Joint Commission International

# Joint Commission International Accreditation Standards for Laboratories

**4th Edition** | Effective 1 January 2022

# Section I: Accreditation Participation Requirements

# Accreditation Participation Requirements (APR)

## Requirements

**APR.1** The laboratory meets all requirements for timely submissions of data and information to Joint Commission International (JCI).

**APR.2** The laboratory provides JCI with accurate and complete information through all phases of the accreditation process.

**APR.3** The laboratory reports any changes in the laboratory's services or information provided to JCI via the E-Application any time throughout the accreditation cycle (i.e. before and between surveys).

**APR.4** The laboratory permits evaluations of standards and policy compliance or verification of quality and patient safety concerns, reports, or regulatory authority sanctions at the discretion of JCI.

**APR.5** The laboratory allows JCI to request (from the laboratory or outside agency) and review an original or authenticated copy of the results and reports of external evaluations from publicly recognized bodies.

**APR.6** Currently not in effect.

**APR.7** Not applicable to laboratories.

**APR.8** The laboratory accurately represents its accreditation status and the programs and services to which JCI accreditation applies. Only laboratories with current JCI accreditation may display the Gold Seal of Approval®.

**APR.9** Any individual laboratory staff member (clinical or administrative) can report concerns about safety and quality of care to JCI without retaliatory action from the laboratory.

To support this culture of safety, the laboratory must communicate to staff that such reporting is permitted. In addition, the laboratory must make it clear to staff that no formal disciplinary actions (**for example**, demotions, reassignments, or change in working conditions or hours) or informal punitive actions (**for example**, harassment, isolation, or abuse) will be threatened or carried out in retaliation for reporting concerns to JCI.

**APR.10** Translation and interpretation services arranged by the laboratory for an accreditation survey and any related activities are provided by licensed and/or qualified translation and interpretation professionals who have no relationship to the laboratory.

Qualified translators and interpreters provide to the laboratory and JCI documentation of their experience in translation and interpretation. The documentation may include, but is not limited to, the following:

- Evidence of advanced education in English and in the language of the host laboratory
- Evidence of translation and interpretation experience, preferably in the laboratory or medical field
- Evidence of employment as a professional translator or interpreter, preferably full-time

- Evidence of continuing education in translation and interpretation, preferably in the laboratory or medical field
- Membership(s) in professional translation and interpretation associations
- Translation and interpretation proficiency testing (external quality control) results, when applicable
- Translation and interpretation certifications, when applicable
- Other relevant translation and interpretation credentials

In some cases, JCI can provide organizations with a list of translators and interpreters who meet the requirements listed above.

**APR.11** The laboratory notifies the public it serves about how to contact its laboratory management and JCI to report concerns about safety and quality of services.

Methods of notice may include, but are not limited to, distribution of information about JCI, including contact information, in published materials such as brochures and/or posting this information on the laboratory's website.

Laboratories seeking initial accreditation should be prepared to discuss their plan on how compliance with this APR will be achieved when accredited.

**APR.12** The laboratory provides services in an environment that poses no risk of an immediate threat to patient safety, public health, or staff safety.

# Section II: Patient-Centered Standards

# International Patient Safety Goals (IPSG)

## Goals

### Goal 1: Identify Patients Correctly

**IPSG.1** The laboratory develops and implements a process to improve the accuracy of patient identifications. Ⓟ

### Goal 2: Improve Effective Communication

**IPSG.2** The laboratory develops and implements a process to improve the effectiveness of verbal and/or telephone communication among caregivers. Ⓟ

**IPSG.2.1** The laboratory develops and implements a process for reporting critical results of diagnostic tests. Ⓟ

### Goal 3: Not applicable to Laboratory

### Goal 4: Not applicable to Laboratory

### Goal 5: Reduce the Risk of Health Care–Associated Infections

**IPSG.5** The laboratory adopts and implements evidence-based hand-hygiene guidelines to reduce the risk of health care–associated infections. Ⓟ

**IPSG.5.1** Not applicable to Laboratory

### Goal 6: Not applicable to Laboratory

# Section III:
# Laboratory Organization Management Standards

# Quality Improvement and Patient Safety (QPS)

## Standards

### Management and Coordination of Quality Improvement and Patient Safety Activities

**QPS.1** A qualified individual guides the implementation of the laboratory's program for quality improvement and manages the activities needed to carry out an effective program of continuous quality improvement within the laboratory.

**QPS.2** The leaders define performance and quality control activities used to monitor the laboratory's processes and the systems used to ensure proper operation and control of these processes. Ⓟ

- **QPS.2.1** Leaders manage the quality management and improvement program and periodically review the effectiveness, adequacy, and relevance of the monitoring and improvement activities. Ⓟ

### Laboratory Processes

**QPS.3** The laboratory designs new and redesigns existing systems and processes according to quality improvement and patient safety principles.

### Measure Selection and Data Collection

**QPS.4** The laboratory prioritizes which laboratory processes will be measured, which improvement activities will be implemented, and how success of these laboratory efforts will be measured.

- **QPS.4.1** The laboratory identifies key measures for each of the laboratory's quality structures, processes, and outcomes.
- **QPS.4.2** The laboratory identifies key measures for each of the laboratory's managerial structures, processes, and outcomes.

### Analysis and Validation of Measurement Data

**QPS.5** Individuals with appropriate experience, knowledge, and skills systematically aggregate and analyze data in the laboratory.

**QPS.6** The laboratory uses an internal process to validate data. Ⓟ

**QPS.7** The laboratory collects and analyzes data to monitor its performance.

### Gaining and Sustaining Improvement

**QPS.8** The laboratory achieves and sustains improvement in quality and safety.

**QPS.9** An ongoing program of risk management is used to identify and to proactively reduce unanticipated adverse events and other safety risks to patients and staff. Ⓟ

# Prevention and Control of Laboratory-Acquired Infections (PCI)

## Standards

### Responsibilities and Resources

**PCI.1** The laboratory identifies the individual(s) responsible for managing the prevention and control of infection activities.

**PCI.2** Laboratory leaders designate resources needed to support the infection prevention and control activities.

### Goals of the Infection Prevention and Control Program

**PCI.3** The laboratory sets goals to minimize the possibility of transmitting infections based on its identified risks. Ⓟ

### Laboratory Equipment, Devices, and Supplies

**PCI.4** The laboratory reduces the risk of infection associated with laboratory equipment, devices, and supplies.

### Transmission of Infections

**PCI.5** The laboratory develops, implements, and evaluates an emergency preparedness program to respond to the presentation of global communicable diseases. Ⓟ

**PCI.6** Gloves, masks, eye protection, other protective equipment, soap, and disinfectants are available and used correctly when required.

# Governance, Leadership, and Direction (GLD)

## Standards

### Governance and Laboratory Leadership Accountability

**GLD.1** The laboratory has a leadership structure that is collectively responsible for defining the laboratory's mission and vision and creating the programs and policies needed to fulfill the mission. Ⓟ

**GLD.1.1** A qualified individual(s) is responsible for managing the laboratory service or pathology service. Ⓟ

**GLD.1.2** A qualified individual is responsible for requiring practices that respect the needs of patients and other customers. Ⓟ

### Service and Resource Decisions

**GLD.2** Leadership communicates with key stakeholders in the community to plan the type and scope of services to be provided. Ⓟ

**GLD.2.1** Laboratory leadership is responsible for providing adequate resources for the provision of planned laboratory services.

**GLD.2.2** Laboratory leadership makes decisions related to the purchase or use of resources—human and technical—with an understanding of the quality and safety implications of those decisions.

### Contract and Reference Laboratory Services

**GLD.3** Laboratory leadership is accountable for review, selection, approval, and monitoring of clinical and nonclinical contracts and reference laboratory services. Ⓟ

**GLD.3.1** Contract and reference laboratories used are licensed and accredited or certified by a recognized authority.

**GLD.3.2** Laboratory leadership is responsible for ensuring the consistent performance of contract and reference laboratory services. Ⓟ

### Communication and Coordination

**GLD.4** Laboratory leaders ensure effective communication and coordination throughout the laboratory and with outside customers.

**GLD.4.1** Laboratory leaders develop and implement priorities for meeting the needs of providers, clinicians, patients, and other users of laboratory services. Ⓟ

**GLD.4.2** Laboratory leaders develop and implement processes for communicating with providers who order tests. Ⓟ

## Quality Management System

**GLD.5** Laboratory leaders develop, implement, and monitor a quality management system and provide adequate resources for the program. Ⓟ

**GLD.5.1** The laboratory's quality management system identifies the goals, components, and methodologies required for process design and quality measurement, analysis, and improvement. Ⓟ

## Culture of Safety and Quality

**GLD.6** Leaders create and support a culture of safety program throughout the laboratory. Ⓟ

**GLD.6.1** Leaders implement, monitor, and take action to improve the program for a culture of safety throughout the laboratory. Ⓟ

# Facility Management and Safety (FMS)

## Standards

### Leadership and Planning

**FMS.1** The laboratory complies with relevant laws, regulations, building and fire safety codes, and facility inspection requirements.

**FMS.2** Laboratory leaders plan and provide for sufficient space and resources to support all laboratory areas.

**FMS.2.1** Laboratory storage areas have sufficient space and are maintained under proper conditions for storage.

**FMS.2.2** Records, information, and other patient data are protected from loss, destruction, tampering, unauthorized access, and unsafe storage conditions.

### Risk Assessment and Monitoring

**FMS.3** The laboratory develops and documents a risk assessment based on facility management and safety risks affecting the laboratory environment and implements improvements to reduce and eliminate risks. Ⓟ

### Safety and Security

**FMS.4** The laboratory develops and implements a program to ensure that laboratory services and facilities are safe and secure. Ⓟ

### Hazardous Materials and Waste

**FMS.5** The laboratory develops and implements a program for the management of hazardous materials and waste. Ⓟ

**FMS.5.1** The laboratory's program for management of hazardous materials and waste includes inventory, handling, storage, and proper use. Ⓟ

**FMS.6** When radioactive materials are used in the laboratory, processes are developed and implemented for their safe handling, monitoring, and use. Ⓟ

### Fire Safety

**FMS.7** The laboratory establishes and implements a program for fire safety that includes ongoing assessment of risks and compliance with national and local codes, laws, and regulations. Ⓟ

**FMS.7.1** The fire safety program includes the prevention, early detection, suppression, and containment of fire and smoke, and the safe exit from the facility when fire and nonfire emergencies occur. Ⓟ

**FMS.7.1.1** All fire safety equipment and systems, including devices related to early detection, alarm notification, and suppression, are inspected, tested, and maintained. Ⓟ

**FMS.7.2** The laboratory involves staff in regular exercises to evaluate fire safety programs. Ⓟ

**FMS.7.3** The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility. Ⓟ

## Laboratory Equipment and Supplies

**FMS.8** Laboratory leaders ensure that analytic and other equipment, as well as other material resources required for the provision of services, are adequate and available. Ⓟ

**FMS.8.1** The laboratory establishes and implements a program for inspecting, testing, and maintaining laboratory equipment and documenting results. Ⓟ

**FMS.8.1.1** A historical record is maintained for each analytical instrument and piece of equipment used by the laboratory.

**FMS.9** The laboratory follows guidelines for the periodic evaluation of all reagents, including water, to provide for accuracy and precision of results. Ⓟ

**FMS.9.1** Laboratory records include documentation of required information for reagents, and reagents are completely and accurately labeled.

## Utility Systems

**FMS.10** The laboratory establishes and implements a program to ensure that all utility systems operate effectively and efficiently. Ⓟ

**FMS.10.1** Utility systems are inspected, maintained, and improved.

**FMS.10.2** There is a system to test critical operating components for utility systems and provide for emergency backup for critical utilities. Ⓟ

## Emergency and Disaster Management Program

**FMS.11** The laboratory develops, maintains, and tests an emergency and disaster management program to respond to internal and external emergencies and disasters that have the potential of occurring within the laboratory and community. Ⓟ

## Construction and Renovation

**FMS.12** When planning for construction, renovation, and demolition projects, or maintenance activities that affect laboratory services, the organization conducts a preconstruction risk assessment. Ⓟ

## Education

**FMS.13** Staff and others are trained and knowledgeable about the laboratory's facility management and safety programs and their roles in ensuring a safe and effective facility.

# Staff Qualifications and Education (SQE)

## Standards

### Planning

**SQE.1** Laboratory leaders define the desired education, skills, knowledge, and other requirements of all staff members.

### Staff Qualifications

**SQE.2** Each staff member's responsibilities are defined in a current job description. Ⓟ

**SQE.2.1** Licensed independent practitioners who provide services to the medical laboratory (such as a pathologist) are required to have education, licensure/registration, and other credentials required by laws and regulations verified and kept current.

**SQE.2.2** Supervisory staff and other leaders have the training and expertise to perform all responsibilities.

### Staff Orientation and Education

**SQE.3** All new staff members are oriented to the organization and the laboratory area(s) where they are assigned, as well as to their specific job responsibilities.

**SQE.3.1** Each staff member receives ongoing in-service and other education and training to maintain or to advance his or her skills and knowledge.

### Competence Assessment and Performance Evaluation

**SQE.4** Following orientation and/or training, and at least annually thereafter, the competence of each staff member to perform assigned responsibilities is assessed. Ⓟ

**SQE.4.1** Documented personnel information is maintained for each staff member. Ⓟ

### Staff Health and Safety Program

**SQE.5** The laboratory provides a staff health and safety program that addresses staff physical and mental health and safe working conditions. Ⓟ

**SQE.5.1** The laboratory identifies staff who are at risk for exposure to and possible transmission of vaccine-preventable diseases and implements a staff vaccination and immunization program. Ⓟ

# Management of Information (MOI)

## Standards

### Laboratory Information System

**MOI.1** The laboratory plans and designs the information management system and processes that meet the needs of those who order tests, the organization's leaders, and those outside the laboratory who require data and information from the laboratory. Ⓟ

**MOI.1.1** The laboratory plans for continuity of its information management process. Ⓟ

**MOI.2** The laboratory protects the privacy of health information through processes to manage and control access. Ⓟ

**MOI.3** The laboratory maintains the security and integrity of health information through processes that protect against loss, theft, damage, unauthorized alteration, unintentional change, and accidental destruction. Ⓟ

**MOI.4** The laboratory informatics system provides reliable patient information. Ⓟ

**MOI.5** The laboratory defines and implements processes for validating and maintaining computer software and information when they are used by the laboratory. Ⓟ

**MOI.6** Laboratory staff are educated and trained on the laboratory information systems, information security, and the principles of information use and management. Ⓟ

### Management and Implementation of Documents

**MOI.7** Documents, including policies, procedures, and programs, are managed in a consistent and uniform manner. Ⓟ

**MOI.7.1** The policies, procedures, plans, and other written documents that guide consistent and uniform clinical and nonclinical processes and practices are fully implemented. Ⓟ

### Pre-examination Policies and Procedures

**MOI.8** The laboratory defines policies and procedures for pre-examination processes. Ⓟ

**MOI.8.1** Policies and procedures are developed to provide step-by-step specimen collection protocols for each type of specimen submitted to the laboratory. Ⓟ

**MOI.8.2** Policies and procedures are developed to guide how specimens are accessioned and processed in the laboratory. Ⓟ

### Examination Policies and Procedures

**MOI.9** The laboratory has current descriptions and instructions for each laboratory test. Ⓟ

### Post-examination Policies and Procedures

**MOI.10** The laboratory develops policies, procedures, and controls for the post-examination processes. Ⓟ

**MOI.10.1** The laboratory has defined the process of measuring turnaround times. Ⓟ

**MOI.10.2** The laboratory develops and implements a policy that defines the storage and maintenance requirements for records, retained specimens, slides, tissues, and blocks. Ⓟ

# Section IV: Laboratory Quality Control Standards

# Quality Control Processes (QCP)

## Standards

### Quality Control Common to All Testing

**QCP.1** The laboratory establishes acceptable parameters for quality control for each test method, and quality control data are available and used to monitor and ensure the stability of test systems. Ⓟ

**QCP.1.1** The laboratory performs quality control in the same manner as it performs patient testing.

### Proficiency Testing

**QCP.1.2** The laboratory establishes a program of external graded interlaboratory comparison testing, or proficiency testing, for analytes for each specialty and subspecialty for which such testing is available. Ⓟ

**QCP.1.2.1** Proficiency sample testing is performed in the same manner as patient sample testing.

**QCP.1.2.2** The laboratory uses a system for verifying the accuracy and reliability of test results obtained for those tests not included in the formal proficiency testing program. Ⓟ

### Correlation

**QCP.1.3** The laboratory performs correlations or comparisons to evaluate the results of the same test performed with different methodologies or instruments or at different locations within the same laboratory system. Ⓟ

### Validation Methods

**QCP.1.4** The laboratory performs initial validation for new instruments and analytic systems to verify that the method(s) will produce accurate and reliable results. Ⓟ

### Internal Quality Control

**QCP.1.5** When electronic or internal quality controls are used for routine quality control, the laboratory implements quality control monitoring systems based on risk management. Ⓟ

### Calibration and Calibration Verification

**QCP.1.6** The laboratory performs calibration, calibration verification, and function checks of instruments and analytic systems used for testing. Ⓟ

### Coordinated Quality Control Review

**QCP.1.7** The quality control processes of the laboratory include a process for a coordinated review of patient results, quality control results, and instrument function checks. Ⓟ

**QCP.1.8** The laboratory takes remedial action for deficiencies identified through quality control measures or authorized inspections and documents such actions. Ⓟ

## Histopathology and Immunohistochemistry

### Quality Control

**QCP.2** The histopathology laboratory follows its quality management plan. Ⓟ

**QCP.2.1** The laboratory implements processes for ensuring proper identification, preservation, and documentation of receipt of surgical specimens sent for analysis. Ⓟ

### Gross Examination

**QCP.2.2** The laboratory implements quality control and assurance processes for evaluating the ongoing qualifications of individuals who perform gross analysis of tissue. Ⓟ

**QCP.2.3** There are defined processes to document the ongoing proficiency of individuals who perform microscopic analysis of tissue. Ⓟ

### Full Evaluation of Pathology Specimens

**QCP.2.4** The laboratory has implemented processes to ensure access to required patient information and cross-reference the information to assist in providing a complete and proper diagnosis.

### Immunohistochemistry

**QCP.2.5** The laboratory implements processes for ensuring accurate results when immunohistochemistry is performed. Ⓟ

## Cytopathology

**QCP.3** A pathologist or physician qualified in cytology maintains the quality of the cytopathology services through direct supervision. Ⓟ

**QCP.3.1** The cytology laboratory has a process to measure, assess, and improve quality. Ⓟ

## Autopsy Services

**QCP.4** The laboratory establishes a quality control process for autopsy services. Ⓟ

## Clinical Chemistry, Hematology, and Coagulation

**QCP.5** The laboratory defines quality control processes for all clinical chemistry, hematology, and coagulation tests. Ⓟ

**QCP.5.1** The laboratory defines quality control processes tests that produce quantitative results. Ⓟ

**QCP.5.1.1** The laboratory establishes quality control limits and ranges for manual and automated tests that produce quantitative results. Ⓟ

**QCP.5.2** The laboratory has quality control processes in place for blood film evaluation and differential counts. Ⓟ

## Point-of-Care Services

**QCP.6** A qualified individual is responsible for the oversight and supervision of the point-of-care testing program. Ⓟ

## Bacteriology, Mycobacteriology, and Mycology

### Quality Control

**QCP.7** The laboratory has quality control processes when performing bacteriology, mycobacteriology, and mycology. Ⓟ

**QCP.7.1** The laboratory verifies antibacterial, antimycobacterial, and antifungal susceptibility testing systems with approved reference organisms.

**QCP.7.2** The laboratory uses quality controls to test stains in bacteriology, mycobacteriology, and mycology.

### Microbiology Culture Media

**QCP.7.3** The laboratory tests each type of microbiological culture media with selected organisms to confirm the required growth characteristics.

### Blood Culture

**QCP.7.4** The laboratory has policies and procedures for collection, transport, processing, and interpretation of blood cultures. Ⓟ

## Parasitology

**QCP.8** The laboratory uses parasitology reference materials and a calibrated measuring device for identification and measurement of ova or parasites. Ⓟ

**QCP.8.1** The laboratory performs quality control testing for parasitology permanent stains.

## Virology

**QCP.9** The laboratory has methodologies that are designed to isolate and identify viruses. Ⓟ

**QCP.9.1** For serodiagnostic tests for viral diseases, the laboratory tests components for reactivity.

## Urinalysis and Clinical Microscopy

**QCP.10** The laboratory implements processes to ensure the quality of tests performed in urinalysis and clinical microscopy. Ⓟ

## Immunology and Serology

**QCP.11** The laboratory provides for the accuracy of immunology tests, including syphilis serology, through the use of quality controls and tests for antigen reactivity. Ⓟ

## Radiobioassay

**QCP.12** The laboratory uses quality control procedures that provide diagnostic reliability and patient and staff safety when it uses in vitro radioisotopes. Ⓟ

**QCP.12.1** Any laboratory performing in vivo testing uses an appropriate quality control system for such testing and equipment performance checks. Ⓟ

## Flow Cytometry

**QCP.13** The laboratory provides accurate flow cytometry results. Ⓟ

## Blood Bank Services

### Director Responsibility

**QCP.14** A qualified individual is responsible for blood bank and/or transfusion services and ensures that services adhere to laws and regulations and recognized standards of practice. Ⓟ

### Blood Typing

**QCP.14.1** The laboratory tests donor blood and recipient blood samples with potent typing sera and reactive cells of a known type to determine the correct ABO group and Rh type. Ⓟ

### Blood and Blood Component Inventory

**QCP.14.2** The laboratory has policies and procedures for maintaining a supply of blood and blood components that meets the needs of the patients, including during emergencies. Ⓟ

## Donor Selection and Testing

**QCP.15** There are defined procedures and practices for blood donor selection and blood collection by trained staff. Ⓟ

**QCP.15.1** A detailed history of a donor is performed prior to selection for blood donation.

**QCP.15.2** An adequate physical examination is performed prior to approving the individual as a blood donor.

**QCP.15.3** Guidelines are implemented when autologous blood is collected. Ⓟ

**QCP.15.4** Blood and related donor records are properly identified, and the identification is maintained from collection through the time the unit is transfused.

**QCP.15.5** Donor blood undergoes routine testing before being used for transfusion. Ⓟ

**QCP.15.5.1** Process controls are used to ensure appropriate tracking and prevent blood from being released prematurely. Ⓟ

## Blood Component Preparation and Processing

### Policies and Procedures

**QCP.16** When blood and blood components are prepared or modified by the organization, there are defined procedures for their processing and storage, and appropriate quality control measures are taken. Ⓟ

### Whole Blood

**QCP.16.1** Tests and processes are used to maintain the quality of whole blood. This includes whole blood from which components and products are to be processed. Ⓟ

### Red Blood Cells

**QCP.16.2** Defined processes are implemented to maintain the quality of red blood cells. Ⓟ

### Platelets

**QCP.16.3** Defined processes are used to ensure the quality of platelets. Ⓟ

### Plasma

**QCP.16.4** Defined processes are used to ensure the quality of plasma. Ⓟ

### Cryoprecipitated AHF

**QCP.16.5** Defined processes are used to ensure the quality of cryoprecipitated AHF. Ⓟ

## Blood and Component Storage Requirements

**QCP.17** Storage areas used for blood and components are appropriate for the volume and variety of components stored.

**QCP.17.1** The laboratory maintains and monitors storage areas for blood and components to ensure appropriate temperatures at all times. Ⓟ

**QCP.17.2** The laboratory implements a process for identification and traceability of specimens; reagents; test results; and blood, blood components, and products. Ⓟ

## Blood Administration

### Testing of Blood Prior to Transfusion

**QCP.18** 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. Ⓟ

**QCP.18.1** The potency and reliability of reagents used for ABO grouping, Rh typing, antibody detection, and compatibility determinations are tested for reactivity. Ⓟ

**QCP.18.2** Before blood is administered, compatibility testing and antibody testing are performed.

### Selecting Blood and Components for Transfusion

**QCP.19** Specific procedures are followed when selecting blood and components for transfusion. Ⓟ

### Blood Issuance and Transfusion

**QCP.20** The director of blood transfusion services provides guidance on the practices and procedures for blood and component transfusion. Ⓟ

**QCP.20.1** There are defined processes for checking blood out of the blood bank before transfusion. Ⓟ

**QCP.20.2** Processes used prior to and during blood administration are defined and implemented. Ⓟ

### Recognizing Suspected Transfusion Reactions

**QCP.20.3** The organization has policies and procedures to monitor and evaluate the patient and report suspected transfusion-related adverse events. Ⓟ

### Blood Donor and Transfusion Services Record Requirements

**QCP.21** The laboratory retains records on receipt, testing, and disposition of blood and blood components.

### Therapeutic Apheresis

**QCP.22** The laboratory (or designated department in a health care organization [**for example**, hospital] setting) performs, monitors, and documents therapeutic apheresis procedures. Ⓟ

## Histocompatibility

### Quality Control and Validation Methods

**QCP.23** The laboratory uses quality control practices and validation methods for histocompatibility testing. Ⓟ

**QCP.23.1** The laboratory performs mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens according to defined methods. Ⓟ

### HLA Serologic Typing

**QCP.23.2** The laboratory performs HLA serologic typing of both donor and recipient as appropriate to the study or individual procedure performed. Ⓟ

### Crossmatching

**QCP.23.3** 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.

**QCP.23.4** The laboratory uses reagents and antisera that are specific and verified with controls when available.

### Specimen Storage

**QCP.23.5** Storage of records and specimens is addressed.

## Cytogenetics

### Cytogenetics Testing

**QCP.24** Laboratory procedures and practices in cytogenetics provide for accurate results. Ⓟ

**QCP.24.1** Laboratory records identify the media used, the reactions observed, and the details of each step of the identification procedure.

**QCP.24.2** The laboratory obtains and includes in the interpretative report all required clinical information.

**QCP.24.3** The laboratory maintains individual sample identification during all phases of testing and reporting. Ⓟ

### Fluorescence In Situ Hybridization (FISH)

**QCP.24.4** The cytogenetic laboratory collects data and establishes quality control procedures for fluorescence in situ hybridization (FISH). Ⓟ

## Molecular Methods and Testing

### Policies and Procedures

**QCP.25** The laboratory establishes policies and procedures for molecular testing. Ⓟ

**QCP.25.1** Validation studies include each specimen type tested in the assay representing the scope of reportable results. Ⓟ

### Quality Management Systems

**QCP.25.2** The laboratory establishes quality management systems for molecular testing.

**QCP.25.3** The laboratory uses appropriate and approved quality control materials to verify each test run or batch of patient samples for molecular testing. Ⓟ

### Molecular Testing Report

**QCP.25.4** The laboratory's molecular testing reports include specific testing information. Ⓟ

### Molecular Genetics

**QCP.25.5** The laboratory establishes policies and procedures for molecular genetic testing. Ⓟ

### Next-Generation Sequencing

**QCP.25.6** The laboratory validates next-generation sequencing bioinformatics pipelines.

### Molecular Microbiology

**QCP.26** There are adequate quality control procedures when molecular microbiology testing is performed.

## Andrology

**QCP.27** The laboratory establishes quality control processes and procedures for an accurate semen analysis. Ⓟ

## Embryology

### Leadership Oversight

**QCP.28** A qualified individual is responsible for the oversight and supervision of the embryology laboratory.

### Quality Control

**QCP.28.1** The embryology laboratory establishes policies and procedures to provide accurate results. Ⓟ

**QCP.28.2** The embryology laboratory documents its quality control and validation methods. Ⓟ

### Special Equipment and Laboratory Environment Maintenance

**QCP.28.3** The embryology laboratory maintains suitable environment, space, and equipment to provide service.

### Specimen Identification and Integrity

**QCP.28.4** The embryology laboratory follows its policies and procedures for maintaining specimen identification and integrity during the receipt or transfer of cryopreserved oocytes, sperm, embryos, and other human tissues. Ⓟ

### Specimen Tracking and Recording

**QCP.28.5** The embryology laboratory has a method of tracking cryopreserved oocytes, sperm, embryos, and other human tissues. Ⓟ

**QCP.28.6** The embryology laboratory maintains records during all phases of testing and reporting. Ⓟ

**QCP.28.7** The embryology laboratory establishes protocols for chain of custody and use of reference laboratories. Ⓟ