboratory exposure to infectious agents, accidental cuts, needlestick injuries, accidental ingestion, and contact with potentially infectious agents from mucus membranes.			
	h) There are processes for handling, decontaminating, and disposing infectious waste.			
	i) Appropriate immunizations are defined.			
	j) Written procedures define safe collection, transport, and handling of all specimens.			
	k) Eating, drinking, smoking, applying cosmetics, manipulating contact			

	lenses, and mouth pipetting in any laboratory area where infectious materials are collected, stored, or handled are strictly prohibited.			
	l) When relevant to their jobs, personnel have received training about precautionary measures, modes of transmission, and prevention of infection with blood borne pathogens.			
SF.3.2	Infections acquired in the laboratory are reported, as required by law and regulation.			
SF.4	When the laboratory uses hazardous chemicals, they are identified, properly labeled, appropriately stored, and disposed according to safe practices, and required law and regulation.			
SF.4.1	Written guidelines describe the processes for selecting, handling, storing, using and disposing hazardous chemicals and waste.			
SF.4.1.1	Employees are provided ready access to material safety data sheets (MSDS) for each chemical used in the laboratory.			
SF.4.2	Containers of hazardous chemicals are labeled with precautionary information, identifying the type and severity of hazard.			
SF.4.3	Formaldehyde and xylene vapor concentrations are maintained below the maximum concentrations allowed by law and regulation.			
SF.4.4	The method used for disposal of all solid and liquid waste is in compliance with applicable law and regulation.			
SF.4.5	Safety cans are generally used for volumes of flammable liquids greater than one liter.			
SF.4.6	Safety cans are used for flammables that are highly volatile (for example ether or pentane) for volumes greater than 500 ml. The only exception is if the purity required mandates storage in glass containers.			
SF.4.7	Bottle carriers are provided for transporting all glass containers containing hazardous chemicals in amounts greater than 500 m.			
	Electron Microscopy			
SF.5	When the laboratory performs electron microscopy, written precautions related to radiation and electrical hazards are implemented and followed.			
	Fire Safety			
SF.6	The laboratory has addressed fire safety, including:			
	a) Providing necessary fire extinguishing equipment; and			
	b) Providing fire alarms, as required.			
SF.6.1	A written procedure defines the steps to take if a fire occurs in the laboratory and/or in the building in which the laboratory is located.			
SF.6.2	Personnel are instructed in			
	a) the proper use of fire extinguishing equipment,			
	b) the necessary steps to take if a fire occurs, and			
	c) steps to take to protect patients if they are present.			
SF.6.2	Personnel training is documented.			
	Safety Devices for the Laboratory			
SF.7	Adequate safety devices are provided, as appropriate. These include:			
	a) Eyewash stations;			
	b) Safety showers, if required for the chemicals used;			
	c) Fire blankets, if required;			

	d) Fire extinguishers; and			
	e) Spill kits.			
SF.7.1	An emergency eyewash station is available within 10 seconds' travel distance from every area in the laboratory where hazardous chemicals or waste are present or used. The eyewash facility should be capable of providing at least a 15- to-20 minute flush of the eyes with safe water or a sterile solution.			
SF.7.2	Puncture-resistant containers are provided for waste sharp disposal.			
SF.7.3	For storage of bulk amounts of flammable liquids beyond a small working supply, the laboratory uses an approved flammable liquid storage cabinet or special room constructed for the storage of flammable liquids.			
SF.7.4	Eyewash stations, safety showers, and fire extinguishers are tested and checked periodically for proper function.			

VI
Quality Control Assurance

	ROLES AND RESPONSIBILITIES	M	N	N/A
	A. Processes Common across Laboratory Specialties			
	A.1 External Quality Control or Assurance (Proficiency Testing)			
QC.1	The laboratory has a program for external graded interlaboratory comparison testing (also known as proficiency testing) for each specialty, subspecialty, and analyte for which such testing is available.			
QC.1.1	Proficiency materials are tested according to a written laboratory protocol.			
QC.1.2	Results are submitted back to the provider within the required time period.			
QC.1.3	The laboratory director or a designated supervisor reviews the returned report in a timely manner, and the review is documented.			
QC.1.4	A more intensive review if performed and documented for any individual result exceeds acceptable limits.			
QC.1.5	Remedial action is documented for any single or multiple challenge(s) of each analyte that does not fall within acceptable limits.			
QC.1.6	Records of test handling, examination, and reporting of results are retained for two years.			
QC.1.7	Records of results, reviews, conclusions, and if indicated, remedial action is retained for at least two years.			
QC.1.8	Proficiency sample testing is performed in the same manner as patient sample testing.			
QC.1.9	Samples are tested along with the laboratory's regular workload by personnel who routinely perform the laboratory test using routine methods.			
QC.2.0	Proficiency testing is rotated among all testing personnel over time.			
QC.2.1	Personnel test samples the same number of times that they routinely test patient samples.			
QC.2.2	Communication between laboratories about the results of proficiency testing occurs only after the date the laboratory must report results for the testing event to the provider.			
QC.2.3	The laboratory does not send samples to another laboratory for analysis.			
QC.2.4	If proficiency testing is not available for one or more tests performed, the laboratory uses another system to verify the accuracy and reliability of test results.			
	Note: Possible ways to meet this requirement include:			
	a) Interlaboratory comparisons of quality control cumulative data.			
	b) Comparing results from a specified number of previously tested specimens with a reference laboratory.			
QC.2.4.1	When this process is used to verify accuracy and precision, it is performed at least every six months.			
QC.2.4.2	The laboratory director defines parameters of acceptability in writing, and when they are not met, review and remedial action are documented.			
QC.2.5	The laboratory follows a written process for evaluating the correlation between results for the same test performed with different methodologies, different			

	instruments, or at different sites.			
QC.2.5.1	The laboratory performs this correlation check at least semiannually, and is documented.			
QC.2.5.2	For the correlation, the laboratory director has defined how many patient specimens should be tested with each system, and how closely they should check to be judged acceptable.			
QC.2.5.3	When the results demonstrate a significant difference, the laboratory director must make a decision whether to continue using both methods.			
QC.2.5.4	If the laboratory continues to use both methods when they are significantly different, the laboratory director notifies ordering clinicians of the difference, and each result is reported with a reference range unique to that method.			
	A.2 Internal Quality Assurance			
	Validation of New Methods			
QC.2.6	The laboratory performs initial validation procedures for each new instrument and analytic system or test to verify that the method will produce accurate and reliable results. All validation procedures are documented, and the documentation is retained for the life of the instrument.			
QC.2.6.1	At a minimum, new analytic methods are verified for			
	a)Accuracy;			
	b)Precision; and			
	c) The reportable range (this is done through a linearity check).			
	d) In addition, the laboratory director confirms that the reference range that will be used applies to the patient population being tested.			
QC.2.6.2	For methods that have been modified; are very complex with more than a few steps; have been developed in-house; or which the manufacturer has not validated, the laboratory tests the full range of performance specifications, including:			
	a) Accuracy;			
	b) Precision,			
	c) Reportable range;			
	d) Analytic sensitivity;			
	e) Analytic specificity; and			
	f) Determine the reference range for the laboratory's population of patients.			
QC2.6.3	When a new method replaces an existing method, and the existing method is still operational, the validation also includes a correlation study between the old and new methods.			
QC.2.6.4	During the validation, the laboratory also establishes the number, type, and frequency of quality control materials to be tested.			
	Validating Analytical Instruments That Use Electronic or Internal Monitoring Systems			
QC.2.6.5	If the laboratory is using a test method with electronic or internal monitoring systems or processes, and wishes to use the internal controls for routine day-of-use quality control, the test method meets specific criteria, and the laboratory performs required validation procedures, including:			
QC.2.6.5.1	The laboratory ensures the test is automated and not highly complex in the			

	number of steps or manual manipulations.			
QC.2.6.5.2	The laboratory has not modified the test from the manufacturer's protocol.			
QC.2.8.5.3	The test method has at least two levels of electronic simulator or internal controls, which are performed and documented at the same frequency as required for the specific specialty or subspecialty in this manual, or at the frequency recommended by the manufacturer, whichever is the more frequent.			
QC2.6.5.3	For each test, the laboratory determines the sources of error and evaluates whether the electronic or internal controls monitor the entire analytic process or only part of the analytic process.			
QC2.6.5.4	The laboratory validates the electronic or internal controls by controls external to the system (liquid controls) in parallel with the electronic or internal controls for at least 20 test runs.			
QC.2.6.5.5	Based on the validation and data analysis, the laboratory director determines and defines in writing, the variety and frequency that traditional external (liquid) controls that will be sufficient to prevent clinically significant errors in patient test results.			
QC.2.6.5.6	The laboratory performs traditional quality control, as required or suggested by the manufacturer and at intervals that meet manufacturers' recommendations, but at least with each new lot number, shipment, or package of reagents.			
QC.2.6 .5.7	If there are two consecutive unacceptable quality control results (internal or external [liquid]) for the same level or measurement, the laboratory must investigate, identify the cause, and restart with the validation process.			
	Calibration, Linearity, and Other Function Checks			
QC.2.7	The laboratory follows written procedures and manufacturers' guidelines for function checks performed on analytical equipment.			
QC.2.7.1	The laboratory specifies in a written policy, the number, type, concentration, and acceptable limits for materials used in calibration, as well as the frequency of performance. At a minimum, manufacturers' recommendations and guidelines are followed.			
QC.2.7.2	Calibration is performed using materials traced to a recognized reference standard, whenever possible.			
QC.2.7.3	The laboratory does not use the same lot number of material for quality control testing as it uses for calibration procedures.			
QC.2.7.4	Linearity testing is performed according to manufacturers' guidelines, but at least every six months.			
QC.2.7.5	Other instrument function checks are performed and documented according to manufacturers' recommendations.			
QC.2.8	The laboratory director or appropriate supervisor conducts a coordinated review of patient results, quality control results, and instrument function checks.			
QC.2.8.1	The process of how the review is performed is defined in writing.			
QC.2.8.2	Patient test results and quality control results are reviewed daily. The review includes a review for test results that do not make sense, unusual trends, significant unexplained changes in results for a patient from the last time the test was performed (delta checks), acceptability of quality control, and any results that need to be called immediately to the ordering physician.			
QC.2.8.3	As part of the review, manually transcribed results and results manually entered			

	into the computer are checked for clerical errors.			
QC.2.8.4	Cumulative quality control results should be reviewed to identify shifts and trends and any other unexplained changes at least monthly.			
QC.2.8.5	When quality control results demonstrate a problem, instrument function checks should also be reviewed to help identify the problem.			
QC.2.9	The laboratory director requires that remedial action is taken and documented for deficiencies identified through quality control measures or authorized inspections.			
QC.2.9.1	Each laboratory area's policies and procedures include written instructions to follow when problems arise or when control results are outside acceptable limits.			
QC.2.9.2	Corrective action is documented when the following situations occur:			
	a) Control results do not meet the laboratory's criteria for acceptability.			
	b) A testing instrument does not meet function check or performance testing requirements.			
	c) Incidents of incorrect test results are reported.			
	d) Other incidents of unsatisfactory specimen collection, testing, or reporting are identified.			
QC.2.9.3	The laboratory's remedial action meets the following criteria:			
	a) It is taken immediately after problem areas have been identified.			
	b) It is consistent with defined quality control policies.			
	c) It is consistent with defined preventive maintenance or performance testing and equipment inspection policies.			
	d) It includes documentation of repeat patient testing and quality control, when indicated.			
	e) It documents correction of patient results, when necessary.			
	f) It is adequate to correct all the deficiencies implied in the problem (for example, if one patient's results are discovered to be incorrect, other patients' results from the same testing sequence are evaluated to ensure correctness).			
	g) It includes a process to review the adequacy of actions taken.			
	If review activities are ongoing and in depth, they can enable the laboratory to take preventive action before major problems arise. The review of appropriate sources of information such as monitoring and assessment results, proficiency testing results, quality control records, and customer complaints can alert the laboratory to take steps to prevent major problems from occurring.			

	B. Processes for Laboratory Specialties			
	1.Surgical Pathology & Autopsy (Histopathology)			
QC.3	The laboratory director has implemented processes to ensure the proper identification, preservation, and documentation of receipt of surgical specimens sent for analysis.			
QC.3.1	These processes			
	a) Ensure that responsible personnel properly identify, label, and preserve surgical specimens, consistent with written guidelines provided by the laboratory.			
	b)Documenting receipt of specimens by the laboratory;			
	c) Maintaining specimen, slide, and block identity throughout processing, slide preparation, and storage, in accordance with written guidelines.			
	d)Labeling specimens, slides, and blocks legibly and in a manner that ensures that labels are securely attached; and			
	e) Using controls for all special stains, verifying stain acceptability before reporting results, and maintaining documentation of control reactivity.			
QC.3.2	When immunohistochemistry is performed, the laboratory director has defined appropriate quality control processes in writing. These controls include:			
	a) For each antibody, controls are used to verify reactivity.			
	b) Control results are documented, as is an assessment of the quality of slide preparation on each day of testing.			
	c) Controls are stored in a way to best preserve antigen reactivity.			
	d) There is appropriate pH monitoring of buffers used.			
	e) Each new lot of antibody is evaluated prior to use or concurrently with first use.			
QC.3.3	All gross analyses of surgical and autopsy tissue are performed by a qualified pathologist or under the direct supervision of a qualified pathologist.			
QC3.4	There are defined processes to document the ongoing proficiency of pathologists who perform microscopic analysis of tissue. These include:			
	a)participation in a formal external quality assurance program for each laboratory where this testing is performed;			
	b) Records of peer review of microscopic slides from surgical pathology performed by a second reading from another pathologist, along with a comparison of results. This should be performed on a defined percentage of slides read (10 – 20%).			
QC.3.5	All autopsies are performed by or under the supervision of a qualified pathologist.			
QC.3.6	The laboratory has implemented processes to ensure access to required patient information and to cross-reference such information to assist in providing a complete and proper diagnosis. The following information is to be sought by and available to the pathologist when at all possible:			
	a) A request for examining surgical specimens is to be accompanied by a concise reason statement for the exam, as well as other pertinent			

	clinical information. This should include, to the degree known, the preoperative and postoperative diagnoses.			
	b) When histology and Cytology testing have previously been performed on a patient's specimens, these results are reviewed, if they are relevant to the current case.			
	c) When special studies are performed, their results are compared to the microscopic findings prior to reporting of results.			
	d) To ensure accurate results, when frozen section and final diagnosis results are discrepant, there is a review of findings, and the discrepancy is resolved, along with communication with the responsible practitioner.			
	e) Available pertinent clinical information is obtained and reviewed prior to performance of an autopsy.			
	2.Cytopathology			
QC.4	A pathologist or physician qualified in Cytopathology maintains the quality of the Cytopathology service through direct supervision. This individual ensures that			
	a) written procedures for adequate specimen collection, identification, preservation, and transport are established and communicated to clinical staff and other clients who collect Cytopathology specimens;			
	b) criteria are defined for unacceptable specimens that are to be rejected and recollected before evaluation;			
	(**Note:** The following list of common criteria can be used to define *unacceptable;*			
	• The name on the slide or specimen container is different from the name on the requisition.			
	• The slide or container is not labeled with the patient's name or other identifier.			
	• The submitted slide is broken or crushed and cannot be repaired for processing.			
	• The specimen is improperly fixed.)			
	c) criteria are defined by the laboratory director for unsatisfactory specimens that, upon evaluation, do not allow for a definitive diagnosis;			
	(**Note:** In defining criteria for *unsatisfactory specimens*, the laboratory can include such items as the following:			
	• The cells on the slide are too few in number or obscured, which would make a definitive diagnosis inaccurate.			
	• Obscuring inflammation			
	• Obscuring red blood cells			
	• Obscuring lubricant			
	• Excessive air drying			
	• Excessive cellular degeneration			
	• Absence of endocervical components			
	• Smears containing too few epithelial cells)			
	d) Stains and staining techniques that provide acceptable quality for proper evaluation are defined. This includes using a Papanicolaou,			

	modified Papanicolaou, or other approved alternative staining method for			
	all gynecologic smears; and			
	e) Effective measures are taken to prevent cross-contamination between gynecologic and non-gynecologic specimens during the staining process.			
QC.4.1	The cytology laboratory has a process to measure, assess, and improve quality. If cytotechnologists perform screening, the following requirements are met:			
	a) The director or other qualified physician or qualified supervisory cytotechnologist reviews all slides of			
	extragenital origins.			
	b) The director or other qualified physician or qualified supervisory cytotechnologist also reviews all of the following:			
	• Suspicious or malignant cells			
	• Dysplasia			
	• Cervical intraepithelial neoplasia (CIN)			
	• Low - and high-grade squamous intraepithelial lesions			
	• Atypical cells of undetermined significance			
	• Smears interpreted as having reactive or reparative changes			
	• At least 10% of the negative gynecological slides, from both low-risk and high-risk individuals			
	c) This review is completed and documented before patient results are reported for those slides selected for review.			
	d) Work load limits are established for all who screen cytology slides. The maximum number of slides examined by an individual should not exceed 100 slides. If an individual screens 100 slides/day, it should cover an 8 hour period. Slide reading should not exceed 12 – 13 slides/hour.			
	e) The workload limit for an individual may be lower than the above guideline, if warranted by a cytotechnologist's performance, as documented in the above review of slides.			
	f) Timely follow-up, reeducation, and other appropriate remedial action is taken and documented when required for cytology personnel whose results are less than acceptable, as defined by the cytopathology director.			
	f) Cytology reports for all results are made in appropriate descriptive nomenclature.			
	g) When an incorrect result is reported, the corrected report is generated as promptly as possible. In such cases, the laboratory communicates directly with the ordering clinician or other authorized individual qualified to follow up with the patient.			
	h) Clinical information and histopathology reports are compared with cytology reports when such information is available.			
	3.Clinical Chemistry, Hematology, and Coagulation			
QC.5	The laboratory leaders have defined quality control processes in writing for all clinical chemistry, hematology, and coagulation tests performed by the			

	laboratory. The quality control procedures include:			
	a) The number and levels of controls to be tested			
	b) The frequency of control testing			
	c) A description of how control ranges are calculated			
	d) A description of the process to follow when quality controls are not acceptable			
QC.5.1	For tests that produce quantitative results (such as many clinical chemistry, hematology, and coagulation analyses), laboratory quality control protocols are at least as rigorous as the protocol required or suggested by the manufacturer or those prescribed by these standards, whichever is the more stringent.			
QC.5.2	At a minimum, the laboratory meets the following guidelines for automated tests:			
	a) For automated clinical chemistry and hematology tests, at least two levels of control are tested for each day of patient testing. When the manufacturer recommends three levels of control for automated hematology testing, the laboratory must follow manufacturers' recommendations.			
	b) For automated coagulation tests, at least two levels of control are tested for each eight hours of patient testing.			
QC.5.3	For automated quantitative tests, the laboratory director ensures that control upper and lower limits are set according to the following requirements:			
	a) Control ranges and limits are established using valid statistical measurements* (mean, standard deviation, coefficient of variation) for each lot number of control material.			
	b) All standard and reference quality control limits are established and made available to staff.			
	c) Control ranges and limits are narrow enough to promote adequate precision and accuracy for reliable patient samples.			
	d) The laboratory has only one set of quality control criteria in effect for each test at one time. (For example, if the policy states that two standard deviations are used to determine quality control ranges, but the laboratory is really using the manufacturer's ranges, this practice would not be considered in			
	Compliance with this requirement.)			
QC.5.4	For manual tests, the following requirements are met:			
	a) For manual hematology tests, two levels of control are provided with each testing batch.			
	b) Cell counts performed using a hemocytometer are tested in duplicate.			
	c) For manual coagulation tests, each individual performing test analyzes two levels of control before testing patient samples and each time a change in reagents occurs.			
	d) For manual coagulation tests, patient and control samples are tested in duplicate.			
	e) For manual and semi automated chemistry tests, each individual			

	performing tests runs and documents at least two levels of control with each run of patient tests.			
QC.5.5	The laboratory has quality control processes in place for blood film evaluation and differential counts that include the following:			
	a) Differential slide analysis includes the 5-part white blood cell differential count and an assessment of red blood cell and platelet morphology.			
	b) There are criteria that define the types of slides that are to be reviewed by a knowledgeable pathologist or technologist. All such reviews are documented.			
	c) Automated differential analyzers are properly validated, and guidelines define limits of agreement for white blood cell types between the automated instrument and manual differentials.			
	d) Data and/or slides are reviewed when results are flagged by the differential instrument, and the review is documented.			
	e) A file of slides for reference from interesting or unusual cases is maintained.			
	4**. Microbiology**			
QC.6.1	The laboratory director has defined in writing the quality control processes used when performing bacteriology, mycobacteriology, and mycology. Quality control processes for chemical and biological solutions, reagents, and antisera meet the following requirements:			
	a) The laboratory tests solutions, reagents, and antisera used for identifying bacteria, mycobacteria, and fungi, and it inspects them for deterioration.			
	b) Positive and, as appropriate, negative controls are used.			
	c) Positive controls of graded reactivity are used, if applicable.			
	d) Biochemical panels are tested at intervals that meet manufacturers' directions, but at least once before use or concurrently with each new batch, lot number, or shipment.			
	e) The following quality control frequencies are acceptable unless problems are identified and more stringent measures are required:			
	• Each day of use: DNA probes, beta-lactamase methods other than Cefinase, and camp test.			
	• Each time a new batch, shipment, and lot number are prepared or opened, and every six months thereafter: bacitracin; optochin; Cefinase; spot indole; **ONP**G; **X**, **V**, and **XV** factor discs or strips; germ tube; yeast morphology media; catalase, coagulase plasma; and oxidase.			
	• Typing sera: when prepared or opened and every six months thereafter.			
	f) For identification methods on automated instruments, the laboratory should follow quality control requirements recommended by the manufacturer.			
	g) All media have been tested for proper growth characteristics by the manufacturer and the laboratory, as required for media used to grow fastidious organisms.			
	(**Note:** If assistance is required, the following references are useful for a			

	guideline: CLSI publication M2-A9, *Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard, ninth edition*; and NCCLS publication M22-A3, *Quality Assurance for Commercially Prepared Microbiology Culture Media, second edition*; *Approved Standard*.			
QC.6.2	The laboratory performs quality control testing for each lot or shipment of antibacterial, antimycobacterial, and antifungal susceptibility testing agents, and meets the following requirements:			
	a) Approved, standardized reference organisms (**ATCC**) are tested each day of patient testing for antibacterial and antifungal susceptibility unless the laboratory has successfully validated the process described in the note below.			
	b) If validation is successful, the laboratory may perform the quality control once a week, unless problems occur with weekly controls.			
	c) Antimycobacterial susceptibility quality control is performed each week of patient testing.			
	d) Susceptibility quality control is documented.			
	(**Note:** For each antimicrobial agent/organism combination, the laboratory should document that appropriate control strains were tested for a minimum of 20 to 30 consecutive test days. No more than 1 out of 20 or 3 out of 30 results for each			
	Antimicrobial agent/organism combination may be outside the acceptable range in order to allow the laboratory to perform quality control weekly.)			
QC.6.3	The laboratory tests staining procedures for intended reactivity by using smears of microorganisms with predictable staining characteristics. This includes the following:			
	a)Gram stains (except virology Gram stains) are tested with each new lot number and weekly thereafter.			
	b)For staff that does not routinely perform Gram stains, such as those on call, Gram stain quality control is performed concurrently with each staining procedure.			
	c)Each day of use, quality control is performed for non-fluorochrome acid-fast stains and special stains (spore, capsule, flagella).			
	d)Each time of use, quality control is performed for fluorochrome acid-fast and other fluorescent stains.			
	e)Stain quality control results are documented.			
	5.Molecular Microbiology Testing			
QC.7.1	There is adequate quality control procedures when molecular microbiology testing is performed. These include at least the following:			
	a) At a minimum, manufacturers' guidelines for test performance and quality control are followed, including selection of control organisms.			
	b) For quantitative tests, two levels of control are run each day of patient testing.			
	c) For qualitative tests, a positive and negative control is run daily.			
	d) If internal, electronic, or procedural controls are used instead of liquid controls, the requirements of standard QCP.1.4 must be met.			
	5. Parasitology			
QC.8.1	If the laboratory is performing parasitology, appropriate reference materials,			

	equipment, and methods are used, including the following:			
	a)Adequate reference materials must be available. These include textbooks with photographs, collections of previously stained slides, preserved gross specimens of identified parasites, and slides from proficiency tests.			
	b)If a calibrated measuring device is provided for determining the size of ova or parasites, there are instructions for calibrating and using the micrometer.			
	c)Permanent stains are not required. However, the laboratory verifies permanent stains through quality control if they are made. Quality control can consist of fecal samples with parasites or added leucocytes to demonstrate staining characteristics. The frequency of performing quality control on permanent stains is in accordance with the laboratory's policy, but at least each month of use.			
	d)If stains are used to detect specific parasites, they are checked with appropriate control organisms each time the stain is used.			
	e)If the slide method is used, both thick and thin films are prepared to provide thorough examination when checking for malarial parasites.			
	f) HAAD required Malaria tests are: a. Thick and thin blood film for malaria parasites; b. Antigen detection for malaria parasites *Laboratory technologists performing these tests are required to be proficient and competent by formal education and training.			
	6.Virology			
QC.9.1	If the laboratory performs tests for identifying viruses, records detailing the systems used and the reactions observed are maintained including the following:			
	a)The laboratory maintains records for host systems used to isolate viruses.			
	b)The laboratory maintains records for the test methods used to isolate viruses.			
	c)The laboratory maintains records for the reactions observed.			
QC.9.2	The laboratory uses and documents controls that will identify erroneous results in tests for identifying viruses, including, as required:			
	a) cell controls;			
	b) control checks of maintenance media;			
	c) sterility checks;			
	d) reagent checks for toxicity to cells;			
	e) controls for neutralization tests;			
	f) hemagglutination inhibition tests;			
	g) immunoassays;			
	h) daily quality control for virology Gram stain;			
	i) direct immunofluorescence tests; and			
	j) Indirect immunofluorescence tests.			
	7.Urinalysis and Clinical Microscopy			
QC.10.1	The laboratory ensures the quality of tests performed in urinalysis and clinical microscopy by implementing the following processes:			

	a) For manual qualitative dipstick biochemical tests, the laboratory defines how often a control that is positive for each constituent will be tested.			
	b) If dipstick testing is performed on an instrument, a positive and negative control is tested each day of use.			
	c) If an automated urine sediment method is used, the method is initially validated against manual microscopic analysis prior to routine use. Based on the validation, the laboratory specifies criteria for urine specimens that may give incorrect results and should be checked manually.			
	d) For the performance of manual urine microscopic examinations, the laboratory has reference materials, such as textbooks with photographs, atlases, or photomicrographs.			
	e) The laboratory documents the reproducibility of microscopic test results among all testing personnel on a periodic basis.			
	8.Diagnostic Immunology and Serology			
QC.11.1	The laboratory runs serologic tests on unknown specimens, including those for syphilis, concurrently with a positive control serum of known titer and a negative control, or controls of graded reactivity, to ensure specificity of antigen reactivity. The quality control processes include the following:			
	a) Positive and negative controls are run for serologic tests on unknown specimens on each day of use.			
	b) If the laboratory uses kits with internal positive and negative procedure controls, liquid controls are performed least as often as recommended by the manufacturer or more frequently, if required by laboratory policy.			
	c) The validation method is based on using liquid quality control initially for each day of patient testing, until confidence in the method is established.			
	d) The laboratory tests all test components (for example, PBS, sorbent, buffers, complement, fluorescent reagents, and graded controls) for reactivity, as necessary.			
	e) The laboratory determines control reactivity patterns for all test components before performing the test.			
	f) The laboratory documents all controls.			
QC.11.2	Equipment, glassware, reagents, controls, and techniques for syphilis tests conform to manufacturers' specifications, as follows:			
	a)Equipment (including rotators and needles) used for syphilis serology is tested according to manufacturers' recommendations and current standards of practice.			
	b)Controls used meet manufacturers' specifications and also current standards of practice.			
	c)The laboratory follows techniques specified by the manufacturer when performing tests for syphilis.			

VII
BLOOD BANK AND TRANSFUSION SERVICES

	ROLES AND RESPONSIBILITY	M	N	NA
	These standards are applicable to facilities that collect, test, process, store, distribute, and/or infuse blood and blood components.			
	Director - Responsibility			
BB.1.1	The director of blood bank and/or transfusion services ensures that the policies and procedures include the scope of services provided and define every process used in the department			
BB.1.2	The policies, procedures, and practices are based on authoritative standards, regulations, and recognized guidelines. E.g. AABB, FDA, JCI Lab Standards, ISBT			
BB.1.3	The director of the blood bank and/or transfusion services ensures that proper storage of blood and blood components is provided at the appropriate temperatures, with continuous monitoring of temperature-controlled spaces.			
BB.1.4	The director of the blood transfusion services provides policies and procedures to guide acceptable practices for blood and blood component transfusion.			
BB.1.5	The director of blood transfusion services has the education, knowledge, and expertise to oversee the process of blood and blood component transfusion and ensures that these procedures are defined and implemented.			
BB.1.6	The director of blood transfusion services has a means to monitor practices to ensure that the guidelines are consistently followed.			
BB.1.7	The director has defined criteria for recognition of transfusion reactions, as well as steps to take when symptoms occur.			
	Blood Transfusion Services			
	Testing of Blood Prior to Transfusion			
BB.14	The laboratory tests donor blood and recipient blood with potent typing sera and adequately reactive cells of a known type to determine the correct ABO blood group and Rh type.			
BB.14.1	The transfusion service performing the cross-match confirms the following according to written procedures:			
	a) The ABO group of all units of whole blood and red blood cell components;			
	(Note: The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.)			
	b) The Rh type of units labeled as Rh negative; (Note: The laboratory must determine the D [Rho] type by testing unknown red cells with anti-D [anti-Rho] blood typing reagent.)			

	c) The ABO group and Rh type of the recipient;			
	d) All Rho (D) negative donor cells are tested for the (Du) variant. This test must be performed by the donor center.			
	e) Manufacturer's instructions for blood typing are followed when applicable.			
	Reliability of ABO and Rh Reagents			
BB.15	There are defined criteria to determine the potency and reliability of sera, antisera, cells, and reagents used for ABO grouping, Rh typing and antibody detection in the laboratory policies and procedures.			
BB.15.1	Sera used are of a known potency that meets international standards of practice.			
BB.15.2	The laboratory defines, in writing, its procedures for reactivity testing or quality control.			
BB.15.3	Each opened vial of antisera, reactive cells, and reagents is tested for reactivity on each day of use and when a new lot of reagents are first used.			
BB.15.4	The laboratory confirms that each reagent reacts as expected before any testing is reported.			
BB.15.5	The results of the potency and reliability of all reagents used for ABO grouping, Rh typing and antibody detection are documented.			
	Administration of Blood			
BB.16	The laboratory performs the following procedures before blood is administered:			
	a) There is confirmation by a knowledgeable staff member that all identifying information on the transfusion requisition matches that on the specimen tube prior to the performance of compatibility testing.			
	b) There is confirmation by a knowledgeable staff member that ABO and Rh typing on all donor units has been performed.			
	c) Tests on recipient blood include			
	i. ABO group and Rh type;			
	ii. screening for unexpected antibodies and antibody identification; and			
	iii. A major cross-match between donor red cells and recipient serum.			
	d) When a direct anti-globulin test is ordered, the test system used is adequate to detect RBC-bound IgG and complement.			
	e) When the screen for unexpected antibodies is negative, serologic testing to detect ABO incompatibility or a validated electronic cross-match is required.			
	f) The laboratory maintains a file on previously tested patients. Before a unit of whole blood or red blood cell component is released for transfusion, the current results obtained are compared with any previous patient records as a process control measure to detect a possible error. This comparison includes			
	• a comparison of ABO and Rh typing during the previous 12 months;			

	• a comparison of results for patients with previous immunohematologic or transfusion problems for the past five years; and			
	• The laboratory investigating and resolving discrepancies for all cases where the ABO and Rh typing do not agree with the historical record for the patient.			
	g) If the laboratory performs a computer crossmatch,			
	i. the computer and process have been validated in-house;			
	ii. the ABO group is verified by repeat testing of the same specimen or a different specimen or by performing a historical search of laboratory records;			
	iii. the laboratory blood bank computer system has a record of the donor unit number, component type, ABO/Rh type of the component, results of the ABO confirmatory test, and the recipient's ABO/Rh type; and			
	iv. if the laboratory does not perform a serologic crossmatch, computer data is verified as being correct before blood or components are issued, and the computer contains logic to alert the laboratory of any discrepancies.			
	Selecting Blood and Components for Transfusion			
BB.17	When selecting blood and blood components for transfusion, procedures and practices include the following:			
	a) ABO group-specific whole blood or red cell components to recipients are given.			
	b) Rh negative whole blood or red cells are given to Rh negative recipients, except in unusual cases when Rh negative blood is in short supply and the medical director of the blood bank approves giving Rh positive blood.			
	c) For patients with significant red cell antibodies or other immunohematologic conditions, appropriately prepared components are used for transfusion.			
	d) When pooled blood components with grossly visible red cells are used, the laboratory ensures that plasma alloantibodies are compatible with the red cells.			
	e) The red cells in granulocyte components are ABO compatible with the recipient’s plasma—and fresh frozen plasma is ABO compatible with the recipient's red cells.			
BB.17.1	Policies and procedures address how to manage life-threatening situations (for example, the use of uncrossmatched blood or abbreviated testing). In these situations, the practitioner responsible for the patient determines and documents by signature the need to bypass the usual steps.			
	Blood Issuance and Transfusion			
BB.18	Written policies and procedures describe the process from procurement of blood from the blood bank or blood storage area, through patient identification, blood administration, monitoring of the patient, and identification and response to signs of potential			

	transfusion reactions.			
BB.18.1	There is a defined process for checking blood out of the blood bank before transfusion. The process of identifying the unit of blood that has been cross matched for a specific recipient and verifying that it is the correct recipient includes the following:			
	a) A clerical verification of blood and blood types of donor and recipient is performed and documented prior to the issuance of blood.			
	b) A compatibility tag is securely attached to the unit before issuance. It is to remain attached to the unit until the transfusion is completed. This tag provides documentation of			
	i. the recipient's two identifiers;			
	ii. the interpretation of compatibility tests; and			
	iii. the donor unit number.			
BB.18.2	Immediately prior to issue, blood and components are inspected for evidence of hemolysis, possible bacterial contamination, and any other abnormality that might be visually detected, and the inspection is documented.			
BB.18.3	Specific policies and processes required before and during blood administration should be clearly defined in writing.			
BB.18.3.1	The processes used prior to blood administration include			
	a) a step-by step description of how the identification of the recipient and the unit of blood is performed and documented at the patient's bedside;			
	b) requiring, when possible, that the identification be performed by two individuals; and			
	c) Defining the length of time allowed from issue until the transfusion is completed.			
BB.18.3.2	The processes used during blood transfusion include			
	a) requiring the transfusion to be performed under medical direction;			
	b) Instructions for using infusion devices and ancillary equipment, such as blood warming and cell salvage devices; (Note: Blood warming is performed with an approved system that has an alarm to warn the user when the temperature is outside acceptable limits.)			
	c) instructions which indicate that, in general, only 0.9% sodium chloride should be added to blood or components unless drugs have been approved for addition to blood or there are records available demonstrating that the addition of a drug is safe and does not negatively affect a blood component;			
	d) appropriate training in all aspects of the transfusion process for staff members who transfuse patients; and			
	e) documentation at least in the patient's clinical record of			
	i. the name of the transfusionist;			
	ii. the time of transfusion;			
	iii. the type and unit number of the blood component			

	transfused;			
	iv. evidence and results of patient monitoring; and			
	v. Any adverse effects of the transfusion.			
	Recognizing Suspected Transfusion Reactions			
BB.19	The following are defined and implemented:			
	a) Staff members who monitor transfusions are trained to recognize the symptoms of a potential transfusion reaction.			
	b) Criteria are defined for recognizing and responding to such reactions.			
	c) Staff has a written plan of action to follow in the event of a suspected reaction, and they report any such reaction immediately to the blood transfusion services and the physician responsible for the patient.			
	d) When symptoms indicate a possible immediate transfusion reaction, the transfusion is interrupted and investigated.			
	e) There is provision for timely clinical management of the patient during the investigation.			
	f) The laboratory promptly investigates the cause of an adverse reaction, using a defined protocol, including determining whether a hemolytic reaction has occurred.			
	g) Investigation of a suspected reaction includes immediate appraisal of the following:			
	i. Identification of the patient and blood unit labels to verify that the correct unit of blood was given to the patient for whom it was cross matched			
	ii. All records at the bedside and in the laboratory to look for possible errors in patient or blood unit identification			
	iii. Visual inspection of the recipient's post-reaction serum or plasma to check for hemolysis. This specimen is to be compared to a pre-reaction specimen from the recipient, if available.			
	iv. A direct antiglobulin test is to be performed on the post-reaction recipient's blood specimen.			
	v. The laboratory has criteria defining which circumstances require additional testing and what that testing should be.			
	h) The director of blood transfusion services interprets the evaluation of test results ordered as part of the adverse reaction protocol, and the interpretation is made a permanent part of the recipient's clinical record.			
	i) The director is actively involved when a transfusion reaction investigation indicates a system failure, such as misadministration of a blood component.			
	j) Donor and recipient blood specimens are stored for retesting in case of symptoms of a suspected transfusion reaction for at least seven days after transfusion,			
	k) When faulty components have or might have caused a potential adverse reaction, there is a process for notifying the blood donor			

	service that provided the component and for follow-up for transfusion transmitted disease, including a procedure that describes how recipients who have been transfused with potentially infectious blood or components are to be notified and counseled.			
BB.19.1	All steps in this process are followed and documented.			
	Blood Donor and Transfusion Services Record Requirements			
BB.20	The following specific records are maintained for at least five years.			
	a) The laboratory records the performance of each significant step in the collection, processing, compatibility testing, storage, distribution, issuance, transfusion, and/or disposition of each unit of blood and blood components.			
	b) The records identify the person performing the work, the date of each entry, test results and interpretation of results, and the expiration date assigned to each product.			
	c) Records are adequately detailed to provide a complete history of the work performed.			
	d) All records are legible and permanent.			
	e) Records of the blood donor center include			
	i. information about all donors drawn;			
	ii. all results of blood testing, including test results of transfusion-transmitted diseases;			
	iii. all quality control testing performed;			
	iv. all temperature records for blood storage units and facilities; and			
	v. Verification of the disposition of all blood components obtained, including the method of destruction or transfer of units unsuitable for transfusion.			
	f) Records of the transfusing facility include			
	i. all results of blood testing;			
	ii. results of all quality control testing performed;			
	iii. records of all blood and components received from another facility;			
	iv. all temperature records for blood storage units and facilities;			
	v. information about all steps involved in the release or issuance of all blood and components;			
	vi. information about the transfusion, including any transfusion-related reaction, and results of the transfusion reaction workup and the director's interpretation of the workup; and			
	vii. Verification of the disposition of all blood components obtained, including the method of destruction or transfer of units unsuitable for transfusion.			
	Donor Selection and Testing			
BB.2.1	Blood donor screening process is available in writing and includes criteria for selection and rejection of blood donors			
BB.2.2	Staff is trained to perform these procedures and their competency is			

	assessed.			
BB.2.3	Screening of potential blood donors includes a detailed history and physical examination.			
BB.2.3.1	The history of the Blood Donor includes the following:			
	a) Age			
	b) Time since last donation			
	c) History of medical illness: heart, liver, or lungs; cancer; or abnormal bleeding tendency			
	d) History of drug therapy			
	e) Risk factors for HIV or other possible transfusion-transmitted agents (such as history of parenteral drug use; history of infectious disease such as malaria or hepatitis or tuberculosis; positive blood test for HBsAg); or, during the preceding 12 months: receipt of a transfusion of blood or blood components, receipt of hepatitis immunoglobulin, skin penetrations such as tattoos or acupuncture; and/or history of incarceration for at least 72 hours in a correctional institution.			
	f) Risk factors for Creutzfeldt-Jakob disease (CJD)			
	g) Screen for any other communicable disease which the donor could have contracted due to recent travel (in the past 3 months) to certain areas at the time of blood donation.			
BB.2.3.2	Criteria for rejection of blood donors should include:			
	a) pregnancy, up to six weeks postpartum;			
	b) after immunization with toxoids or killed vaccines, including rabies vaccination (unless bitten by a rabid animal), for one year;			
	c) after inoculation with attenuated vaccines, for two weeks;			
	d) After rubella or varicella zoster, for four weeks.			
BB.2.3.3	Donors who are not suitable are advised to seek appropriate medical care.			
BB.2.3.4	During the screening process, educational materials are given to the potential donors, including materials on the risk of disease, unusual antibodies, and feasible drugs.			
BB.2.4	Informed Consent for blood donation is taken before the procedure.			
BB.2.5	A proper physical examination is performed by a qualified individual and documented. It should include the following, with defined criteria for acceptance of the donor:			
	a) Temperature, blood pressure, and pulse			
	b) Weight			
	c) Hemoglobin or hematocrit			
	d) Arm inspection to ensure the absence of skin punctures or scars indicating injection of narcotics, and no infectious skin diseases that would become a risk of contamination of the blood.			
BB.2.6	Donor blood is collected safely and aseptically according to a defined protocol.			
BB.2.6.1	There is a written blood collection procedure that includes			
	• descriptions of solutions and methods used to prepare the site			

	of phlebotomy;			
	• how identification of the donor and blood are established and maintained;			
	• step-by-step description of how the phlebotomy is performed;			
	• the procedure for identifying and responding to donor reactions;			
	• labeling procedures for blood and components, including safeguards to avoid labeling errors; and,			
	• How to accurately measure the quantity of blood removed from the donor.			
BB.2.6.2	At all times that donor blood is being collected, a qualified physician and emergency facilities are readily available.			
BB.2.6.3	Either a qualified physician or staff members under his or her supervision perform the phlebotomy.			
BB.2.6.4	Phlebotomist training for drawing blood from donors includes:			
	•in-depth proper aseptic technique (including donor site preparation);			
	•criteria for recognizing donor reactions and actions to take when such a reaction occurs; and			
	•The procedures used to maintain the identity of donors' blood units, other specimens, and records.			
BB.2.7	The phlebotomy is performed using proper aseptic technique, including a closed sterile system. Solutions for skin preparation are stored in sterile containers and are changed frequently.			
BB.2.8	When a donor reaction occurs, phlebotomists and the medical supervisor take appropriate actions, and the symptoms and actions taken are documented.			
	Blood Donor Records			
BB.3.1	Blood and related donor records are properly identified, and the identification is maintained from collection through the time the unit is transfused.			
BB.3.2	Records include documentation of all donor histories, physical examinations, and screening test results, as well as the informed consent signed by the donor.			
BB.3.3	Sample tubes, blood units, and related donor records are all identified with the same numeric identification, and there is a well-defined process of checking to make sure the identification is consistent.			
BB.3.4	The confidentiality, security, and integrity of donor records are ensured and maintained.			
	Donor Blood Testing			
BB 4.1	Donor blood undergoes routine testing before being used for transfusion. In addition, process controls are used to ensure appropriate tracking and prevent blood from being released prematurely.			
BB.4.2	Donor blood is routinely tested for ABO group and Rh type as well as communicable diseases prior to being released for transfusion.			
BB.4.2.1	Written procedures describe testing and quality control processes of			

	donor blood. The following requirements are met:			
	a) The ABO group is determined by testing the red cells with anti-A and anti-B reagents and the serum or plasma with A and B red cells.			
	b) The Rh type is performed using anti-D. Blood testing negative for anti-D is further tested to detect weak D.			
	c) For communicable disease testing, the laboratory follows the regimen followed by current standards of practice. At a minimum, blood is tested with a serologic test for			
	• syphilis;			
	• HBsAg, and anti-HBc;			
	• anti-HTLV-I and anti-HTLV-II;			
	• HIV-1-Ag and anti-HIV-2; and			
	• Anti-HCV.			
BB.4.2	Results for quality control, standards, and instrument function checks are confirmed to be acceptable before reporting donor test results. Records for these quality control reactions, instrument function checks, and donor blood results are maintained.			
BB.4.3	Process controls are used to track blood and to ensure that blood is not released until appropriate.			
BB.4.3.1	These process controls include			
	a) a system for tracking samples;			
	b) a written process is in place to ensure that blood is quarantined and also for unit disposal;			
	c) documentation of all steps of storage and release of blood from quarantine;			
	d) a process to identify previous donations from individuals who now test positive for viral marker tests; the process includes the method for notifying organizations who have received components from these previous units;			
	e) a check of each donor's name against a list of unacceptable donors before the blood is released for distribution;			
	f) not releasing donor blood that gives abnormal communicable disease test results;			
	g) A review of abnormal donor blood testing results by a qualified physician, with donor notification of these results.			
	Autologous Blood Collection			
BB.5	Written guidelines are developed by the blood bank director for autologous blood collection and are implemented.			
BB.5.1	Autologous blood collection is performed only when there is a written request from the patient's physician.			
BB.5.2	The unit of autologous blood is labeled with the same information as other blood units.			
BB.5.3	The blood is tested for blood-transmitted diseases; same as for other blood units. [Refer BB.4.1.1 c)]			
	Blood Component Preparation or Modification			
BB.6	There are defined written procedures for the collection, preparation,			

	and storage of all components prepared and stored in the organization.			
BB.6.1	Written protocols define quality control measures for each component prepared or modified in the organization.			
BB.6.2	Records indicate that quality control is acceptable, or if quality control requirements are not met, immediate corrective action is taken and documented.			
BB.6.3	Protocols specify the requirements for maintaining sterility, and expiration dates are assigned for all final components and products.			
BB.6.4	Laboratory filtration of blood and blood components is performed according to current acceptable standards of practice. E.g. AABB, FDA, JCI Lab Standards			
BB.6.5	Labeling of each component is according to acceptable standards of practice. E.g. AABB, ISBT			

	ISBT 128 Label Anatomy			
	• The ISBT 128 label is divided into 4 quadrants with 5 barcodes. • Each quadrant is 2" X 2" in size. • Upper left quadrant has the Donor Identification Number barcode. • Upper right quadrant has the ABO/Rh Blood Group barcode. • Lower left quadrant has the Product Code barcode (to identify blood product such as whole blood, red blood cells, plasma, platelets, etc.) • Lower right quadrant has the Expiration Date and Special Testing barcodes. **Upper Left Quadrant** Donor Identification Number **Upper Right Quadrant** ABO/Rh Blood Group **Lower Left Quadrant** Product Code **Lower Right Quadrant** Expiration Date Special Testing			
	Whole Blood			
BB.7	For whole blood, a specimen of blood taken from the donor at the time of collecting the unit and before use is tested for the following:			
	• Serologic test for syphilis: whole blood is used only if it is negative to the serologic test for syphilis.			
	• One or more segments are provided with each unit of whole blood or red blood cells when issued or reissued.			
	• Before they are filled, all segments are marked or identified in order to relate them to the donor of that unit of whole blood.			
	• Determination of blood group: each container is classified as to ABO blood group. At least two blood group tests are made, and the unit is not issued until grouping tests by different methods or with different lots of antisera are in agreement.			
	• Determination of the Rh factors: each container is classified as to the Rh type on the basis of tests performed on the sample. If the test using anti-D blood grouping reagent is positive, the container may be labeled “Rh positive.” If the test is negative, the results are confirmed by further testing, which includes tests for the “weak D (formerly Du).” Blood is labeled “Rh negative” if further testing is negative. Units testing positive after additional, more specific testing shall be labeled “Rh positive.”			
	• Whole blood intended for transfusion is not tested for sterility by a method that entails entering the final container before the blood is used for transfusion.			
	• Whole blood is inspected visually during storage and immediately			

	before issue. If the color or physical appearance is abnormal or there is any indication or suspicion of microbial contamination, the unit of whole blood is not issued for transfusion.			
	• Whole blood is tested for communicable disease agents according to standard practice and as indicated in the standard for testing of blood bags.			
	Red Blood Cells			
BB.8	To maintain the quality of red blood cells, the following requirements are defined and implemented:			
	• Immediately after processing, the red blood cells are placed in storage and maintained at a temperature between 1°C and 6°C.			
	• Units of red blood cells are provided with one or more appropriately marked segments, as in the requirement for whole blood.			
	• All segments are filled at the time the blood is collected or at the time the final product is prepared.			
	• Red blood cells are prepared either by centrifugation, in a manner that will not tend to increase the temperature of the blood, or by normal undisturbed sedimentation. This is done within the time frame specified in the directions for use for the blood collecting, processing, and storage system used. A portion of the plasma sufficient to ensure optimal cell preservation is left with the red cells, except when a cryoprotective substance or additive solution is added for prolonged use.			
	• All surfaces that come in contact with the red cells are sterile and pyrogen free.			
	• The final container used for red blood cells is the original container unless the method of processing requires a different container.			
	• The component is inspected immediately after separation of the plasma, periodically during storage, and at the time of issue. It is not to be issued if there is any abnormality in color or physical appearance or if there is any indication of microbial contamination.			
	• Any cryophylactic substances added to the red cells for extended manufacturer's storage at –65°C or colder do not compromise the required standards of safety, purity, and potency for red blood cells, and the frozen product maintains those properties for the prescribed dating period.			
	• If frozen red blood cells are prepared or stored, the materials used and the processing methods result in a final product that meets required standards of safety, purity, and potency for red blood cells.			
	• Frozen red blood cells are frozen within an appropriate time from collection or following rejuvenation.			
	• For washed red blood cells, the methods used ensure removal of almost all the plasma.			
	• For leucocyte-reduced red blood cells, the method of preparation			

	provides a final component that meets current acceptable • Standards of practice requirements for the reduced number of leucocytes.			

	Platelets			
BB.9	To maintain the quality of platelets, the following requirements are defined and implemented:			
	a. Testing as required for whole blood is performed on a sample of blood collected at the time of collecting the source blood, and the sample container is labeled with the donor's identification before the container is filled.			
	b. Separation of plasma and platelets and re-suspension of the platelets is in a closed system. Platelets are not pooled during processing.			
	c. Immediately after collection, the whole blood or plasma is held in storage between 20°C and 24°C unless it must be transported from the collection center to the processing laboratory. During such transport, all reasonable methods are used to maintain the temperature as close as possible to a range between 20°C and 24°C until it arrives at the processing laboratory, where it is held in the same temperature range until the platelets are separated.			
	d. The platelet concentrate is separated within four hours or within the time frame specified in the directions for use for the blood collecting, processing, and storage system.			
	e. The laboratory has demonstrated that the time and speed of centrifugation produces an un-clumped product, without visible hemolysis, that yields a count of at least 5.5 × 10(10) platelets per unit in at least 75% of the units tested.			
	f. The volume of original plasma used for resuspension of the platelets is to be determined by the maintenance of a pH of not less than 6.0 during the storage period. The pH is measured on a sample of platelets that has been stored for the maximum dating period at the selected storage temperature.			
	g. Platelets are stored at a continuous temperature of 20°C to 24°C.			
	h. Final containers used for platelets are colorless and transparent to permit visual inspection of the contents; any closure maintains a hermetic seal and prevents contamination of the contents. The container material does not interact with the contents, under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, potency, or efficacy of the product. At the time of filling, the final container is marked or identified by number so as to relate it to the donor.			
	i. Immediately after re-suspension, platelets are placed in storage at 20°C to 24°C, and a continuous gentle agitation of the platelet concentrate is maintained throughout the storage period.			
	j. Each month, four units prepared from different donors are quality control tested at the end of the storage period for:			
	i. platelet count;			
	i. pH of not less than 6.2, measured at the storage temperature of the unit			
	i. measurement of actual plasma volume			

	If the results of quality control testing indicate that the product does not meet the prescribed requirements, immediate corrective action is taken, and a record of actions taken is maintained.			
	Plasma			
BB.10	To maintain the quality of plasma, the following requirements are defined and implemented:			
	a. When whole blood is intended for plasma, fresh frozen plasma, and liquid plasma, it is maintained at a temperature between 1°C and 6°C until the plasma is removed. Whole blood intended for platelet-rich plasma is maintained between 20°C and 24°C until the plasma is removed. The red cells are placed in storage at a temperature between 1°C and 6°C immediately after the plasma is separated.			
	b. Plasma is separated from the red blood cells and is stored at –18°C or colder within six hours after transfer to the final container or within the time frame specified in the directions for use for the blood collecting, processing, and storage system unless the product is to be stored as liquid plasma.			
	c. Fresh frozen plasma is prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma is separated from the red blood cells and placed in a freezer within eight hours or within the time frame specified in the directions for use for the blood collecting, processing, and storage system, and stored at –18°C or colder.			
	d. Fresh frozen plasma is thawed at 30°C to 37°C. There is protection against water contamination of outlet ports.			
	e. Liquid plasma is separated from the red blood cells and is stored at a temperature of 1°C to 6°C within four hours after filling the container or within the time frame specified in the directions for use for the blood collecting, processing, and storage system if it is other than four hours			
	f. Platelet-rich plasma is prepared from blood collected by a single uninterrupted venipuncture with minimal damage to and minimal manipulation of the donor's tissue. The plasma is separated from the red blood cells by centrifugation within four hours after completion of the phlebotomy or within the time frame specified in the directions for use for the blood collecting, processing, and storage system. The time and speed of the centrifugation are shown to produce a product with at least 250,000 platelets per microliter. The plasma is stored at a temperature between 20°C and 24°C immediately after filling the final container. A gentle and continuous agitation of the product is maintained throughout the storage period, if stored at a temperature of 20°C to 24°C.			
	g. When there is modification by separating platelets and/or cryoprecipitated antihemophilic factor (AHF) from plasma, the following apply:			
	h. Platelets are separated as described above before the plasma is frozen. The remaining plasma is considered "fresh frozen plasma" if			

	frozen within six hours after filling the final container or within the time frame specified in the directions for use for the blood collecting, processing, and storage system.			
	i. Cryoprecipitated AHF is removed as required in QCP.11.4.5 the remaining plasma is labeled "plasma, cryoprecipitate reduced."			
	j. The final container has no color added to the plastic and is transparent to permit visual inspection of the contents; any closure maintains a hermetic seal and prevents contamination of the contents.			
	k. The final container material does not interact with the contents, under the customary conditions of storage and use, in such a manner as to have an adverse effect on the safety, purity, potency, and effectiveness of the product.			
	l. Before filling, the final container is identified by number so as to relate it to the donor.			
	m. The final product is inspected immediately after separation of the plasma and is not issued for transfusion if there is any abnormality in color or physical appearance or any indication of contamination.			
	n. With the exception of platelet-rich plasma and liquid plasma, the final product is inspected for evidence of thawing or breakage at the time of issuance. However, the containers need not be stored in a manner that shows evidence of thawing if records of continuous monitoring of the storage temperature establish that the temperature remained at –18°C or colder. If continuous monitoring of the product is not available, the final product is stored in a manner that will show evidence of thawing and is not to be issued if there is any evidence of thawing.			
	o. No preservative is added to the final product.			
	Cryoprecipitated AHF			
BB.11	To maintain the quality of cryoprecipitated AHF, the following requirements are defined and implemented:			
	• The plasma is separated from the red blood cells by centrifugation to obtain essentially cell-free plasma.			
	• The plasma is placed in a freezer within eight hours after blood collection or within the time frame specified in the directions for use for the blood collecting, processing, and storage system if it differs.			
	• A combination of dry ice and organic solvent may be used for freezing, provided that the procedure has been shown not to cause the solvent to penetrate the container or leach plasticizer from the container into the plasma.			
	• Immediately after separation and freezing of the plasma, the plasma is stored and maintained at –18°C or colder until thawing of the plasma for further processing to remove the cryoprecipitated AHF.			
	• The cryoprecipitated AHF is separated from the plasma using a procedure that has been shown to produce an average of no less than 80 units of AHF per final container.			

	• No diluent is added to the product by the manufacturer before freezing.			
	• The final container used for cryoprecipitated AHF is colorless and transparent to permit visual inspection of the contents; any closure maintains a hermetic seal and prevents contamination of the contents.			
	• The container material does not interact with the contents, under customary conditions of storage and use, in such a manner as to have an adverse effect on the safety, purity, potency, and effectiveness of the product.			
	• At the time of filling, the final container is identified by a number so as to relate it to the donor.			
	• Quality control tests for potency of AHF are conducted each month on at least four representative containers of cryoprecipitated AHF.			
	• If the average potency level of AHF in the containers is less than 80 units of AHF per container, corrective actions are taken immediately, and a record of these actions is maintained.			
	Blood and Blood Component Storage Requirements (for Donor Facility and Blood			
	Transfusion Services)			
BB.12	The laboratory provides proper storage facilities for blood and blood components.			
BB.12.1	Policies guiding storage of blood and blood components are defined in writing and are implemented.			
BB. 12.2	The policies are implemented by organization personnel.			
BB.12.3	Required temperatures for blood and components are as follows:			

Blood Component	**Storage Temperature**
Whole blood and packed red cells	1ºC – 6ºC
Frozen plasma	≤ –18ºC
Platelet-rich plasma	20ºC – 24ºC
Platelets	20ºC – 24ºC
Granulocytes	20ºC – 24ºC
Cyroprecipitated AHF	≤ –18C
Red cells frozen in 40% glyc rol	≤ –65ºC
Red c lls frozen in 20 glycerol	≤ –120ºC

BB.12.4	Storage areas are used exclusively for blood, components, and derivatives; donor and recipient blood specimens; blood banking reagents and supplies; and tissues for transplantation.			
BB.12.5	Storage areas are sufficient in size for blood and components to be arranged by separating blood types and types of components so that the risk of issuing or releasing the wrong unit is reduced.			
	Monitoring of Storage Areas for Blood and Blood components			

BB.12.6	Requirements for ongoing monitoring of temperatures for blood storage areas include the following:			
	a) Refrigerators and freezers and other blood storage areas have a system to monitor the temperature continuously, and it is recorded either by			
	• an automated continuous recording of the temperature; or			
	• Manually recording of the temperature at least every four hours.			
	b) For large storage units, there is evidence that all areas in the unit have been maintained at the proper temperature.			
	c) The proper functioning of each refrigerator and freezer is constantly monitored by:			
	i. an audible alarm system, including remote alarms when no one is in the laboratory;			
	ii. the system is battery operated or powered by a different circuit than the refrigerator or freezer; and			
	iii. The alarms are set to sound before blood or components reach unacceptable temperatures.			
	d) The temperature-recording probe is located in a container of fluid with the same volume as the smallest units stored and that has heat transfer characteristics similar to those of blood.			
	e) The laboratory performs and documents periodic function checks of the temperature recording and alarm systems.			
	f) When acceptable storage temperatures have been exceeded, there are procedures to follow, and staff document remedial actions taken and that documentation is maintained for at least five years.			
	g) Periodic function checks are conducted of the temperature recording and alarm systems.			
	Identification and Traceability of Blood and Blood Components			
BB.13	All specimens; reagents; test results; and blood, blood components, and products must be labeled correctly. Their identities are carefully maintained throughout the testing of the donor blood and patient specimen.			
BB.13.1	The processes are defined, implemented and consistently followed.			
BB.13.1.1	The following processes are in place and maintained in writing:			
	a) The patient is positively identified by the specimen collector, using two distinct identifiers, before the specimen is collected.			
	b) The system for identifying the patient is defined in writing and consistently used.			
	c) There is a process for identifying patients who are unconscious or unknown.			
	d) The specimen collector, at the time of collection,			
	i. labels the specimen with the recipient's full name and a unique identification number or other system;			
	ii. labels the specimen immediately and in the recipient's presence;			
	iii. notes the collection time; and			
	iv. documents the specimen collector's identity			

	e) There is a system for maintaining positive identification of all patient specimens, specimen types, and aliquots at all times.			
	f) The laboratory maintains records on the receipt and disposition of all blood components and products.			
	g) Blood and blood components are disposed in an appropriate manner when they have become outdated according to the expiration date.			
	h) The laboratory retains blood bank and transfusion records for at least for five years.			

VIII
HISTOCOMPATIBILITY TESTING

	ROLES AND RESPONSIBILITY	M	NM	NA
HC.1	When performing histocompatibility testing, the laboratory uses appropriate screening techniques for donors and recipients. Donors and recipients undergo adequate testing and screening to minimize the risk of incompatibility and rejection.			
HC.1.1	The laboratory performs the following in the screening and testing processes for HLA testing:			
	a) Define and follow criteria for:			
	• selecting appropriate patient serum samples for cross matching;			
	• the technique used in cross matching;			
	• preparing donor lymphocytes for cross matching; and			
	• Reporting cross matching results.			
	b) Provide results of final cross matches available before an organ tissue is transplanted, when appropriate.			
	c) Make a reasonable attempt to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for transplantation cross match, and after sensitizing events, such as transfusion and transplant loss.			
	d) The laboratory screens potential transplant recipient sera for preformed HLA-A and -B antibodies with a suitable lymphocyte panel on sera collected at the time of the recipient's initial HLA typing and following sensitizing events, as well as upon request.			
	e) A suitable cell panel is used for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits.			
	f) The laboratory			
	• HLA types all potential transplant recipients;			
	• types cells from organ donors referred to the laboratory; and			
	• follows criteria defining when antigen redefinition and retyping are required.			
HC.1.2	The laboratory's screening and donor selection processes are supported by written procedures.			
HC.1.2.1	The laboratory documents all screening and testing processes.			
HC.2	The laboratory performs mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens according to defined methods.			
HC.2.1	The laboratory's written culture criteria meet the following requirements:			
	a) Viability of all suspensions exceeds 80% at the start of the culture.			
	b) Sera used in media must have a demonstrated lack of Cytotoxic			

	antibodies.			
	c) Each mixed lymphocytic culture (MLC) test includes an autologous control as well as unrelated control responders and stimulators. Stimulator cell suspensions from three or more unrelated control individuals and a pool of at least three or more unrelated individuals are used for each responder cell tested.			
	d) Incubating and labeling techniques are adequate to discriminate positive from negative results.			
HC.2.1.1	These processes are defined in written procedures.			
HC.2.1.2	All testing is documented.			
HC.3	The laboratory performs HLA serologic typing of both donor and recipient as appropriate to the study or individual procedure performed.			
HC.3.1	The laboratory's written procedures and practices for HLA typing of donors and recipients includes the following:			
	a) Reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA-A, -B, and -DR specificities for which reagents are readily available.			
	b) Each HLA-A, -B, and -C antigen is defined by at least two or three different antisera, depending on whether monospecific or multispecific sera are used.			
	c) Each HLA-DR antigen is defined by at least five antisera or by three antisera that are operationally monospecific.			
	d) The laboratory uses a technique that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.			
	e) The laboratory defines the processes for the preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed.			
	f) The laboratory's reagent typing sera inventory (when using locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining.			
	g) Reagents used for histocompatibility typing are adequate to define HLA-A, -B, and -DR specificities that are officially recognized by the most recent World Health Organization (WHO) Committee on Nomenclature for which sera are readily available.			
	h) The typing trays for disease-associated testing permit characterization of at least those antigens accepted by the WHO for which sera are readily available.			
	i) The laboratory follows written procedures specifying the histocompatibility testing (that is, HLA typing, antibody screening, and compatibility testing and crossmatching) to be performed for each type of cell, tissue, or organ to be transfused or transplanted.			
	j) The laboratory's procedures include the following:			
	• Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants			
	• Testing protocols for patients at high risk for allograft rejection			

	• The level of testing required to support clinical transplant protocols (for example, antigen or allele level)			
HC.3.1.1	All procedures performed are documented.			
HC.3.2	Before transplantation is performed, the laboratory crossmatches potential recipients and donors using the most reactive and recent sera, as appropriate to the study or individual procedure performed.			
HC.3.2.1	The laboratory makes every effort to screen out donors who have any incompatibility potential.			
	a) The laboratory documents that crossmatching			
	• includes methods to enhance sensitivity; and			
	• is performed with the most reactive sample collected within one month of testing.			
	b) If the recipient has had a sensitizing event, or if the history is uncertain, the crossmatch is done with a serum sample collected within two days of the transplant.			
HC.3.2.2	All testing is performed according to written procedures and is documented.			
HC.3.3	The laboratory uses reagents and antisera that are specific and verified with appropriate controls when available.			
HC.3.3.1	Reagent and antisera controls include the following:			
	a) Each typing tray is checked using			
	• positive and negative control sera; and			
	• Positive controls for specific cell types, when applicable (that is, T cells, B cells, and monocytes).			
	b) Each compatibility test (that is, MLCs, homozygous typing cells, or DNA analysis) is checked and typed for disease-associated antigens, using controls to monitor the test components and each phase of the test system.			
	c) If the laboratory uses immunologic reagents (for example, antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the methods are verified with appropriate quality control procedures.			
	d) Control procedures are established to test each new batch of complement and to ensure reactivity of stored complement.			
	e) New reagents are checked for appropriate reactivity before being used.			
	f) Control results are documented and verified as acceptable before results are reported.			
	g) When quality control results are unacceptable, remedial action is documented.			
HC.3.3.2	All quality controls are documented, along with remedial action, when indicated.			
HC.4	The laboratory participates in at least one national or regional cell-exchange program, if available, or develops an exchange system with another laboratory to validate interlaboratory reproducibility.			
HC.4.1	As part of this program, the following are implemented:			
	a) The establishment of valid interlaboratory reproducibility criteria			

	b) Documentation of performance levels			
	c) Implementation and documentation of remedial action when criteria are not met			
	d) The retention of a cumulative record of participation in the program for at least two years			
	e) Timely review and documentation of results by the director or appropriate supervisor.			
HC.5	The laboratory addresses the storage of records and specimens.			
HC.5.1	Storage and maintenance of specimens and records include the following:			
	a) Recipient sera are			
	• stored at an acceptable temperature range;			
	• stored in an area that has a temperature alarm system and an emergency plan for alternative storage if temperature control should fail; and			
	• Properly identified and easily retrievable.			
	b) The laboratory properly labels and stores cells, complement, buffers, dyes, and all other reagents and specimens.			
	c) If the laboratory uses frozen panels, it has a suitable storage system.			
	d) Records of results of all cell typing or crossmatch studies are retained and readily accessible.			
	e) The organization participates in and maintains records of patient and donor transplant information in the United Network for Organ Sharing (UNOS) Clinical Transplant Registry or its equivalent.			

IX

CYTOGENETICS TESTING

	ROLES AND RESPONSIBILITIES			
CYT.1	Laboratory procedures and practices in Cytogenetics provide for accurate results.			
CYT.1.1	The Cytogenetics laboratory's quality control procedures and practices include the following:			
	a) Duplicate or independently established cultures for all specimen types			
	b) Determination of sex, performed by X and Y chromatin counts, based on examination of an adequate number of cells			
	c) Confirmatory testing performed for all atypical results			
	d) Two cells karyotyped for each case			
	e) Use of the level of band resolution necessary for interpretation purposes			
CYT.1.1.1	All processes are defined in written procedures, which are followed.			
CYT.1.2	Test results are not reported unless control processes are acceptable.			
CYT.2.	Laboratory records identify the media used, the reactions observed, and the details of each step of the identification procedure.			
CYT.2.1	The laboratory's records and results accurately and completely reflect all stages of the process and all results obtained.			
	a) Records include the:			
	• media used;			
	• reactions observed;			
	• number of cells counted;			
	• number of cells karyotyped;			
	• number of chromosomes counted for each metaphase spread; and			
	• Quality of the banding.			
CYT.2.1.1	The resolution is appropriate for the type of tissue or specimen and the type of study required, based on the clinical information provided to the laboratory.			
CYT.2.1.2	An adequate number of karyotypes are prepared for each patient.			
CYT.2.1.3	The laboratory permanently retains slides, negatives, prints, or magnetic media for all abnormal cases.			
CYT.3	The laboratory obtains and includes in the interpretative report all required clinical information.			
CYT.3.1	The laboratory report includes the following:			
	a) Correct use of appropriate nomenclature			
	b) A summary of the observations			
	c) The number of cells counted and analyzed			
	d) Documentation of any preliminary report, such as a verbal or telephone report			
	e) All required clinical information			
CYT.4	The laboratory maintains individual sample identification during all phases of testing and reporting.			
CYT.4.1	The laboratory uses a systematic process to ensure that individual samples and reports are not misidentified.			

CYT.4.1.1	The laboratory follows written policies and procedures for individual sample identification.			
CYT.4.1.2	Samples are identified in all phases of analysis, including the following:			
	• Specimen collection and accessioning			
	• Cultures			
	• Cell preparations			
	• Photography or other image reproduction technique			
	• Photographic printing and storage			

X
MOLECULAR TESTING

	ROLES AND RESPONSIBILITIES			
	Molecular testing is the analysis or the detection of nucleic acids by hybridization, with or without amplification.			
MT.1	The laboratory follows written policies and procedures for molecular testing that describe the following:			
	a) Appropriateness of testing (Note: For genetic testing, additional information might be required to select appropriate tests and to ensure accurate test interpretation and reporting of results.)			
	b) Prevention of nucleic acid contamination (including in work areas, equipment, personal protective equipment, and reagents) during specimen preparation and testing			
	c) Documentation of all nucleic acid reagents, including probes and primers, used in a particular test			
	d) Quality and quantity of nucleic acid needed for a particular test			
	e) Investigation and corrective action taken for internal controls that fail to amplify			
	f) Competition between target and internal controls (for example, false negatives or presence of a target signal is strong, with a negative internal control signal)			
	g) Investigation of discrepant results between different methods			
	h) Reuse of patient specimens for quality control purposes			
MT 1.1	Validation studies include representatives from each specimen type expected to be tested in the assay and specimens representing the scope of reportable results. The laboratory performs validation studies that include the following:			
	a) Positive and negative representatives from each specimen type expected to be tested in the assay			
	b) Specimens representing the scope of reportable results			
	c) The laboratory performs initial validation for the instruments and analytic systems to verify that the method(s) will produce accurate and reliable results			
	d) Documentation of all aspects of the validation			
MT.2	The laboratory establishes quality control limits, reference ranges, and reportable ranges to ensure that when patient results are reported, they reflect actual normal and abnormal conditions.			
MT.2.1	The laboratory has established control limits for each test. Results are not reported when outside of those limits.			
MT.2.1.1	For quantitative tests, control limits are narrow enough to promote the precision and accuracy of patient test results.			
MT.2.2	The laboratory verifies each test run of patient samples in molecular pathology, using quality controls.			
MT.2.2.1	The laboratory defines the quality control procedure for each testing			

	system or methodology, including the frequency of quality control testing.			
MT.2.2.2	Procedures are consistent with current practice standards for this or similar methodologies and are at least as rigorous as those required or recommended by the manufacturer.			
MT.2.2.3	The laboratory documents quality control.			
MT.3	Molecular testing reports include specific testing information.			
MT.3.1	The laboratory report includes the following information:			
	a) Testing methodology used			
	b) Limitations of the method used			
	c) Any interpretation of findings			
	d) Any recommendations for additional testing			
	e) For assays developed by the laboratory, a statement that the assay was developed by the laboratory			
MT.3.1.1	Reports filed in the patient's clinical record that require specific interpretation are authenticated by the qualified individual making the interpretation.			
	Molecular Genetics			
MT.4	The laboratory follows written policies and procedures for molecular genetic testing.			
MT.4.1	The laboratory follows written policies and procedures that address recommending referral for genetic counseling.			
MT.4.2	The laboratory follows written policies and procedures that address reporting of results when additional information necessary for interpreting test results is not received by the laboratory.			
MT.5	Molecular genetic testing reports include specific testing information.			
MT.5.1	The laboratory reports include the following information:			
	a) List of mutant genes for alleles tested			
	b) Any recommendations for referral to a genetic counselor			
	c) Detection rate of the test			
	d) Use of standard nomenclature for genes and mutations			
	e) Clinical implications of mutations detected			