The Joint Commission

• Issued June 20, 2023 •

# Revisions and Deletions Related to the Standards Simplification Project

Laboratory (LAB) Accreditation Program

## Document and Process Control (DC) Chapter

### DC.01.02.01

**Current Requirement Text:**

The laboratory performs testing based on written (paper or electronic) laboratory test orders.

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| **DC.01.02.01** | **EP:** 3 | **DC.01.02.01** | **EP:** 3 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Laboratory test orders are made in writing (paper or electronic).<br>Note: The test order may be located in the clinical record. | | Laboratory test orders are made in writing (paper or electronic).<br>Note 1: The test order may be located in the clinical record.<br>Note 2: Laboratory test orders are legible. | |
| **DC.01.02.01** | **EP:** 4 | **DC.01.02.01** | **EP:** 3 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Orders for laboratory tests are legible. | | Laboratory test orders are made in writing (paper or electronic).<br>Note 1: The test order may be located in the clinical record.<br>Note 2: Laboratory test orders are legible. | |

# Environment of Care (EC) Chapter

## EC.01.01.01

**Current Requirement Text:**

The laboratory plans activities that minimize risks in the environment of care.
Note: One or more persons can be assigned to manage risks associated with the management plans described in this standard.

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| **EC.01.01.01** | **EP:** 4 | **EC.01.01.01** | **EP:** 4 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has a written plan for providing a safe environment for everyone who enters the laboratory's facilities. | | The laboratory has a written plan for providing a safe and secure environment for everyone who enters the laboratory's facilities. | |

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| **EC.01.01.01** | **EP:** 5 | **EC.01.01.01** | **EP:** 4 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has a written plan for providing a secure environment for everyone who enters the laboratory's facilities. | | The laboratory has a written plan for providing a safe and secure environment for everyone who enters the laboratory's facilities. | |

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| **EC.01.01.01** | **EP:** 8 |
| **Current EP Text:** | **Revision Type:** Deleted |
| The laboratory has a written plan for managing the following: Laboratory equipment. | |

## EC.02.03.05

**Current Requirement Text:**

The laboratory maintains fire safety equipment and fire safety building features. Note: This standard does not require laboratories to have the types of fire safety equipment and building features described in the elements of performance of this standard. However, if these types of equipment or features exist within the building, then the following maintenance, testing, and inspection requirements apply.

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| **EC.02.03.05** | **EP:** 21 | **EC.02.03.05** | **EP:** 21 |
| **Current EP Text:** | **Revision Type:** Revised | **New EP Text:** | |
| The laboratory tests fire-alarm and fire-detection systems in time frames it establishes. The completion date of the tests is documented. | | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): The laboratory tests fire-alarm and fire-detection systems in time frames it establishes. The completion date of the tests is documented. | |
| **EC.02.03.05** | **EP:** 22 | **EC.02.03.05** | **EP:** 22 |
| **Current EP Text:** | **Revision Type:** Revised | **New EP Text:** | |
| Every 12 months, the laboratory performs preventive maintenance on fire-alarm and fire-detection system components. The completion date of the maintenance is documented. | | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Every 12 months, the laboratory performs preventive maintenance on fire-alarm and fire-detection system components. The completion date of the maintenance is documented. | |
| **EC.02.03.05** | **EP:** 23 | **EC.02.03.05** | **EP:** 23 |
| **Current EP Text:** | **Revision Type:** Revised | **New EP Text:** | |
| Every 12 months, the laboratory inspects and tests (with or without discharge) automatic fire-extinguishing systems. The completion date of the tests is documented. | | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Every 12 months, the laboratory inspects and tests (with or without discharge) automatic fire-extinguishing systems. The completion date of the tests is documented. | |
| **EC.02.03.05** | **EP:** 24 | **EC.02.03.05** | **EP:** 24 |
| **Current EP Text:** | **Revision Type:** Revised | **New EP Text:** | |
| Fans or dampers in air-handling and smoke-management systems are functional. | | For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): Fans or dampers in air-handling and smoke-management systems are functional. | |

## EC.02.05.01

**Current Requirement Text:**

The laboratory manages risks associated with its utility systems.

**EC.02.05.01** **EP:** 9

**Current EP Text:** **Revision Type:** Revised

The laboratory labels utility system controls so that staff are able to partially or completely shut down systems in emergencies.

**EC.02.05.01** **EP:** 9

**New EP Text:**

For laboratories that are independent organizations (not owned by or affiliated with a health care organization, such as reference laboratories): The laboratory labels utility system controls so that staff are able to partially or completely shut down systems in emergencies.

## EC.02.06.05

**Current Requirement Text:**

The laboratory manages its environment during demolition, renovation, or new construction to reduce risk to those in the laboratory.

**EC.02.06.05** **EP:** 5

**Current EP Text:** **Revision Type:** Deleted

When site conditions or specific clinical needs require modification of design criteria, the laboratory identifies the need to train staff about using space and equipment.

## EC.03.01.01

**Current Requirement Text:** **Revision Type:** Deleted

Staff are familiar with their roles and responsibilities relative to the environment of care.

**EC.03.01.01** **EP:** 2

**Current EP Text:** **Revision Type:** Deleted

Staff can describe or demonstrate actions to take in the event of an environment of care incident.

## EC.04.01.01

**Current Requirement Text:**

The laboratory collects information to monitor conditions in the environment.

**EC.04.01.01** **EP:** 1

**Current EP Text:** **Revision Type:** Revised

The laboratory establishes a process(es) for continually monitoring, internally reporting, and investigating the following:
- Injuries to patients or others within the laboratory
- Occupational illnesses and staff injuries
- Incidents of damage to its property or the property of others in locations it controls
- Security incidents involving patients, staff, or others in locations it controls
- Hazardous materials and waste spills and exposures
- Fire safety management problems, deficiencies, and failures
- Laboratory equipment management problems, failures, and use errors
- Utility systems management problems, failures, or use errors

Note 1: All the incidents and issues listed above may be reported to staff in quality assessment, improvement, or other functions. A summary of such incidents may also be shared with the person designated to coordinate safety management activities.
Note 2: Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve laboratory services, or to prevent similar incidents, are not lost as a result of following the legal process.

**EC.04.01.01** **EP:** 1

**New EP Text:**

The laboratory develops and implements process(es) for continually monitoring, internally reporting, and investigating the following:
- Injuries to patients or others within the laboratory
- Occupational illnesses and staff injuries
- Incidents of damage to its property or the property of others in locations it controls
- Security incidents involving patients, staff, or others in locations it controls
- Hazardous materials and waste spills and exposures
- Fire safety management problems, deficiencies, and failures
- Laboratory equipment management problems, failures, and use errors
- Utility systems management problems, failures, or use errors

Note 1: All the incidents and issues listed above may be reported to staff in quality assessment, improvement, or other functions. A summary of such incidents may also be shared with the person designated to coordinate safety management activities.
Note 2: Review of incident reports often requires that legal processes be followed to preserve confidentiality. Opportunities to improve laboratory services, or to prevent similar incidents, are not lost as a result of following the legal process.

**EC.04.01.01** **EP:** 3

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Injuries occurring in the laboratory.

**EC.04.01.01** **EP:** 4

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Occupational illnesses and staff injuries.

**EC.04.01.01** **EP:** 5

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Incidents of damage to its property or the property of others in locations it controls.

**EC.04.01.01** **EP:** 6

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Security incidents involving patients, staff, or others in locations it controls.

**EC.04.01.01** **EP:** 8

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Hazardous materials and waste spills and exposures.

**EC.04.01.01** **EP:** 9

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Fire safety management problems, deficiencies, and failures.

**EC.04.01.01** **EP:** 10

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Laboratory equipment management problems, failures, and use errors.

**EC.04.01.01** **EP:** 11

**Current EP Text:** **Revision Type:** Deleted

The laboratory reports and investigates the following: Utility systems management problems, failures, or use errors.

**EC.04.01.01** **EP:** 15

**Current EP Text:** **Revision Type:** Consolidated

Every 12 months, the laboratory evaluates each environment of care management plan, including a review of the plan’s objectives, scope, performance, and effectiveness.

**EC.04.01.01** **EP:** 15

**New EP Text:**

Every 12 months, the laboratory evaluates each environment of care management plan, including a review of the plan’s objectives, scope, performance, and effectiveness. Based on the results of the analysis, the lab identifies opportunities to resolve any environmental safety issues and takes action on them.

## EC.04.01.03

**Current Requirement Text:** **Revision Type:** Deleted

The laboratory analyzes identified environment of care issues.

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| **EC.04.01.03** | **EP:** 2 | **EC.04.01.01** | **EP:** 15 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory uses the results of data analysis to identify opportunities to resolve environmental safety issues. | | Every 12 months, the laboratory evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness. Based on the results of the analysis, the lab identifies opportunities to resolve any environmental safety issues and takes action on them. | |

## EC.04.01.05

**Current Requirement Text:** **Revision Type:** Deleted

The laboratory improves its environment of care.

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| **EC.04.01.05** | **EP:** 1 | **EC.04.01.01** | **EP:** 15 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory takes action on the identified opportunities to resolve environmental safety issues. | | Every 12 months, the laboratory evaluates each environment of care management plan, including a review of the plan's objectives, scope, performance, and effectiveness. Based on the results of the analysis, the lab identifies opportunities to resolve any environmental safety issues and takes action on them. | |

# Human Resources (HR) Chapter

## HR.01.06.01

**Current Requirement Text:**

Staff are competent to perform their responsibilities.

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| **HR.01.06.01** | **EP:** 15 | **HR.01.06.01** | **EP:** 18 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory takes action when a staff member's competence does not meet expectations. | | The laboratory conducts the following competency assessments for staff and takes action when a staff member's competence does not meet expectations:<br>- Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing<br>- Monitoring, recording, and reporting of test results<br>- Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance<br>- Direct observation of performance of instrument maintenance function checks and calibration<br>- Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples)<br>- Problem-solving skills as appropriate to the job<br>(See also WT.03.01.01, EP 6) | |

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| **HR.01.06.01** | **EP:** 18 | **HR.01.06.01** | **EP:** 18 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The staff member's competency assessment includes the following:<br>- Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing<br>- Monitoring, recording, and reporting of test results<br>- Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance<br>- Direct observation of performance of instrument maintenance function checks and calibration<br>- Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples)<br>- Problem-solving skills as appropriate to the job<br>(See also WT.03.01.01, EP 6) | | The laboratory conducts the following competency assessments for staff and takes action when a staff member's competence does not meet expectations:<br>- Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen collection, handling, processing, and testing<br>- Monitoring, recording, and reporting of test results<br>- Review of intermediate test results or worksheets, quality control, proficiency testing, and preventive maintenance performance<br>- Direct observation of performance of instrument maintenance function checks and calibration<br>- Test performance as defined by laboratory policy (for example, testing previously analyzed specimens, internal blind testing samples, external proficiency, or testing samples)<br>- Problem-solving skills as appropriate to the job<br>(See also WT.03.01.01, EP 6) | |

# Information Management (IM) Chapter

## IM.02.01.03

**Current Requirement Text:**

The laboratory maintains the security and integrity of health information.

**IM.02.01.03** **EP:** 7

**Current EP Text:** **Revision Type:** Deleted

The laboratory controls the intentional destruction of health information.

## IM.02.02.01

**Current Requirement Text:**

The laboratory effectively manages the collection of health information.

**IM.02.02.01** **EP:** 2

**Current EP Text:** **Revision Type:** Deleted

The laboratory uses standardized terminology, definitions, abbreviations, acronyms, symbols, and dose designations.

# Leadership (LD) Chapter

## LD.02.01.01

**Current Requirement Text:**

The mission, vision, and goals of the laboratory support the safety and quality of laboratory services.

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| **LD.02.01.01** | **EP:** 1 | **LD.02.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Leaders work together to create the laboratory's mission, vision, and goals. | | Leaders work together to create the laboratory's mission, vision, and goals, which guide the leaders' actions and are communicated to staff and the population(s) the laboratory serves. | |
| **LD.02.01.01** | **EP:** 2 | **LD.02.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's mission, vision, and goals guide the actions of leaders. | | Leaders work together to create the laboratory's mission, vision, and goals, which guide the leaders' actions and are communicated to staff and the population(s) the laboratory serves. | |
| **LD.02.01.01** | **EP:** 3 | **LD.02.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Leaders communicate the mission, vision, and goals to staff and the population(s) the laboratory serves. | | Leaders work together to create the laboratory's mission, vision, and goals, which guide the leaders' actions and are communicated to staff and the population(s) the laboratory serves. | |

## LD.03.05.01

**Current Requirement Text:**

Leaders manage change to improve the performance of the laboratory.

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| **LD.03.05.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Deleted |
| The laboratory has a systematic approach to change and performance improvement. | |

## LD.03.06.01

**Current Requirement Text:**

Those who work in the laboratory are focused on improving safety and quality.

**LD.03.06.01** **EP:** 4

**Current EP Text:** **Revision Type:** Deleted

Leaders evaluate the effectiveness of those who work in the laboratory to promote safety and quality.

## LD.03.07.01

**Current Requirement Text:**

Leaders establish priorities for performance improvement. (Refer to the "Performance Improvement" [PI] chapter.)

**LD.03.07.01** **EP:** 1

**Current EP Text:** **Revision Type:** Consolidated

Performance improvement occurs laboratorywide.

**LD.03.07.01** **EP:** 2

**New EP Text:**

As part of performance improvement, leaders do the following laboratorywide:
- Set priorities for performance improvement activities and patient health outcomes
- Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities
- Identify the frequency of data collection for performance improvement activities
- Reprioritize performance improvement activities in response to changes in the internal or external environment

(See also PI.01.01.01, EPs 2, 6, 7, 17; PI.02.01.01, EP 1)

**LD.03.07.01** **EP:** 2

**Current EP Text:** **Revision Type:** Consolidated

As part of performance improvement, leaders do the following:
- Set priorities for performance improvement activities and patient health outcomes
- Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities
- Identify the frequency of data collection for performance improvement activities
- Reprioritize performance improvement activities in response to changes in the internal or external environment

(See also PI.01.01.01, EPs 2, 6, 7, 17; PI.02.01.01, EP 1)

**LD.03.07.01** **EP:** 2

**New EP Text:**

As part of performance improvement, leaders do the following laboratorywide:
- Set priorities for performance improvement activities and patient health outcomes
- Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities
- Identify the frequency of data collection for performance improvement activities
- Reprioritize performance improvement activities in response to changes in the internal or external environment

(See also PI.01.01.01, EPs 2, 6, 7, 17; PI.02.01.01, EP 1)

## LD.04.02.01

**Current Requirement Text:** **Revision Type:** Revised

The leaders address any conflict of interest involving licensed practitioners and/or staff that affects or has the potential to affect the safety or quality of laboratory services.

## LD.04.02.01

**New Requirement Text:**

The leaders address any conflict of interest that affects or has the potential to affect the safety or quality of laboratory services.

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**LD.04.02.01** **EP:** 2

**Current EP Text:** **Revision Type:** Consolidated

The leaders follow a written policy that defines situations that represent a conflict of interest involving licensed practitioners and/or staff and how the laboratory will address these conflicts of interest.

**LD.04.02.01** **EP:** 2

**New EP Text:**

The leaders follow a written policy that defines situations that represent a conflict of interest, the need to disclose the conflicts, and how the laboratory will address these conflicts of interest.

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**LD.04.02.01** **EP:** 3

**Current EP Text:** **Revision Type:** Consolidated

Existing or potential conflicts of interest involving licensed practitioners and/or staff, as defined by the laboratory, are disclosed.

**LD.04.02.01** **EP:** 2

**New EP Text:**

The leaders follow a written policy that defines situations that represent a conflict of interest, the need to disclose the conflicts, and how the laboratory will address these conflicts of interest.

# National Patient Safety Goals (NPSG) Chapter

## NPSG.02.03.01

**Current Requirement Text:**

Report critical results of tests and diagnostic procedures on a timely basis.

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| **NPSG.02.03.01** | **EP:** 1 | **NPSG.02.03.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Collaborate with organization leaders to develop written procedures for managing the critical results of tests and diagnostic procedures that address the following:<br>- The definition of critical results of tests and diagnostic procedures<br>- By whom and to whom critical results of tests and diagnostic procedures are reported<br>- The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures | | Collaborate with organization leaders to develop and implement written procedures for managing the critical results of tests and diagnostic procedures that address the following:<br>- The definition of critical results of tests and diagnostic procedures<br>- By whom and to whom critical results of tests and diagnostic procedures are reported<br>- The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures | |

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| **NPSG.02.03.01** | **EP:** 2 | **NPSG.02.03.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Implement the procedures for managing the critical results of tests and diagnostic procedures. | | Collaborate with organization leaders to develop and implement written procedures for managing the critical results of tests and diagnostic procedures that address the following:<br>- The definition of critical results of tests and diagnostic procedures<br>- By whom and to whom critical results of tests and diagnostic procedures are reported<br>- The acceptable length of time between the availability and reporting of critical results of tests and diagnostic procedures | |

# Quality System Assessment for Nonwaived Testing (QSA) Chapter

## QSA.04.04.01

**Current Requirement Text:**

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

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| **QSA.04.04.01** | **EP:** 5 | **QSA.04.04.01** | **EP:** 5 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory performs quality control testing on each batch, lot number, and shipment of specialized microbiological culture media with a relatively high failure rate for identifying fastidious organisms. The quality control results are documented. | | The laboratory performs quality control testing on each batch, lot number, and shipment of specialized microbiological culture media with a relatively high failure rate for identifying fastidious organisms, and reports any detected deterioration to the manufacturer. The quality control results are documented. | |
| **QSA.04.04.01** | **EP:** 6 | **QSA.04.04.01** | **EP:** 5 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory reports deterioration in the microbiological culture media to the manufacturer. This report is documented. | | The laboratory performs quality control testing on each batch, lot number, and shipment of specialized microbiological culture media with a relatively high failure rate for identifying fastidious organisms, and reports any detected deterioration to the manufacturer. The quality control results are documented. | |

## QSA.04.07.01

**Current Requirement Text:**

The laboratory has written policies and procedures for the collection, transport, processing, and interpretation of blood cultures.

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| **QSA.04.07.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Deleted |
| The laboratory defines the recommended volume of blood to be drawn for each blood culture. Definition is based on an approved clinical guideline, * manufacturers' requirements, and instrument specifications.<br>Footnote *: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document M47 (Principles and Procedures for Blood Cultures). | |

## QSA.05.02.01

**Current Requirement Text:**

A supply of blood and blood components that meets the needs of the patients, the services provided by the organization, and the clinical staff is available at all times to the organization.

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| **QSA.05.02.01** | **EP:** 1 | **QSA.05.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has written policies and procedures for maintaining a minimum inventory of blood and blood components. | | The laboratory develops and implements written policies and procedures for maintaining a minimum inventory of blood and blood components based on the needs of the patients, the services provided by the organization, and the clinical staff. | |
| **QSA.05.02.01** | **EP:** 2 | **QSA.05.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory establishes a minimum inventory of blood and blood components based on the needs of the patients, the services provided by the organization, and the clinical staff. | | The laboratory develops and implements written policies and procedures for maintaining a minimum inventory of blood and blood components based on the needs of the patients, the services provided by the organization, and the clinical staff. | |
| **QSA.05.02.01** | **EP:** 3 | **QSA.05.02.01** | **EP:** 3 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| A written agreement with a blood supplier includes the following:<br>- The responsibilities of both parties and approval by the transfusion service director or administrator<br>- The process for procurement, transfer, and availability of blood and blood components if the laboratory itself does not provide blood banking services on site<br>- The notification by the blood supplier to the laboratory's transfusion service that a donor of blood or blood product shipped for the transfusion subsequently tests positive for human immunodeficiency virus (HIV) or hepatitis C (HCV) | | A written agreement with a blood supplier includes the following:<br>- The responsibilities of both parties and approval by the transfusion service director or administrator<br>- The process for procurement, transfer (including transport), and availability of blood and blood components if the laboratory itself does not provide blood banking services on site<br>- The notification by the blood supplier to the laboratory's transfusion service that a donor of blood or blood product shipped for the transfusion subsequently tests positive for human immunodeficiency virus (HIV) or hepatitis C (HCV) | |

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| **QSA.05.02.01** | **EP:** 4 | **QSA.05.02.01** | **EP:** 3 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Transportation for the blood and blood components from the supplier is available. | | A written agreement with a blood supplier includes the following:<br>- The responsibilities of both parties and approval by the transfusion service director or administrator<br>- The process for procurement, transfer (including transport), and availability of blood and blood components if the laboratory itself does not provide blood banking services on site<br>- The notification by the blood supplier to the laboratory's transfusion service that a donor of blood or blood product shipped for the transfusion subsequently tests positive for human immunodeficiency virus (HIV) or hepatitis C (HCV) | |

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| **QSA.05.02.01** | **EP:** 5 | **QSA.05.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory follows its policies and procedures for maintaining a minimum inventory of blood and blood components. | | The laboratory develops and implements written policies and procedures for maintaining a minimum inventory of blood and blood components based on the needs of the patients, the services provided by the organization, and the clinical staff. | |

## QSA.05.02.03

**Current Requirement Text:**

The laboratory has policies and procedures for maintaining blood and blood components for emergencies.

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| **QSA.05.02.03** | **EP:** 1 | **QSA.05.02.03** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations. | | The laboratory develops and implements written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations that address the following, at a minimum:<br>- The minimum inventory of blood and blood components to be maintained by the blood bank<br>- The arrangements for obtaining blood and blood components from community blood sources within a time frame defined by the organization | |

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| **QSA.05.02.03** | **EP:** 2 | **QSA.05.02.03** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Policies and procedures for obtaining blood or blood components needed in urgent or emergent situations address the following:<br>- The minimum inventory of blood and blood components to be maintained by the blood bank<br>- The arrangements for obtaining blood and blood components from community blood sources within a time frame defined by the organization | | The laboratory develops and implements written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations that address the following, at a minimum:<br>- The minimum inventory of blood and blood components to be maintained by the blood bank<br>- The arrangements for obtaining blood and blood components from community blood sources within a time frame defined by the organization | |

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| **QSA.05.02.03** | **EP:** 3 | **QSA.05.02.03** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory follows its policies and procedures for obtaining blood or blood components needed in urgent or emergent situations. | | The laboratory develops and implements written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations that address the following, at a minimum:<br>- The minimum inventory of blood and blood components to be maintained by the blood bank<br>- The arrangements for obtaining blood and blood components from community blood sources within a time frame defined by the organization | |

## QSA.05.05.01

**Current Requirement Text:**

The laboratory uses sera, antisera, cells, and reagents of the same quality as federally licensed equivalents.

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| **QSA.05.05.01** | **EP:** 1 | **QSA.05.05.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory defines in writing its criteria for use of sera, antisera, cells, and reagents. | | The laboratory defines in writing and follows its criteria for use of sera, antisera, cells, and reagents. | |

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| **QSA.05.05.01** | **EP:** 6 | **QSA.05.05.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory follows its criteria for use of sera, antisera, cells, and reagents. | | The laboratory defines in writing and follows its criteria for use of sera, antisera, cells, and reagents. | |

## QSA.05.07.01

**Current Requirement Text:**

The organization labels blood specimens drawn from a recipient for typing and crossmatching.

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| **QSA.05.07.01** | **EP:** 1 | **QSA.05.07.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The organization has written policies and procedures addressing specimen collection for typing and crossmatching. | | The organization develops and implements written policies and procedures addressing specimen collection for typing and crossmatching. | |
| **QSA.05.07.01** | **EP:** 7 | **QSA.05.07.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The organization follows its policies and procedures addressing specimen collection for typing and crossmatching. | | The organization develops and implements written policies and procedures addressing specimen collection for typing and crossmatching. | |

## QSA.05.09.01

**Current Requirement Text:**

The laboratory has policies and procedures for serologic and computer (if performed) compatibility testing of donor blood with recipient blood.

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| **QSA.05.09.01** | **EP:** 1 | **QSA.05.09.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has written policies and procedures for compatibility testing of the donor’s blood with the recipient’s blood. | | The laboratory develops and implements written policies and procedures for compatibility testing of the donor’s blood with the recipient’s blood, including but not limited to evaluating the compatibility of the donor's blood and the recipient's blood for any blood products containing more than 2 milliliters of red blood cells. The results are documented. | |
| **QSA.05.09.01** | **EP:** 4 | **QSA.05.09.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood for any blood products containing greater than 2 mL of red blood cells. The results are documented. | | The laboratory develops and implements written policies and procedures for compatibility testing of the donor’s blood with the recipient’s blood, including but not limited to evaluating the compatibility of the donor's blood and the recipient's blood for any blood products containing more than 2 milliliters of red blood cells. The results are documented. | |

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| **QSA.05.09.01** | **EP:** 9 | **QSA.05.09.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood. The results of this test are documented. | | The laboratory develops and implements written policies and procedures for compatibility testing of the donor’s blood with the recipient’s blood, including but not limited to evaluating the compatibility of the donor's blood and the recipient's blood for any blood products containing more than 2 milliliters of red blood cells. The results are documented. | |

## QSA.05.13.01

**Current Requirement Text:**

The laboratory has written policies and procedures that address Rh immune globulin (RhIG) administration.

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| **QSA.05.13.01** | **EP:** 1 | **QSA.05.13.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory’s written policies and procedures for the administration of Rh immune globulin address:<br>- Criteria to identify patients eligible for prophylaxis<br>- Procedure to determine dose of RhIG required<br>- Optimal timing of administration following exposure | | The laboratory develops and implements written policies and procedures for the administration of Rh immune globulin that address the following:<br>- Criteria to identify patients eligible for prophylaxis<br>- Procedure to determine dose of RhIG required<br>- Optimal timing of administration following exposure | |
| **QSA.05.13.01** | **EP:** 2 | **QSA.05.13.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory follows its policies and procedures for RhIG administration. | | The laboratory develops and implements written policies and procedures for the administration of Rh immune globulin that address the following:<br>- Criteria to identify patients eligible for prophylaxis<br>- Procedure to determine dose of RhIG required<br>- Optimal timing of administration following exposure | |

## QSA.13.02.01

**Current Requirement Text:**

Surgical specimens are accompanied by supporting clinical information and preoperative and postoperative diagnoses to the degree known.

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| **QSA.13.02.01** | **EP:** 1 | **QSA.13.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Requests for examining surgical specimens are accompanied by preoperative and postoperative diagnoses to the degree known. | | Requests for examining surgical specimens are accompanied by preoperative and postoperative diagnoses to the degree known and supporting clinical information as indicated by patient history and laboratory policy. | |
| **QSA.13.02.01** | **EP:** 2 | **QSA.13.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| Requests for examining surgical specimens are accompanied by supporting clinical information as indicated by patient history and laboratory policy. | | Requests for examining surgical specimens are accompanied by preoperative and postoperative diagnoses to the degree known and supporting clinical information as indicated by patient history and laboratory policy. | |

## QSA.13.05.01

**Current Requirement Text:**

The laboratory manages hazards associated with the use of an electron microscope.

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| **QSA.13.05.01** | **EP:** 1 | **QSA.13.05.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope. | | The laboratory develops and implements written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope. | |
| **QSA.13.05.01** | **EP:** 2 | **QSA.13.05.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory uses precautions related to radiation and electrical hazards of an electron microscope. | | The laboratory develops and implements written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope. | |

## QSA.15.01.01

**Current Requirement Text:**

The laboratory uses written policies and procedures for molecular testing.

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| **QSA.15.01.01** | **EP:** 1 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory follows its written policies and procedures for molecular testing. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 2 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Appropriateness of testing.<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships). | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 3 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 4 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Prevention of sample degradation. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 5 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Documentation of all nucleic acid reagents, including probes and primers, used in a particular test. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 6 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>The quality and quantity of nucleic acid required for a particular test. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 7 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Investigation and corrective action for internal controls that fail to amplify. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 8 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal). | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 9 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Investigation of discrepant results between different methods. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 10 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Reuse of patient specimens for quality control purposes. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 11 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production). | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 12 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>The criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal). | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 13 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Verification of patient nucleic acid integrity and labeling. | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

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| **QSA.15.01.01** | **EP:** 14 | **QSA.15.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's policies and procedures for molecular testing address the following:<br>Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors.<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | | The laboratory develops and implements written policies and procedures for molecular testing that address but are not limited to the following:<br>- Appropriateness of testing<br>Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).<br>- Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing<br>- Prevention of sample degradation<br>- Documentation of all nucleic acid reagents, including probes and primers, used in a particular test<br>- Quality and quantity of nucleic acid required for a particular test<br>- Investigation and corrective action for internal controls that fail to amplify<br>- Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal)<br>- Investigation of discrepant results between different methods<br>- Reuse of patient specimens for quality control purposes<br>- Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production)<br>- Criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal)<br>- Verification of patient nucleic acid integrity and labeling<br>- Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors<br>Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments). | |

## QSA.15.02.01

**Current Requirement Text:**

The laboratory performs validation studies for molecular testing.

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| **QSA.15.02.01** | **EP:** 1 | **QSA.15.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's validation studies for molecular testing include positive and negative representatives from each specimen type expected to be tested in the assay. | | The laboratory's validation studies for molecular testing include the following:<br>- Positive and negative representatives from each specimen type expected to be tested in the assay<br>- Specimens representing the scope of reportable results<br>- All steps from extraction to final results<br>Note: When a laboratory does not perform all or part of the testing process on site, the laboratory performing the test is responsible for documenting proper validation of the entire testing process (for example, next-generation sequencing and bioinformatics). | |
| **QSA.15.02.01** | **EP:** 2 | **QSA.15.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's validation studies for molecular testing include specimens representing the scope of reportable results. | | The laboratory's validation studies for molecular testing include the following:<br>- Positive and negative representatives from each specimen type expected to be tested in the assay<br>- Specimens representing the scope of reportable results<br>- All steps from extraction to final results<br>Note: When a laboratory does not perform all or part of the testing process on site, the laboratory performing the test is responsible for documenting proper validation of the entire testing process (for example, next-generation sequencing and bioinformatics). | |
| **QSA.15.02.01** | **EP:** 3 | **QSA.15.02.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory's validation studies for molecular testing cover all steps from extraction to final results.<br>Note: When a laboratory does not perform all or part of the testing process on site, the laboratory performing the test is responsible for documenting proper validation of the entire testing process (for example, next-generation sequencing and bioinformatics). | | The laboratory's validation studies for molecular testing include the following:<br>- Positive and negative representatives from each specimen type expected to be tested in the assay<br>- Specimens representing the scope of reportable results<br>- All steps from extraction to final results<br>Note: When a laboratory does not perform all or part of the testing process on site, the laboratory performing the test is responsible for documenting proper validation of the entire testing process (for example, next-generation sequencing and bioinformatics). | |

## QSA.17.01.01

**Current Requirement Text:**

The laboratory uses parasitology reference materials and a calibrated measuring device for determining the size of ova or parasites.

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| **QSA.17.01.01** | **EP:** 1 | **QSA.17.01.01** | **EP:** 4 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has written procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites. | | The laboratory develops and implements its procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites. | |
| **QSA.17.01.01** | **EP:** 4 | **QSA.17.01.01** | **EP:** 4 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory follows its procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites. | | The laboratory develops and implements its procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites. | |

## QSA.19.01.01

**Current Requirement Text:**

When the laboratory uses in vivo or in vitro radioisotopes, it uses procedures that are safe to patients and staff and that provide accurate results.

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| **QSA.19.01.01** | **EP:** 1 | **QSA.19.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory has written procedures for quality control, reagent handling, and specimen handling for radiobioassay tests.<br>Note: For quality control requirements, please refer to the clinical chemistry section of this chapter, Standard QSA.06.01.01. | | The laboratory develops and implements written procedures for quality control, reagent handling, and specimen handling for radio bioassay tests that address the following:<br>- Performing background counts<br>- Calibrating equipment<br>- Safety measures for decontamination<br>- Handling radioactive isotopes<br>- Handling radioactive waste<br>- Posting for the presence of radioactive materials<br>- Monitoring the radiation area (for example, wipe tests)<br>Note: For activities to minimize risks associated with radioactive materials, please refer to the "Environment of Care" (EC) chapter, Standard EC.02.02.01. For quality control requirements, please refer to the clinical chemistry section of this chapter, Standard QSA.06.01.01. For guidelines, see the Nuclear Regulatory Commission requirements and National Council on Radiation Protection and Measurements. | |

**QSA.19.01.01** **EP:** 2

**Current EP Text:** **Revision Type:** Consolidated

The laboratory addresses the following related to radiobioassay tests: *
- Performing background counts
- Calibrating equipment
- Safety measures for decontamination
- Handling radioactive isotopes
- Handling radioactive waste
- Posting for the presence of radioactive materials
- Monitoring the radiation area (for example, wipe tests)

Note: For activities to minimize risks associated with radioactive materials, please refer to the "Environment of Care" (EC) chapter, Standard EC.02.02.01.
Footnote *: For guidelines, see the Nuclear Regulatory Commission requirements and National Council on Radiation Protection and Measurements.
(See also EC.02.02.01, EP 6)

**QSA.19.01.01** **EP:** 1

**New EP Text:**

The laboratory develops and implements written procedures for quality control, reagent handling, and specimen handling for radio bioassay tests that address the following:
- Performing background counts
- Calibrating equipment
- Safety measures for decontamination
- Handling radioactive isotopes
- Handling radioactive waste
- Posting for the presence of radioactive materials
- Monitoring the radiation area (for example, wipe tests)

Note: For activities to minimize risks associated with radioactive materials, please refer to the "Environment of Care" (EC) chapter, Standard EC.02.02.01. For quality control requirements, please refer to the clinical chemistry section of this chapter, Standard QSA.06.01.01. For guidelines, see the Nuclear Regulatory Commission requirements and National Council on Radiation Protection and Measurements.

**QSA.19.01.01** **EP:** 3

**Current EP Text:** **Revision Type:** Consolidated

The laboratory follows its procedures for quality control, reagent handling, and specimen handling for radiobioassay tests.

**QSA.19.01.01** **EP:** 1

**New EP Text:**

The laboratory develops and implements written procedures for quality control, reagent handling, and specimen handling for radio bioassay tests that address the following:
- Performing background counts
- Calibrating equipment
- Safety measures for decontamination
- Handling radioactive isotopes
- Handling radioactive waste
- Posting for the presence of radioactive materials
- Monitoring the radiation area (for example, wipe tests)

Note: For activities to minimize risks associated with radioactive materials, please refer to the "Environment of Care" (EC) chapter, Standard EC.02.02.01. For quality control requirements, please refer to the clinical chemistry section of this chapter, Standard QSA.06.01.01. For guidelines, see the Nuclear Regulatory Commission requirements and National Council on Radiation Protection and Measurements.

## QSA.20.01.01

**Current Requirement Text:**

The laboratory obtains and maintains information and records of complete semen analysis.

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| **QSA.20.01.01** | **EP:** 1 | **QSA.20.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The collection information for semen analysis includes the following: Method of collection. The information is documented. | | The collection information for semen analysis includes the following:<br>- Method of collection.<br>- Type of specimen container<br>- Days of abstinence<br>The information is documented. | |
| **QSA.20.01.01** | **EP:** 2 | **QSA.20.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The collection information for semen analysis includes the following: Type of specimen container. The information is documented. | | The collection information for semen analysis includes the following:<br>- Method of collection.<br>- Type of specimen container<br>- Days of abstinence<br>The information is documented. | |
| **QSA.20.01.01** | **EP:** 3 | **QSA.20.01.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The collection information for semen analysis includes the following: Days of abstinence. The information is documented. | | The collection information for semen analysis includes the following:<br>- Method of collection.<br>- Type of specimen container<br>- Days of abstinence<br>The information is documented. | |
| **QSA.20.01.01** | **EP:** 4 | **QSA.20.01.01** | **EP:** 4 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The sample quality for semen analysis includes the following: Collection or transport problems (for example, exposure to temperatures, incomplete specimen). The information is documented. | | The sample quality for semen analysis includes the following:<br>- Collection or transport problems (for example, exposure to temperatures, incomplete specimen)<br>- Time of specimen receipt and analysis<br>- Abnormalities of liquefaction<br>The information is documented. | |

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| **QSA.20.01.01** | **EP:** 5 | **QSA.20.01.01** | **EP:** 4 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The sample quality for semen analysis includes the following: Time of specimen receipt and analysis. The information is documented. | | The sample quality for semen analysis includes the following:<br>- Collection or transport problems (for example, exposure to temperatures, incomplete specimen)<br>- Time of specimen receipt and analysis<br>- Abnormalities of liquefaction<br>The information is documented. | |

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| **QSA.20.01.01** | **EP:** 6 | **QSA.20.01.01** | **EP:** 4 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The sample quality for semen analysis includes the following: Abnormalities of liquefaction. The information is documented. | | The sample quality for semen analysis includes the following:<br>- Collection or transport problems (for example, exposure to temperatures, incomplete specimen)<br>- Time of specimen receipt and analysis<br>- Abnormalities of liquefaction<br>The information is documented. | |

## QSA.21.03.01

**Current Requirement Text:**

The laboratory maintains records of virology testing processes.

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| **QSA.21.03.01** | **EP:** 1 | **QSA.21.03.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory maintains records on the following: Cell lines used to isolate viruses. | | The laboratory maintains records on the following:<br>- Cell lines used to isolate viruses.<br>- Test methods used to detect or identify viruses<br>- Reactions observed as part of the virology testing processes (for example, cytopathic effects [CPE]) | |

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| **QSA.21.03.01** | **EP:** 2 | **QSA.21.03.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory maintains records on the following: Test methods used to detect or identify viruses. | | The laboratory maintains records on the following:<br>- Cell lines used to isolate viruses.<br>- Test methods used to detect or identify viruses<br>- Reactions observed as part of the virology testing processes (for example, cytopathic effects [CPE]) | |

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| **QSA.21.03.01** | **EP:** 3 | **QSA.21.03.01** | **EP:** 1 |
| **Current EP Text:** | **Revision Type:** Consolidated | **New EP Text:** | |
| The laboratory maintains records on the following: Reactions observed as part of the virology testing processes (for example, cytopathic effects [CPE]). | | The laboratory maintains records on the following:<br>- Cell lines used to isolate viruses.<br>- Test methods used to detect or identify viruses<br>- Reactions observed as part of the virology testing processes (for example, cytopathic effects [CPE]) | |