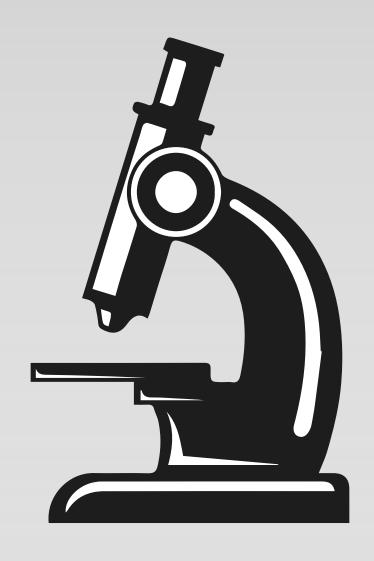
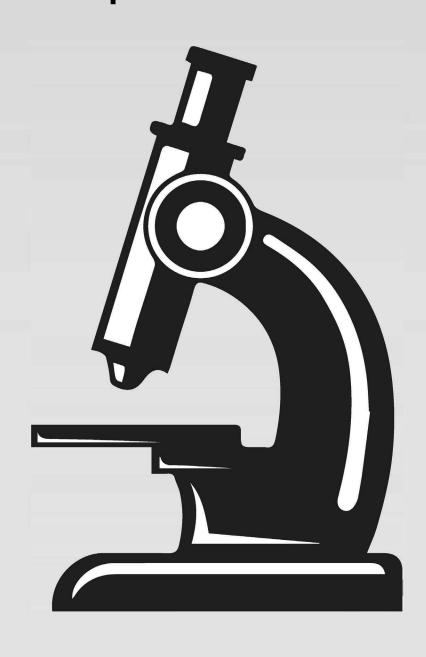


Joint Commission International Accreditation Standards for

Laboratories



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.

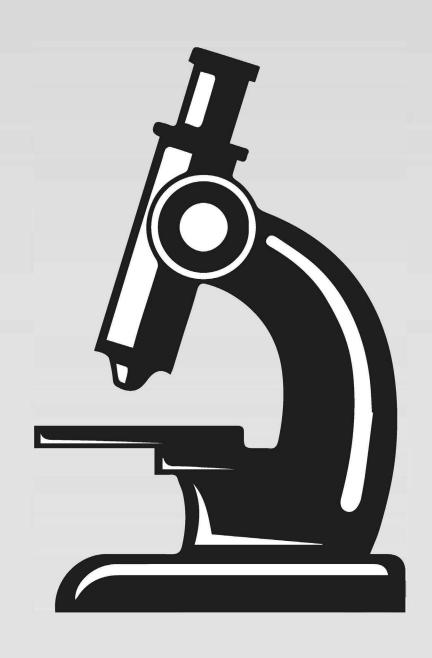
APR.11 The laboratory notifies the public it serves about how to contact its laboratory management and JCI to report concerns about safety and quality of services.

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

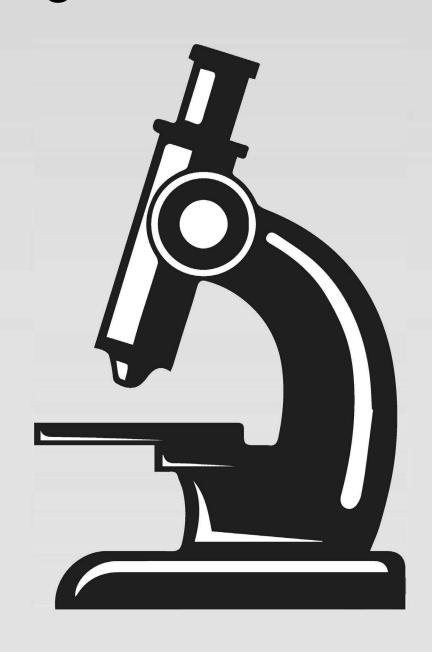


International Patient Safety Goals (IPSG)

Goals

- **Goal 1: Identify Patients Correctly**
- **Goal 2: Improve Effective Communication**
- - **IPSG.2.1** The laboratory develops and implements a process for reporting critical results of diagnostic tests. **(P)**
- Goal 3: Not applicable to Laboratory
- Goal 4: Not applicable to Laboratory
- Goal 5: 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. (P)
 - **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. (P)

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. **P**
- **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.

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

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. **(P)**
- **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. **(P)**
 - **GLD.1.1** A qualified individual(s) is responsible for managing the laboratory service or pathology service. **P**
 - **GLD.1.2** A qualified individual is responsible for requiring practices that respect the needs of patients and other customers. **P**

Service and Resource Decisions

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

Communication and Coordination

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

Quality Management System

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

 ②

Culture of Safety and Quality

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

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.

①

Safety and Security

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

Hazardous Materials and Waste

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

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

 ①

Fire Safety

- - **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. **P**

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

 ①
- **FMS.7.3** The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility.

 ①

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.

 ①
 - **FMS.8.1** The laboratory establishes and implements a program for inspecting, testing, and maintaining laboratory equipment and documenting results.

 ①
 - **FMS.8.1.1** A historical record is maintained for each analytical instrument and piece of equipment used by the laboratory.
- - **FMS.9.1** Laboratory records include documentation of required information for reagents, and reagents are completely and accurately labeled.

Utility Systems

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

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.

①

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. P
 - **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.4.1** Documented personnel information is maintained for each staff member. **②**

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. (P)

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. **(P)**
 - **MOI.1.1** The laboratory plans for continuity of its information management process. **(P)**
- **MO1.2** The laboratory protects the privacy of health information through processes to manage and control access. **(P)**
- **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. (P)
- **MOI.4** The laboratory informatics system provides reliable patient information. **(P)**
- **MOI.5** The laboratory defines and implements processes for validating and maintaining computer software and information when they are used by the laboratory. **(P)**
- **MOI.6** Laboratory staff are educated and trained on the laboratory information systems, information security, and the principles of information use and management. **P**

Management and Implementation of Documents

- - **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. (P)

Pre-examination Policies and Procedures

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

Examination Policies and Procedures

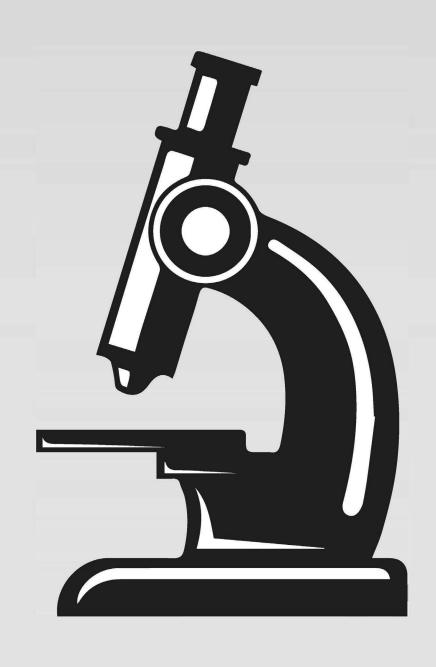
MOI.9 The laboratory has current descriptions and instructions for each laboratory test. **(P)**

Post-examination Policies and Procedures

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

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

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.

②

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

Proficiency Testing

QCP.1.2

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

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.

①

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.

②

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. (P)

Calibration and Calibration Verification

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

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. (P)

Histopathology and Immunohistochemistry

Quality Control

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.

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

Cytopathology

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

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

Autopsy Services

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

①

Clinical Chemistry, Hematology, and Coagulation

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

- **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. **(P)**

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.

 ②
 - **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

Parasitology

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

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. **(P)**

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. (P)

Immunology and Serology

Radiobioassay

Flow Cytometry

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

Blood Bank Services

Director Responsibility

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. **(P)**
 - **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.15.4** 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.

 ②

Blood Component Preparation and Processing

Policies and Procedures

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.

②

Red Blood Cells

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

Platelets

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

Plasma

Cryoprecipitated AHF

QCP.16.5 Defined processes are used to ensure the quality of cryoprecipitated AHF. **②**

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

 Output

 Description:

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.

 ②

 - **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.20.2** 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. **②**

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.

②

Histocompatibility

Quality Control and Validation Methods

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

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.

②

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.24.1** 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

Fluorescence In Situ Hybridization (FISH)

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

①

Molecular Methods and Testing

Policies and Procedures

Quality Management Systems

- **QCP.25.2** The laboratory establishes quality management systems 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. **(P)**

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.

②

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. (P)

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. **(P)**

Specimen Tracking and Recording

- **QCP.28.5** The embryology laboratory has a method of tracking cryopreserved oocytes, sperm, embryos, and other human tissues. **(P)**
- **QCP.28.6** The embryology laboratory maintains records during all phases of testing and reporting. **(P)**
- **QCP.28.7** The embryology laboratory establishes protocols for chain of custody and use of reference laboratories. **(P)**