



The Joint Commission

Accreditation Program: Laboratory
Quality System Assessment for Nonwaived
Testing

Standard QSA.01.01.01

The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.

Note: This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).

Rationale for QSA.01.01.01

Proficiency testing determines how well a laboratory’s results compare with those of other laboratories that use the same methodologies. Such testing can identify patterns of performance problems that may not be otherwise recognized by internal mechanisms (for example, quality control, preventive maintenance, competence evaluations).

Elements of Performance for QSA.01.01.01

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| 1. | <p>D The laboratory participates in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program that meets regulatory requirements for variety and frequency of testing. (See also LD.04.05.07, EP 4)</p> <p>Footnote 1: For information on current proficiency testing providers, see http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp#TopOfPage.</p> <p>Footnote 2: The Joint Commission annually verifies enrollment in a proficiency testing program onsite and by review of proficiency testing enrollment verification. For more information on proficiency testing, see http://www.jointcommission.org/AccreditationPrograms/LaboratoryServices/ProficiencyTesting/.</p> | A |
| 2. | <p>The laboratory authorizes the proficiency testing program to release all data required to determine the laboratory's compliance for proficiency testing and makes proficiency testing results available to the public as required in the Public Health Service Act, Section 353(f)(3)(F).</p> | A |
| 3. | <p>The laboratory uses a proficiency testing program for each regulated analyte performed.</p> | A |
| 4. | <p>The laboratory participates in the same approved proficiency testing program(s) for a full calendar year before designating a different proficiency testing program. If the laboratory designates a different proficiency testing program before the conclusion of a full calendar year, it notifies the Centers for Medicare & Medicaid Services (CMS) or The Joint Commission before this change is made.</p> | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

5. For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation. **C**
- Note 1: Satisfactory performance criteria in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, include the following:
- Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.
 - Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing
 - Attaining a score of 100% for ABO group and Rho(D) typing or compatibility testing
 - Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.
 - Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.
- Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer. (For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)
6. The laboratory's proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation. **A**
- Note: Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, as a failure to achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.

7. Individuals who examine gynecologic preparations participate in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program that meets regulatory requirements for variety and frequency of testing and satisfactory performance criteria. **A**
- Note 1: For an individual who fails an annual proficiency testing event (< 90% on a 10-slide proficiency test), the laboratory schedules a retesting event that takes place not more than 45 days after the receipt of the notification of failure. Steps of retesting include the following:
- A 10-slide retest (event #2), performed within 2 hours, in which a score of 90% is acceptable
 - For an individual who fails the 10-slide retest (event #2), the laboratory provides remedial training and education in the area of failure and has evidence that all patient gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide proficiency test (event #3), performed within 4 hours, in which a score of 90% is acceptable.
 - An individual who fails the last 20-slide proficiency test (event #3) ceases examining gynecologic slide preparations immediately upon notification of test failures and may not resume examining gynecologic slides until the laboratory has evidence that the individual obtained at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until the individual is retested with another 20-slide proficiency test and scores at least 90%.
 - This final cycle continues until the individual successfully participates in another 20-slide proficiency test.
- Note 2: Unexcused absence by an individual for a retest will result in a test failure.
(See also QSA.01.02.01, EP 5)

Standard QSA.01.02.01

The laboratory maintains records of its participation in a proficiency testing program.

Rationale for QSA.01.02.01

The laboratory uses results outside acceptable ranges as an opportunity to correct problems, educate staff, prevent recurrence of problems, and improve the quality of services it provides.

Elements of Performance for QSA.01.02.01

1. The laboratory analyzes and reports results for each testing period during the two years prior to survey for accreditation by The Joint Commission. **A**
- Note: The laboratory may consider retaining records for a minimum of five years to address potential Centers for Medicare & Medicaid Services (CMS)–required follow-up for repeated unsuccessful proficiency testing.
2. **D** For individual unacceptable proficiency testing results, the laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action sufficient to address and correct the issues identified in the investigation. **A**
- These actions are documented. (See also QSA.01.01.01, EP 5)
- Note 1: This requirement also applies when the proficiency testing program does not obtain consensus for scoring purposes, or the laboratory receives a score of 0 for nonparticipation or late return of results.
- Note 2: This requirement also applies when the laboratory’s cumulative score for the event meets the Clinical Laboratory Improvement Amendments of 1988 (CLIA ‘88) requirements for satisfactory performance.

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- 3. **D** The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented. **A**
- 4. The laboratory retains proficiency testing records for at least two years from the date of participation for the following proficiency testing events: **A**
 - Each proficiency testing result
 - Test handling
 - Preparation
 - Processing
 - Examination
 - Each step in the testing
 - Signed attestation statement(s) provided by the proficiency program
 - A copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results
 - Corrective action taken
- 5. **D** For cytology proficiency testing, the laboratory maintains records of acceptable testing performance, or documentation of retesting and corrective action, for individuals engaged in the examination of gynecologic preparations. (See also QSA.01.01.01, EP 7) **A**

Standard QSA.01.03.01

The laboratory has a process for handling and testing proficiency testing samples.

Elements of Performance for QSA.01.03.01



- 1. **D** The laboratory has written policies and procedures for testing proficiency testing samples. **A**
- 2. The laboratory tests proficiency testing samples according to its policies and procedures. **A**
- 3. The laboratory performs proficiency testing for each test method used as the primary method under each Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate for each regulated analyte. **A**
 Note: Proficiency testing for secondary analyzers is not required.
 (See also QSA.02.08.01, EP 1 for correlation study requirements between primary and secondary methods)
- 4. Proficiency testing samples are tested along with the laboratory's regular patient testing workload by staff who perform the laboratory's testing. **A**
- 5. The laboratory rotates proficiency testing samples among the staff who perform patient testing. **A**
- 6. The laboratory's staff tests the proficiency testing samples the same number of times that they test patient samples. **A**
- 7. **D** The laboratory staff who performed the proficiency testing and the laboratory director or technical supervisor sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens. **A**

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Standard QSA.01.04.01

The laboratory performs its proficiency testing independent of other laboratories.




Elements of Performance for QSA.01.04.01





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| 1. | The laboratory does not send the proficiency testing samples to another laboratory for analysis. (See also APR.01.02.01, EP 1) |  A |
| 2. | Communication between laboratories (interlaboratory and laboratories with multiple sites or separate locations) about the results of proficiency testing samples does not occur until after the date by which the laboratory must report proficiency testing results to the program for the testing event. |  A |
| 3. | The laboratory notifies the Centers for Medicare & Medicaid Services (CMS) or The Joint Commission of proficiency testing samples received from another laboratory for testing. | A |

Standard QSA.01.05.01

The laboratory verifies the accuracy and reliability of results obtained for nonregulated analytes and for those regulated analytes for which compatible proficiency testing samples are not available.

Elements of Performance for QSA.01.05.01

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| 1. | <p> The laboratory has written policies and procedures that include acceptability criteria to verify the accuracy and reliability of results obtained for nonregulated analytes and for those regulated analytes for which compatible proficiency testing samples are not available.</p> <p>Note: Acceptable methods of accuracy verification for nonregulated analytes include the following:</p> <ul style="list-style-type: none"> - The laboratory uses proficiency testing. - Every six months, the laboratory sends five specimens to a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)-certified reference laboratory for comparison with its own results. - Interlaboratory quality control results are used to verify the continuing reliability of the tests not included in the proficiency testing program (for example, peer comparisons). - Throughout the year, the technical supervisor of the laboratory retests a random sample of microscopic tests from each staff who performs such testing. - Duplicate testing is performed by two different individuals who perform such tests as reticulocyte counts, urine sediments, and crystal identification. | A |
| 2. | <p> The laboratory performs verification testing at least every six months. The verification is documented.</p> | A |
| 3. | <p> When performance verification is unacceptable, the laboratory performs an investigation of all potential causes, evidence of review, and corrective action sufficient to address and correct the issues identified in the investigation. These activities are documented.</p> | A |




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

Standard QSA.02.01.01

The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.

Note: This standard also applies to instruments on loan when the original instrument is under repair.

Elements of Performance for QSA.02.01.01

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| <p>1. D When adding or replacing an unmodified U.S. Food and Drug Administration (FDA)–approved test, method, or instrument, the laboratory verifies the manufacturer’s performance specifications, including the following:</p> <ul style="list-style-type: none"> - Accuracy - Precision - Reportable range <p>The verification is documented.</p> | <p> A</p> |
| <p>2. D When adding or replacing a modified test, method, or instrument, the laboratory establishes written performance specifications that include the following:</p> <ul style="list-style-type: none"> - Accuracy - Precision - Reportable range - Analytical sensitivity - Analytical specificity <p>Note: Modified tests, methods, or instruments include the following:</p> <ul style="list-style-type: none"> - Test procedures with modifications to the U.S. Food and Drug Administration (FDA)–approved use for specimen type, reagents, instrument, procedural steps, or other components - Tests or methods developed in the laboratory with no FDA evaluation - Tests, methods, or instruments not subject to FDA clearance | <p> A</p> |
| <p>3. D When replacing an old test, method, or instrument, the laboratory’s verification includes a correlation between the old and new test, method, or instrument. The correlation is documented.</p> <p>Note 1: This element of performance also applies when reference tests are brought in-house.</p> <p>Note 2: The laboratory has the discretion to determine the minimum number of data points and acceptable levels of correlation required for statistical validity and clinical usage of the test result.</p> | <p>A</p> |
| <p>4. D For a new test, method, or instrument, the laboratory verifies that the reference intervals (normal ranges) apply to the test, method, or instrument and population served. The verification is documented.</p> | <p>A</p> |
| <p>5. D The laboratory performs verifications for each new test, method, or instrument prior to reporting patient results. These verifications are documented.</p> | <p> A</p> |
| <p>6. D The laboratory’s verification includes the establishment of written quality control procedures for each testing system or methodology.</p> | <p>A</p> |

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| 7. | The laboratory's quality control procedure for each testing system or methodology includes the following: <ul style="list-style-type: none"> - The range of quality control values used - The frequency of quality control testing - Adherence to the manufacturer's recommendations - The predicted reliability based on history - The specialty and subspecialty requirements included in this chapter | A |
| 8. | Over time, the laboratory monitors the accuracy and precision of test performance that may be influenced by changes in the following: <ul style="list-style-type: none"> - Test system performance - Environmental conditions - Variance in operator performance | A |

Standard QSA.02.02.01

The laboratory performs calibration and recalibration.

Rationale for QSA.02.02.01

Calibration requirement and methods are based on manufacturer's directions. Procedures that may be exempt from calibration requirements include manual procedures that do not use instrumentation, microscopic procedures, and procedures involving instruments that do not lend themselves to calibration.

Elements of Performance for QSA.02.02.01

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| 1. | D The laboratory has a written procedure for calibration that includes, at a minimum, the following: <ul style="list-style-type: none"> - The requirements established by the instrument manufacturer - The number of calibration levels - The type of calibration materials used - The concentration of the calibration materials - The frequency of calibration - The acceptable performance limits for the calibration | A |
| 2. | The laboratory performs calibration using materials traceable to a national reference standard, when available. | A |
| 3. | If quality control materials are used for calibration, the laboratory uses different lot numbers than those used for routine quality control testing. | A |
| 4. | D The laboratory follows its procedure for calibration. The calibration performance is documented. | A |

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5. **D** The laboratory recalibrates when indicated by evaluation of the following data: **A**
- Calibration
 - Calibration verification
 - Quality control results
 - Performance and function checks
- The recalibration is documented. (See also EC.02.04.01, EP 3; QSA.02.11.01, EPs 1-7)

Standard QSA.02.03.01

The laboratory performs calibration verification.

Elements of Performance for QSA.02.03.01

1. **D** The laboratory has a written procedure for calibration verification that includes the following, at a minimum: **A**
- The requirements established by the instrument manufacturer
 - The number of calibration verification levels
 - The type of calibration verification materials used
 - The concentration of the calibration verification materials
 - The frequency of calibration verification
 - The acceptable performance limits for the calibration verification
2. The laboratory tests the reportable range of results during the calibration verification process, including a minimal value, a midpoint value, and a maximum value based on the manufacturer’s directions and instrument history. **A**
 Note: The Joint Commission does not require the purchase of commercial linearity kits to meet this requirement. Quality control materials, previously tested proficiency testing samples with known results, and calibration materials are acceptable to use for calibration verification.
3. Calibration verification is performed every six months. **A**
 Note: Semiannual calibration verification is not required when the laboratory performs calibration at least once every six months using three or more levels of calibration materials that include a low, mid, and high value.
4. Calibration verification is performed whenever the following events occur: **A**
- A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.
 - Major preventive maintenance is performed, or critical parts are replaced that may influence test performance.
 - Quality control results indicate that there may be a problem with the test system.
 - An environmental change occurs, including instrument relocation.
 - An instrument has been replaced.
 - Quality control materials reflect an unusual trend or shift or are outside the laboratory’s acceptable limits, and other means of assessing and correcting unacceptable quality control values fail to identify and correct the problem.
5. **D** The laboratory follows its procedure for calibration verification. The calibration verification performance is documented. **A**

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Standard QSA.02.04.01

The laboratory evaluates instrument-based testing with electronic or internal systems prior to using them for routine quality control.

Rationale for QSA.02.04.01

Advancements in laboratory technology have led to test systems that often include alternative quality control monitoring systems, such as electronic simulators, internal controls, or procedural controls. These systems can monitor the entire analytical process or part of the analytic process. They may be used as the routine daily quality control when they have been properly validated and when external quality control is performed on a periodic basis. For test systems without internal monitoring systems, the frequency of external controls may not be reduced and traditional external quality control is required each day of patient testing.

Note: When using internal monitoring systems as the routine quality control, the laboratory still complies with other Joint Commission standards scored elsewhere in this manual, including, but not limited to, method validation, daily surveillance of results, ongoing competency assessment of the staff performing tests, ongoing instrument maintenance and testing, proficiency testing or other means of verifying accuracy of the method, performance improvement, and adequate oversight of the testing activity.

Elements of Performance for QSA.02.04.01

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| 1. | When the laboratory evaluates instrument-based testing with electronic or internal systems, the test being performed is a moderately complex test in routine chemistry or hematology. | A |
| 2. | <p>D For each test system, the laboratory evaluates the sources of error, including personnel, training, and competency, and determines whether the electronic or internal quality controls monitor the entire analytical process or a portion of the analytical process. The results are documented.</p> <p>Note: This information may be included in the manufacturer's package insert or requested from the manufacturer via written documentation.</p> | A |
| 3. | <p>D The laboratory conducts an evaluation of the electronic or internal quality controls by testing external quality controls in parallel with the electronic or internal quality controls for the following:</p> <ul style="list-style-type: none"> - 10 consecutive days of testing for test systems that monitor the entire analytical process - 30 consecutive days of testing for test systems that monitor a portion of the analytical process <p>The evaluation of the electronic or internal quality controls is documented.</p> <p>Note: Consecutive days include only those days when the laboratory actually performs or would perform the test.</p> | A |
| 4. | <p>Through its evaluation and data analysis activities, the laboratory defines the variety and frequency of external quality control sufficient to prevent clinically significant errors in patient test results.</p> <p>Note 1: Unless the manufacturer requires more frequent testing, the frequency of testing external quality controls may be reduced from daily to at least the following:</p> <ul style="list-style-type: none"> - Once monthly for test systems that monitor the entire analytical process - Once weekly for test systems that monitor a portion of the analytical process <p>Note 2: For a test system without internal quality controls, frequency of external quality controls may not be reduced.</p> | A |

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- M** 5. **D** The laboratory performs at least two levels of electronic or internal quality controls at the same frequency as required in the specialty and subspecialty sections of this manual, or more frequently if recommended by the manufacturer or defined by laboratory procedure. The electronic or internal quality control results are documented. **C**

Note: The minimum frequency for performing two levels of electronic or internal quality controls can be found at the following specialties/subspecialties:

 - Routine chemistry (refer to QSA.06.01.01)
 - Blood gases (refer to QSA.06.02.01)
 - Hematology (refer to QSA.11.01.01)
 - Coagulation (refer to QSA.11.02.01)
- 6. **D** The laboratory performs external quality controls at the following frequencies: **A**

 - As defined by the evaluation (either weekly or monthly)
 - According to the manufacturer's recommendations
 - With each new lot number, shipment, or package of reagents

The external quality control results are documented.
- 7. **D** The laboratory performs external quality controls at the number of levels specified by the specialty and subspecialty requirements (for example, blood gases require three levels of quality control). The external quality control results are documented. **A**
- 8. **D** The laboratory conducts an investigation, identifies the root causes, performs corrective action, and restarts the evaluation of the electronic or internal quality controls if any of the following occur: **A**

 - Proficiency testing is unsatisfactory
 - Analytic system quality assessment is unacceptable
 - Competency assessment is unacceptable
 - There are two consecutive unacceptable quality control results (internal or external) for the same level or measurement either during the evaluation process or after the laboratory has reduced the frequency of testing external quality control materials. (After the first unacceptable quality control result, the laboratory repeats the quality control and meets the criteria for acceptability before reporting patient results.)

The corrective action is documented. (See also QSA.02.12.01, EPs 4-8)

Standard QSA.02.05.01

The laboratory evaluates noninstrument-based testing with internal quality control systems prior to using them for routine quality control.

Elements of Performance for QSA.02.05.01

- 1. If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it performs an evaluation of the internal quality controls against the external quality controls. **A**

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- 2. **D** If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it defines in writing the frequency of external quality controls based on the following: **A**
 - Its evaluation
 - An interval that meets manufacturers' recommendations
 - The use of each new lot number, shipment, or package of reagents
- 3. **D** If the laboratory uses noninstrument-based testing with internal positive and negative quality controls as the daily quality control, it performs external quality controls at its defined frequencies. The external quality controls are documented. **A**

Standard QSA.02.06.01

Each laboratory specialty and subspecialty has a quality control policy.

Elements of Performance for QSA.02.06.01

- 1. **D** A written quality control policy exists for each specialty and subspecialty offered as part of pathology and clinical laboratory services. **A**
- 2. The quality control policy defines the number, type, and frequency of quality control materials according to the following: **A**
 - Manufacturers' recommendations
 - Performance specifications verified or established by the laboratory
 - Specialty and subspecialty requirements found in this chapter for quality control testing
- 3. The quality control policy includes the quality control criteria for acceptability for each test. **A**
- 4. The quality control policy includes acceptable quality control limits and reportable ranges for each test. **A**
- 5. Quality control limits are strict enough to promote precision and accuracy for reliable patient test results. **A**
- 6. Quality control limits and reportable ranges provide results with meaningful clinical applications. **A**

Note 1: Package insert quality control limits may be too wide to meet the elements of performance (EPs) for this standard. Quality control limits are based at least in part on laboratory-specific data, except as indicated in the EPs for standard QSA.02.07.01.

Note 2: For manual tests that do not lend themselves to traditional quality control methods, alternative procedural controls with established limits may be used to verify the results. For example, manual reticulocyte counts could be verified by a specified percentage agreement of the results from two slides.
- 7. The laboratory's quality control policy is accessible to staff. **A**

Standard QSA.02.07.01

The laboratory has its own quality control ranges with valid statistical measurements for each procedure.

Elements of Performance for QSA.02.07.01

- 1. **D** Before using control material for quality control purposes, the laboratory defines, in writing, control ranges for each lot number. **A**

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- 2. **D** The laboratory determines through repetitive testing the statistical parameters for each lot number of control material, including mean, standard deviation, and coefficient of variation. The parameters are documented. **A**
- 3. If the laboratory's calculated control ranges reflect variance from previously established ranges, the laboratory investigates, resolves discrepancies, and provides the rationale for its decision. **A**
- 4. The stated values of an assayed control material may be used as the target values, provided the stated values correspond to the methodology and instrumentation used by the laboratory and are verified by the laboratory through repetitive testing. **A**
- 5. **D** A manufacturer's control range may be used if the laboratory can verify that the mean it obtained reflects the manufacturer's mean. The verification is documented. **A**
 Note: The laboratory may use values from package inserts only until it has established its own control ranges, or if the test is used so infrequently that calculations of valid statistics are not possible, or if a pattern of using package insert values does not exist.
- 6. **D** A manufacturer's control range may be used if the laboratory director determines, in writing, that the manufacturer's range is narrow enough to provide results with meaningful clinical applications. **A**
- 7. **D** The laboratory establishes statistical parameters for unassayed control materials over time through concurrent testing of control materials with previously determined statistical parameters. The established statistical parameters are documented. **A**
- 8. **D** For hematology and coagulation testing: The laboratory generates statistics using the standard deviation of duplicate pairs when using patient samples as controls. The statistics are documented. **A**
 Note: Patient controls may be used to supplement the commercial controls if an acceptable level of precision has been defined.

Standard QSA.02.08.01

The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.

Elements of Performance for QSA.02.08.01

- 1. **D** The laboratory has written policies and procedures to perform correlations between analytes when the same analytes are tested using different methodologies or instruments or at different locations. (See also QSA.01.03.01, EP 3) **A**
 Note 1: This element of performance is not applicable when both of the following criteria are met:
 - Testing is performed under a separate Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate.
 - The tests are used for a separate patient population (for example, blood gas analysis for patients throughout the hospital versus scalp pH analysis for neonates).
 Note 2: Correlations are not required for test methods classified as waived procedures.
- 2. **D** The laboratory performs correlations at least once every six months. The correlations are documented. **A**
- 3. The laboratory informs the ordering practitioner of clinically significant differences in correlation results between analytes when the same analytes are tested using different methodologies or instruments or at different locations. **A**

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Standard QSA.02.09.01

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

Elements of Performance for QSA.02.09.01

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| 1. | Only staff who perform patient testing perform quality control testing. | A |
| 2. | Staff who perform patient testing test quality control materials in the same manner as they test patient specimens. | A |
| 3. | The laboratory rotates quality control testing among staff who perform patient testing.
Note: Not all staff are required to perform quality control testing each day they perform patient testing, but all staff are included in the quality control testing over time. | A |

Standard QSA.02.10.01

The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.

Note: This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires three levels of quality control materials each day of patient testing).

Elements of Performance for QSA.02.10.01

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| M | 1. | D The laboratory uses quality control materials that challenge each step of the testing process. The quality control results are documented. | C |
| M | 2. | The laboratory uses quality control materials at levels and a frequency consistent with manufacturers' recommendations. | C |
| M | 3. | D The laboratory uses two quality control materials of different concentrations for each quantitative procedure on each day the procedure is performed. The quality control results are documented. | C |
| M | 4. | D The laboratory uses negative and positive control material for each qualitative procedure on each day the procedure is performed. The quality control results are documented. | C |
| M | 5. | D The laboratory uses a negative and graded or titered positive reactivity control material for procedures that produce graded or titered results each day the procedure is performed. The quality control results are documented. | C |
| M | 6. | D The laboratory uses a negative and positive reactivity control material to test staining materials for intended reactivity each day the procedure is performed. The quality control results are documented. | C |
| M | 7. | D The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each day the procedure is performed. The quality control results are documented. | C |
| M | 8. | D When direct antigen systems include an extraction phase, the laboratory uses two quality control materials, one of which is capable of detecting extraction errors. The quality control results are documented. | C |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- M** 9. **D** For each electrophoretic determination, the laboratory tests at least one quality control material containing the substances being identified or measured in patient testing. The quality control material is tested concurrent with patient specimens. The quality control result is documented. **C**
- M** 10. **D** For thin layer chromatography, each plate or card is spotted with a calibrator containing the substances or drug groups identified or reported by the laboratory. The calibrator includes at least one control material on each plate or card and is processed through each step of patient testing, including the extraction phase. The quality control result is documented. **C**
- M** 11. **D** If quality control materials are not available, the laboratory performs alternative quality control testing. The alternative quality control results are documented. **C**
 Note: Alternative quality control testing includes split sampling for testing by another method or in another laboratory or previously tested patient specimens tested in duplicate. This element of performance does not apply to Standard QSA.02.04.01 regarding the validation of electronic and internal monitoring systems.
- 12. The laboratory does not report individual patient results unless quality control criteria are met. **A**
- 13. The laboratory does not report individual patient results that exceed the reportable range. **A**
- 14. **D** The laboratory performs quality control testing before resuming patient testing when the following occurs: **A**

 - A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and quality control results are not adversely affected by reagent lot number changes.
 - Major preventive maintenance or replacement of critical parts influence test performance.

The quality control results are documented.

Standard QSA.02.11.01

The laboratory conducts surveillance of patient results and related records as part of its quality control program.

Elements of Performance for QSA.02.11.01

- 1. **D** The laboratory has written policies and procedures for surveillance activities that include a coordinated review of the following: **A**

 - Patient test results
 - Work records
 - Equipment performance testing records
 - Quality control results

(See also QSA.02.02.01, EP 5)
- 2. The policies and procedures include criteria to determine acceptability of patient results before they are released. (See also QSA.02.02.01, EP 5) **A**

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| <p>M 3. D The general supervisor performs or delegates to technical staff the daily supervisory review of patient results. The supervisory review is documented.
 Note: Technical staff performing the review use specific criteria or computer algorithms to identify outlier results for manual review. Examples of criteria include the following:
 - Unacceptable quality control results
 - Test results that do not correlate with a patient’s known condition, age, sex, diagnosis, or pertinent clinical data; distribution of patient test results; and relationship with other test parameters
 - Incongruent test results on one patient
 - Abnormal test results
 - Critical values
 (See also LD.04.05.01, EP 1; QSA.02.02.01, EP 5)</p> | <p>C</p> |
| <p>4. For high-complexity testing performed by trained high school graduates qualified under 42 CFR 493.1489(b)(5), the laboratory director, general supervisor, or technical supervisor reviews all results within 24 hours of patient testing. (See also QSA.02.02.01, EP 5)</p> | <p>A</p> |
| <p>M 5. D The laboratory performs daily screening for errors in patient test results due to handwritten or manual data entry (for example, clerical errors). The daily screening is documented. (See also QSA.02.02.01, EP 5)
 Note: Screening a sample of data is acceptable for compliance with this element of performance.</p> | <p>C</p> |
| <p>M 6. D The laboratory performs screening for errors (for example, electronic transmission errors, formatting errors) in electronic and printed patient test results at a frequency defined by the laboratory. The screening is documented. (See also QSA.02.02.01, EP 5)</p> | <p>C</p> |
| <p>7. D The laboratory performs review of other records (for example, work records, equipment records, quality control summaries) at a frequency defined by the laboratory, but at least monthly. The review is documented. (See also QSA.02.02.01, EP 5)</p> | <p>A</p> |

Standard QSA.02.12.01

The laboratory investigates and takes corrective action for deficiencies identified through quality control surveillance.

Elements of Performance for QSA.02.12.01

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| <p>1. D The laboratory has written policies and procedures to monitor, assess, and correct problems identified in the preanalytical, analytical, and postanalytical processes.</p> | <p>A</p> |
| <p>2. The laboratory’s policies and procedures include the identification of alternatives for providing patient testing, including backup systems and alternative facilities (for example, reference laboratories).</p> | <p>A</p> |
| <p>3. The laboratory follows its policies and procedures to monitor, assess, and correct problems identified in preanalytical, analytical, and postanalytical processes.</p> | <p>A</p> |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| <p>4. D The laboratory performs corrective action when the following situations occur:</p> <ul style="list-style-type: none"> - Quality control results do not meet the laboratory's criteria for acceptability. - An instrument does not meet function check or performance testing requirements. - Incidents of incorrect test results are reported. - Patient test results are reported outside of the laboratory's reportable range of test results. - Criteria for proper storage of reagents and specimens are not met. - Other incidents of unsatisfactory specimen collection, testing, or reporting are identified. <p>The corrective action is documented. (See also QSA.02.04.01, EP 8)</p> | <p>3 A</p> |
| <p>5. D For each quality control result outside acceptable limits, the laboratory conducts an investigation of all potential causes, provides evidence of review, and takes corrective action. These activities are documented. (See also QSA.02.04.01, EP 8)</p> | <p>3 A</p> |
| <p>6. For each quality control result outside acceptable limits, the laboratory takes corrective action before patient testing is resumed. (See also QSA.02.04.01, EP 8)</p> | <p>3 A</p> |
| <p>7. D As part of the corrective action, the laboratory documents the following:</p> <ul style="list-style-type: none"> - Related quality control results - Related repeat patient testing - Related correction of individual results <p>(See also QSA.02.04.01, EP 8)</p> | <p>A</p> |
| <p>8. As part of the corrective action, the laboratory performs the following:</p> <ul style="list-style-type: none"> - Review of the effectiveness of the corrective action - Revision of policies and procedures to prevent recurrence - Discussion of the investigation and corrective action with affected staff <p>(See also QSA.02.04.01, EP 8)</p> | <p>A</p> |
| <p>9. D When the laboratory becomes aware of an incorrect test result, it notifies the practitioner who ordered the test or will receive the results. The notification is documented. (See also QSA.08.08.01, EP 5)</p> | <p>3 A</p> |
| <p>10. D The laboratory issues a written corrected report to the practitioner who ordered the test or will receive the results as soon as the patient test results become available.</p> | <p>A</p> |
| <p>11. As part of the corrective action, the laboratory retains an exact copy of the original and corrected paper or electronic reports.</p> | <p>A</p> |

Standard QSA.02.13.01

The laboratory stores, prepares, evaluates, and tracks reagents.

Elements of Performance for QSA.02.13.01

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| <p>1. D The laboratory has written policies and procedures for storing, preparing, evaluating, and tracking reagents.</p> | <p>A</p> |
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KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| <p>M 2. The laboratory stores reagents as described on the label or by the manufacturer.
 Note: Reagents include, but are not limited to, quality control materials, calibration materials, standards, substrates, water, alcohols, diluents, and other test kit components.</p> <p>3. The laboratory reconstitutes reagents that are not prepackaged as indicated on the label or by the manufacturer.</p> <p>4. D The laboratory evaluates kits, including reagents, standards, diluents, and other ancillary reagents. The evaluation is documented.</p> <p>M 5. D The laboratory checks the following opened or prepared items for positive and negative reactivity, as well as graded reactivity, if necessary:</p> <ul style="list-style-type: none"> - Each batch of reagents prepared in-house - Lot number and shipment of commercially prepared reagents - Disks - Stains - Antisera - Identification systems using two or more substrates or reagents, or a combination of substrates and reagents <p>The reactivities are documented.</p> <p>M 6. D The laboratory documents the lot numbers of reagents in a manner that permits tracking when specific reagents are in use.</p> <p>7. The laboratory does not interchange components of reagent kits of different lot numbers unless permitted by the manufacturer.</p> <p>8. The laboratory uses kits, reagents, media, and supplies according to manufacturers' specifications. (See also QSA.02.14.01, EP 5)</p> <p>9. The laboratory uses water that meets the criteria for the test method and does not interfere with specificity, accuracy, or precision of the test (for example, culturing deionized or distilled water, verifying pH).</p> | <p>C</p> <p>A</p> <p>A</p> <p>C</p> <p>C</p> <p>A</p> <p>A</p> <p>A</p> |
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Standard QSA.02.14.01

The laboratory labels reagents and solutions completely and accurately.

Elements of Performance for QSA.02.14.01

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| <p>1. D The laboratory has written policies and procedures for labeling reagents and solutions.</p> <p>2. The policy for labeling reagents and solutions includes the following:</p> <ul style="list-style-type: none"> - Identity - Strength - Titer - Concentration - Cautionary and accessory information - Preparation and expiration dates | <p>A</p> <p>A</p> |
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KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- 3. The laboratory identifies reagents that could pose a hazard for staff safety. A
 Note: For more information on hazardous materials and waste, please refer to the "Environment of Care" (EC) chapter, EC.02.02.01.
- 4. The laboratory does not use deteriorated or substandard reactivity materials. A
- 5. The laboratory does not use expired reagents or solutions. (See also QSA.02.13.01, EP 8) A
- M** 6. The laboratory follows its policies and procedures for labeling reagents and solutions. C

Standard QSA.03.01.01

A pathologist or a qualified physician performs or supervises each autopsy.
 Note: This standard does not apply to autopsies conducted for forensic purposes only.

Elements of Performance for QSA.03.01.01

- 1. **D** Autopsies are performed by pathologists or physicians whose credential files document their qualifications in anatomic pathology, or by qualified individuals under the direct supervision of pathologists or qualified physicians. (If the pathologist is also serving as a laboratory director, see also HR.01.02.03, EP 1, for qualifications.) A
- 2. A pathologist qualified in anatomic pathology makes all microscopic interpretations related to autopsies. A
- 3. A pathologist prepares a diagnostic report of each autopsy performed. A

Standard QSA.03.02.01

Refrigeration is available for the storage and preservation of cadavers.

Rationale for QSA.03.02.01

Laboratories located in facilities that manage the disposition of cadavers provide for storage. Refrigeration for cadavers can be provided within the organization or at a facility close to the organization (for example, a mortuary).

Elements of Performance for QSA.03.02.01

- 1. The organization provides for refrigeration for cadaver storage and preservation. A

Standard QSA.03.03.01

Clinical autopsy results performed within or outside the organization are included in the patient's clinical record.
 Note: This standard does not apply to autopsies conducted for forensic purposes only.

Elements of Performance for QSA.03.03.01

- 1. When a clinical autopsy is performed, provisional anatomic diagnoses are recorded in the patient's clinical record within three days. A

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 2. | When a clinical autopsy is performed, the results (including a gross, microscopic, and final diagnostic report) are included in the patient's clinical record within 60 days of the autopsy unless exceptions for special studies (for example, chromosome analysis) are established in writing by the clinical staff. | A |
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Standard QSA.04.01.01

The laboratory tests chemical and biological solutions, reagents, and antisera used in bacteriology, mycobacteriology, and mycology for reactivity and deterioration.

Elements of Performance for QSA.04.01.01

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| 1. | The laboratory tests and inspects chemical and biological solutions, reagents, and antisera used for identification of bacteria, mycobacteria, and fungi for deterioration. | A |
| 2. | <p>D The laboratory uses a positive and, as appropriate, a negative control material for each qualitative procedure in bacteriology, mycobacteriology, and mycology, at a frequency consistent with laboratory policy or the manufacturer's instructions, if more stringent, unless the laboratory demonstrates satisfactory performance that would qualify the laboratory to perform streamlined quality control. The quality control results are documented.</p> <p>Note 1: Streamlined quality control is applicable only for commercial microbial identification systems (MIS) and follow the Clinical and Laboratory Standards Institute (CLSI) document, "Quality Control for Commercial Microbial Identification Systems Approved Guideline," M50-A.</p> <p>Note 2: A negative control is not required for the mycology germ tube test.</p> | A |
| 3. | D The laboratory uses a positive control material with graded reactivity for procedures that produce graded results in bacteriology, mycobacteriology, and mycology, at a frequency consistent with laboratory policy or the manufacturer's instructions, if more stringent. The quality control results are documented. | A |
| M 4. | D The laboratory performs quality controls on biochemical panels at least once prior to or concurrent with patient testing for each new batch, lot, or shipment, and at a frequency that meets the manufacturer's instructions, if more stringent. The quality control results are documented. | C |
| M 5. | D The laboratory performs quality controls each day the procedure is performed for deoxyribonucleic acid (DNA) probes, camp tests, and beta-lactamase methods other than the Cefinase brand method. The quality control results are documented. | C |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- M** 6. **D** The laboratory performs quality controls each time a new batch, shipment, and lot number are prepared or opened and every six months thereafter or at a frequency consistent with laboratory policy or manufacturer's instructions, if more stringent, for the following: **C**
- Bacitracin
 - Catalase
 - Coagulase plasma
 - The Cefinase brand method
 - Germ tube
 - ONPG
 - Optochin
 - Oxidase
 - Spot indole
 - X, V, and XV factor discs or strips
 - Yeast morphology media
- The quality control results are documented.
- M** 7. **D** The laboratory performs quality controls for typing sera when prepared or opened and every six months thereafter or at a frequency consistent with laboratory policy or the manufacturer's instructions, if more stringent. The quality control results are documented. **C**

Standard QSA.04.02.01

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

Elements of Performance for QSA.04.02.01

1. **D** Prior to reporting patient results, the laboratory performs quality control testing using approved reference organisms for each lot or shipment of antibacterial, antimycobacterial, and antifungal susceptibility testing agents. The quality control results are documented. **A**
- Footnote: A complete description of the requirements for antimicrobial susceptibility testing, including acceptable quality control limits, can be located in the Centers for Medicare & Medicaid Services (CMS) Operations Manual, Appendix C, available at http://www.cms.hhs.gov/clia/03_Interpretive_Guidelines_for_Laboratories.asp#TopOfPage.
2. **D** The laboratory performs antibacterial and antifungal susceptibility quality control testing each day the procedure is performed unless the laboratory demonstrates satisfactory performance that would qualify the laboratory to perform quality control testing on a weekly basis. The quality control results are documented. **A**
- Note: To qualify for weekly quality control, the laboratory documents that control strains were tested for a minimum of 20 to 30 consecutive test days for each antimicrobial agent/organism combination. No more than 1 out of 20 or 3 out of 30 results for each antimicrobial agent/organism combination may be outside the acceptable range.

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- 3. **D** To sustain weekly quality control testing, for each nonobvious error, the laboratory retests the out-of-control antimicrobial agent/organism combination on the day the error occurred and performs daily quality control for a total of 5 consecutive patient test days. The activities are documented. **A**
 Note: If quality control is not sustained for a total of 5 days, then to requalify for weekly quality control, the laboratory documents that control strains were tested for a minimum of 20 to 30 consecutive test days for each antimicrobial agent/organism combination. No more than 1 out of 20 or 3 out of 30 results for each antimicrobial agent/organism combination may be outside the acceptable range.
- 4. **D** The laboratory performs antimycobacterial susceptibility quality control testing on a weekly basis. The quality control results are documented. **A**

Standard QSA.04.03.01

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

Elements of Performance for QSA.04.03.01

- 1. **D** The laboratory tests staining procedures for intended reactivity by using smears of microorganisms with predictable staining characteristics. The reactivity is documented. **A**
- M** 2. **D** The laboratory performs quality control testing on stains at the following frequencies: With each new lot number and weekly for Gram stains. The quality control results are documented. **C**
- M** 3. **D** The laboratory performs quality control testing on stains at the following frequencies: Concurrent with each staining procedure for staff who do not routinely perform Gram stains (for example, staff on call). The quality control results are documented. **C**
- M** 4. **D** The laboratory performs quality control testing on stains at the following frequencies: Each day of use for nonfluorochrome acid-fast stains and special stains (for example, spore, capsule, flagella). The quality control results are documented. **C**
- M** 5. **D** The laboratory performs quality control testing on stains at the following frequencies: Each time of use for fluorochrome acid-fast and other fluorescent stains. The quality control results are documented. **C**

Standard QSA.04.04.01

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

Footnote: One source to determine specific organism recommendations is the current Quality Control for Commercially Prepared Microbiological Culture Media (Clinical and Laboratory Standards Institute (CLSI) M22).

Elements of Performance for QSA.04.04.01

- 1. The laboratory has access to nationally accepted protocols for testing microbiological culture media, whether tests are performed by the user or preparer. **A**

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| <p>2. D The laboratory documents its receipt of each microbiological culture media shipment and the condition of the following:</p> <ul style="list-style-type: none"> - Cracks in the Petri dishes - Unequal filling of plates - Cracked media - Hemolysis - Freezing - Excessive number of bubbles - Contamination | <p>A</p> |
| <p>3. D Either the laboratory or the preparer performs quality control testing on new batches of microbiological culture media, including sterility testing, using recommended organisms before or concurrently with the use of new batches of media. The quality control results are documented.</p> | <p>A</p> |
| <p>4. D The laboratory maintains documentation of microbiological culture media quality control results performed by the manufacturer if the laboratory does not retest before use.</p> | <p>A</p> |
| <p>5. D 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.
Footnote: One source to determine failure rates is the current Quality Control for Commercially Prepared Microbiological Culture Media (CLSI M22). Refer to Table 1B for the current nonexempt listing.</p> | <p>A</p> |
| <p>6. D The laboratory reports deterioration in the microbiological culture media to the manufacturer. This report is documented.</p> | <p>A</p> |

Standard QSA.04.05.01

If the laboratory incubates cultures in bacteriology, mycobacteriology, and mycology, it uses incubating equipment that supports optimal growth for the recovery of organisms.

Elements of Performance for QSA.04.05.01

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| <p>1. If the laboratory incubates cultures in bacteriology, mycobacteriology, and mycology, it uses incubating equipment that supports the optimal temperature and atmospheric conditions (for example, aerobic, anaerobic, increased carbon dioxide conditions, temperature) for the recovery of the intended organisms.</p> | <p>A</p> |
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Standard QSA.05.01.01

The laboratory has written policies and procedures for the blood transfusion service.

Elements of Performance for QSA.05.01.01

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| <p>1. D The laboratory has written policies and procedures for the blood transfusion service that are consistent with AABB standards.</p> | <p>A</p> |
| <p>2. The policies and procedures for the blood transfusion service are current and are revised whenever standards of practice change.</p> | <p>A</p> |
| <p>3. The policies and procedures for the blood transfusion service are available to staff involved in transfusion services.</p> | <p>A</p> |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- 4. **D** The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology conducts an annual review of the policies and procedures of the blood transfusion service. The annual review is documented. **A**
 Note: A designee is not permitted to conduct this review.
 Footnote: Qualifications for a technical supervisor in immunohematology are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.
- 5. The laboratory follows its policies and procedures for the blood transfusion service. **A**

Standard QSA.05.02.01

The laboratory has written policies and procedures related to blood donation.

Elements of Performance for QSA.05.02.01

- 1. **D** The laboratory has written policies and procedures for blood donation that are consistent with AABB standards. **3 A**
- 2. The policies and procedures for blood donation include criteria for donor screening. **3 A**
 Footnote: Criteria are described in AABB Standard Table 5.4.1A, "Requirements for Allogeneic Donor Qualifications."
- 3. The policies and procedures for blood donation address phlebotomy and testing. **A**
- 4. The policies and procedures for blood donation address quality control testing and maintenance. **A**
- 5. The laboratory performs a history and physical examination of the blood donor. **A**
- 6. The laboratory makes emergency medical care available at all times while blood is being drawn from donors. **A**
- 7. The laboratory follows its policies and procedures for blood donation. **A**
- 8. The laboratory provides the equipment and staff to obtain donor blood. **A**
- 9. **D** The laboratory maintains a current list of available donors. **A**
- 10. The laboratory retains indefinitely the testing records for blood donors who are permanently deferred. **A**




Standard QSA.05.03.01

The laboratory safely collects, stores, handles, processes, tests, and labels blood or blood components.

Elements of Performance for QSA.05.03.01

- 1. **D** The laboratory has written policies and procedures that address blood donor collection, including handling, processing, testing, dating, labeling, storing, and distributing, according to standards of practice. **A**
 Note: Standards of practice can include the specifications of the U.S. Food and Drug Administration (FDA) or the AABB.
- 2. The policies and procedures for blood donor collection address the making of blood components. **A**



KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required





- 3. The laboratory tests a sample from each blood donation for ABO, RH typing, and antibody screening. A
- 4. The laboratory tests a sample from each blood donation for infectious agents as specified by the U.S. Food and Drug Administration (FDA).  A
Footnote: A list of the tests required by the FDA for blood donations is located at <http://www.fda.gov/opacom/factsheets/justthefacts/15blood.html>.
- 5. The laboratory does not use blood or blood components if its tested sample for an infectious agent is reactive. A
- 6.  The laboratory complies with U.S. Food and Drug Administration (FDA) specifications for donor blood labels.  A
Footnote: AABB Standard 5.1.6.3 details the requirements for blood and blood component labels.
- 7. The laboratory follows its policies and procedures for blood donor collection. A

Standard QSA.05.04.01

If blood or blood components have been administered that are potentially infected with human immunodeficiency virus (HIV), the laboratory identifies recipients and informs them of the risk of infection.

Elements of Performance for QSA.05.04.01



- 1. Blood suppliers notify the transfusing facility of receipt of units from blood donors subsequently confirmed as positive for human immunodeficiency virus (HIV).  A
- 2.  The laboratory has written procedures for the notification of blood recipients of potential human immunodeficiency virus (HIV) infection. A
- 3. The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to make several attempts to notify the blood recipient's attending licensed independent practitioner (physician of record) of the recipient's potential for HIV infection and ask him or her to inform the recipient or, as needed, another authorized person of the need for HIV testing and counseling. A
- 4. The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to make several attempts to notify the blood recipient or, as needed, another authorized person, of the potential for HIV infection and to inform him or her of the need for HIV testing and counseling, if the physician is unavailable or declines to notify the recipient. A
- 5. The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to document the attempts to notify the blood recipient of the potential for HIV infection, including whether the recipient was located. A
Note: Federal guidelines require that at least three notification attempts to contact the recipient occur within eight weeks of testing.
- 6. The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to maintain strict confidentiality of records related to recipient health and donor suitability. A
- 7. The laboratory follows its procedures for notification of blood recipients of potential human immunodeficiency virus (HIV) infection. A

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

Standard QSA.05.05.01

If blood or blood components have been administered that are potentially infected with hepatitis C (HCV), the laboratory identifies recipients and informs them of the risk of infection.




Elements of Performance for QSA.05.05.01





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| 1. | Blood suppliers notify the transfusing facility of receipt of units from blood donors subsequently confirmed as positive for hepatitis C (HCV). |  A |
| 2. |  The laboratory has written procedures for the notification of blood recipients of potential hepatitis C (HCV) infection. | A |
| 3. | The laboratory's hepatitis C (HCV) procedures require the transfusing facility to make several attempts to contact the blood recipient's attending licensed independent practitioner (physician of record) of the recipient's potential for HCV infection and ask him or her to inform the recipient or, as needed, another authorized person of the need for HCV testing and counseling. | A |
| 4. | The laboratory's hepatitis C (HCV) procedures require the transfusing facility to make several attempts to notify the blood recipient or, as needed, another authorized person of the potential for HCV infection and inform him or her of the need for HCV testing and counseling, if the physician is unavailable or declines to notify the recipient. | A |
| 5. | The laboratory's hepatitis C (HCV) procedures require the transfusing facility to document the attempts to notify the blood recipient of the potential for HCV infection, including whether the recipient was located. | A |
| 6. | The laboratory's hepatitis C (HCV) procedures require the transfusing facility to maintain strict confidentiality of records related to recipient health and donor suitability. | A |
| 7. | The laboratory follows its procedures for notification of blood recipients of potential hepatitis C (HCV) infection. | A |

Standard QSA.05.06.01

The laboratory has policies and procedures for compatibility testing of donor blood with recipient blood.

Elements of Performance for QSA.05.06.01

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| 1. |  The laboratory has written policies and procedures for compatibility testing of the donor's blood with the recipient's blood. | A |
| 2. | Policies and procedures for compatibility testing include the following:
- A crossmatching protocol
- An antibody screening protocol
- Actions to be taken in cases of incompatible crossmatches and positive antibody screens
- A time frame during which a sample may be used for crossmatching before obtaining a new sample
Note: The time frame may not exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or history is unknown or unavailable. The day the sample is drawn is day zero. | A |
| 3. |  The laboratory evaluates the compatibility of the donor's blood with the recipient's blood. The results of this test are documented. |  A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

Standard QSA.05.07.01

The laboratory has policies and procedures for identifying donor blood and recipient blood.

Elements of Performance for QSA.05.07.01

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| 1. D | The laboratory has written policies and procedures for identifying donor blood and recipient blood. | A |
| 2. | Policies and procedures for identifying donor blood and recipient blood include the following:
- The blood recipient’s full name
- An additional patient identifier (for example, a clinical record number, health care account number)
- An identification system for tracking patients whose identities are unknown (because they are unresponsive, noncommunicative, or incoherent) until the patients’ identification has been confirmed
- A protocol for labeling of donor blood and recipient blood, including securely affixing the label to the units after crossmatching and retention of the label on the units until the transfusion is completed | A |
| 3. | The laboratory follows its policies and procedures for identifying donor blood and recipient blood. | A |

Standard QSA.05.08.01

The laboratory has policies and procedures for transfusion-related activities.

Elements of Performance for QSA.05.08.01

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| 1. D | The laboratory has written policies and procedures for transfusion-related activities. | A |
| 2. | Policies and procedures for transfusion-related activities address the following:
- Positive identification of the blood recipient and the blood container, including matching the recipient information to the blood or blood component being transfused
- Other transfusion steps
- Use of filters, warming devices, and cell salvage processes, including the transfusion service director’s responsibilities for these activities
- Special or urgent situations (for example, neonates, life-threatening emergencies) | A |
| 3. | The laboratory follows its policies and procedures for transfusion-related activities. | A |

Standard QSA.05.09.01

The laboratory has policies and procedures for returning unused blood and blood components previously issued for transfusion to the blood bank.

Elements of Performance for QSA.05.09.01

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| 1. D | The laboratory has written policies and procedures for controlling transport, storage, and return of unused blood (including reissuance of returned blood) from other parts of the organization to the blood bank. | A |
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KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 2. | Policies and procedures for returning unused blood previously issued for transfusion to the blood bank address the following:
- Temperature and time restriction
- Requirements for intact labeling and intact ports on the blood unit
- Storage, transport, and expiration of blood or blood components
- Retention of documentation
- Adherence to AABB Standards for Blood Bank and Transfusion Services, Table 5.1.8A for storage, transport, and expiration guidelines | A |
| 3. | The laboratory follows its policies and procedures for controlling transport, storage, or return of unused blood. | A |

Standard QSA.05.10.01

For blood and blood components that will not be used within the organization, the laboratory has policies and procedures for releasing it to the blood supplier or another organization.

Elements of Performance for QSA.05.10.01

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| 1. | ⓓ The laboratory has written policies and procedures for releasing blood and blood components to the blood supplier or another organization. | A |
| 2. | Policies and procedures for releasing blood and blood components to the blood supplier or another organization address the following:
- How to determine the availability of blood and blood components for release
- The agreement between the laboratory and the blood supplier for return and transfer of blood and blood components
- The safe transport of blood and blood components
- Record maintenance | A |
| 3. | The laboratory follows its policies and procedures for releasing blood and blood components to the blood supplier or another organization. | A |

Standard QSA.05.11.01

The laboratory has policies and procedures for reporting and investigating suspected transfusion-related adverse events.

Elements of Performance for QSA.05.11.01

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| 1. | ⓓ The laboratory has written policies and procedures for investigating suspected transfusion-related adverse events. | A |
| 2. | Policies and procedures for investigating suspected transfusion-related adverse events address the following:
- Laboratory responsibility for investigation
- The transfusion service director's review and interpretation
- Record maintenance
- Nursing responsibility for monitoring and reporting events to the laboratory
- Nursing responsibility for monitoring and reporting events to a physician responsible for the patient | A |


KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 3. | The written policies and procedures for investigating suspected transfusion-related adverse events are readily accessible to nursing staff.
Footnote: Refer to AABB Standards, Section 7.4, and the AABB Technical Manual for reaction categories. | A |
| 4. | The laboratory follows its policies and procedures for investigating suspected transfusion-related adverse events. | A |

Standard QSA.05.12.01

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

Elements of Performance for QSA.05.12.01





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| 1. | ① The laboratory has written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations. | A |
| 2. | Policies and procedures for obtaining blood or blood components needed in urgent or emergent situations address the following:
- The minimum inventory of blood and blood components to be maintained by the blood bank
- The arrangements for obtaining blood and blood components from community blood sources within a time frame defined by the organization | A |
| 3. | The laboratory follows its policies and procedures for obtaining blood or blood components needed in urgent or emergent situations. |  A |

Standard QSA.05.13.01

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

Elements of Performance for QSA.05.13.01

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| 1. | ① The organization has written policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration. | A |
| 2. | Policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration address the following:
- The protocol for monitoring patients during blood and blood component administration
- The criteria for recognizing a suspected transfusion-related adverse event
- The protocol to follow if a suspected transfusion-related adverse event occurs
- The requirement that suspected transfusion-related adverse events are reported immediately to the physician responsible for the patient
- The requirement that suspected transfusion-related adverse events are reported immediately to the laboratory, whether or not the physician responsible for the patient deems it necessary to report the event | A |
| 3. | Policies and procedures for nursing services related to blood and blood component administration do not conflict with the laboratory's policies and procedures. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

- 4. **D** Patient care staff monitor the patient during blood and blood component administration to detect suspected transfusion-related adverse events. The monitoring is documented. **A**
- 5. **D** The organization provides training for staff who administer and monitor blood and blood component transfusions. The training is documented. **A**
- 6. **D** The organization assesses competency for staff who administer and monitor blood and blood component transfusions. The competency is documented. **A**
- 7. The organization follows its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration. **3 A**

Standard QSA.05.14.01

The laboratory investigates the cause of suspected transfusion-related adverse events immediately upon notification.

Elements of Performance for QSA.05.14.01

- 1. **D** The laboratory has written policies and procedures for investigating a suspected transfusion-related adverse event, including the protocol for a transfusion reaction workup. **A**
- 2. **D** The transfusion reaction workup protocol includes written criteria to determine if a hemolytic reaction has occurred. **3 A**
- 3. The laboratory evaluates the suspected transfusion-related adverse event immediately upon notification and to the extent determined by the transfusion service director. **3 A**
- 4. When a transfusion-related adverse event has been confirmed by the transfusion service director, the laboratory reviews all policies and procedures to prevent recurrence and provide for the safety of individuals being transfused. **A**
- 5. **D** When a suspected transfusion-related adverse event has been confirmed by the transfusion service director, the laboratory takes corrective action to prevent recurrence. The corrective action is documented. **A**
- 6. The laboratory reports all confirmed fatal transfusion reactions to the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER). (Refer to the "Sentinel Events" (SE) chapter.) **A**
Footnote: For information on how and when to report information to the FDA, see <http://www.fda.gov/Cber/transfusion.htm>.

Standard QSA.05.15.01

The transfusion service director interprets each suspected transfusion-related adverse event.

Elements of Performance for QSA.05.15.01





- 1. **D** The transfusion service director interprets the evaluation of test results provided as part of the transfusion reaction workup. The interpretation is documented. **A**
- 2. The interpretation of the transfusion reaction workup provided by the transfusion service director is documented in the patient's clinical record. **A**

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.05.16.01

The laboratory maintains temperature ranges for the safe storage and transport of blood and blood components.


Elements of Performance for QSA.05.16.01





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| <p>1. The laboratory has procedures on temperature ranges for blood and blood components that include the following:</p> <ul style="list-style-type: none"> - Whole blood and packed red cells: 1°C to 6°C - Frozen plasma: less than or equal to -18°C - Cryoprecipitated AHF: less than or equal to -18°C - Red cells frozen in 40% glycerol: less than or equal to -65°C - Red cells frozen in 20% glycerol: less than or equal to -120°C - Platelets: 20°C to 24°C - Granulocytes: 20°C to 24°C <p>Note: Additional information on storage and transportation can be found in the current edition of the AABB's Standards for Blood Banks and Transfusion Services, Table 5.1.8A.</p> | <p> A</p> |
| <p>2. The laboratory maintains temperature ranges for the storage of blood and blood components.</p> | <p> A</p> |
| <p>3. The laboratory maintains temperature ranges for the transport of blood and blood components.</p> | <p> A</p> |
| <p>4.  The laboratory records blood and blood components storage temperatures continuously or at least once every four hours. The temperatures of blood storage are documented.</p> | <p>A</p> |

Standard QSA.05.17.01

The laboratory uses alarm systems for refrigerators and freezers to monitor storage temperatures for blood and blood components.

Elements of Performance for QSA.05.17.01

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| <p>1. The laboratory has alarm systems for each refrigerator or freezer that meet the following requirements:</p> <ul style="list-style-type: none"> - Alarms are audible. - Remote alarms are present for use when staff are not in the immediate area. - Alarms, including remote alarms, are monitored continuously. - The alarm system is battery operated or powered by a different circuit than the refrigerator(s) and freezer(s). | <p>A</p> |
| <p>2.  The laboratory has written policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.</p> | <p>A</p> |
| <p>3. Policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers include the following:</p> <ul style="list-style-type: none"> - A list of staff to notify, in order of priority - Backup or alternative provisions for blood storage - A process for maintaining records | <p>A</p> |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

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| 4. | The laboratory makes available to blood bank staff its policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers. | A |
| 5. | The laboratory follows its policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers. | A |

Standard QSA.05.18.01

The laboratory inspects stored or issued blood or blood components for any abnormality in appearance.




Elements of Performance for QSA.05.18.01





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| 1. | ⓓ The laboratory inspects stored or issued blood or blood components for evidence of hemolysis and bacterial contamination. The inspection is documented. | A |
| 2. | If an abnormality is found, the blood or blood component is not used unless authorized by the transfusion service director. | A |

Standard QSA.05.19.01

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.

Elements of Performance for QSA.05.19.01

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| 1. | ⓓ The laboratory has written policies and procedures for obtaining a supply of blood and blood components at all times. | A |
| 2. | The blood supply needs are determined by the needs of the patients, the services provided by the organization, and the clinical staff. | A |
| 3. | ⓓ A written agreement with a blood supplier includes the following:
- The responsibilities of both parties and approval by the transfusion service director or administrator
- The process for procurement, transfer, and availability of blood and blood components if the laboratory itself does not provide blood banking services on site
- 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 |
| 4. | Telephone numbers for the blood supplier are available to the staff. |  A |
| 5. | Transportation for the blood and blood components from the supplier is available. |  A |
| 6. | The laboratory follows its policies and procedures for obtaining a supply of blood and blood components. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

Standard QSA.05.20.01

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

Elements of Performance for QSA.05.20.01

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| 1. | ⓓ The organization has written policies and procedures addressing specimen collection for typing and crossmatching. | A |
| 2. | Policies and procedures addressing specimen collection for typing and crossmatching include the requirement that the recipient be positively identified at the time of collection using two unique identifiers (neither of which is the patient room number). | △ ₃ A |
| 3. | Policies and procedures addressing specimen collection for typing and crossmatching include the requirement to label specimens legibly and immediately upon collection, in the presence of the recipient. | △ ₃ A |
| 4. | ⓓ The request forms and the specimen label for typing and crossmatching include the following:
- The recipient's full name
- The unique identifying number
- The specimen collection date | △ ₃ A |
| 5. | Policies and procedures addressing specimen collection for typing and crossmatching include a consistent approach to identify recipients who are unknown, incoherent, or unconscious. | △ ₃ A |
| 6. | The organization identifies the individuals who draw blood for typing and crossmatching. | A |
| 7. | The organization follows its policies and procedures addressing specimen collection for typing and crossmatching. | A |

Standard QSA.05.21.01

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

Elements of Performance for QSA.05.21.01

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| 1. | ⓓ The laboratory has written policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type. | A |
| 2. | According to its policies and procedure(s), the transfusion service performing the crossmatch confirms the following: The ABO group of all units of whole blood and red blood cell components.
Note: The laboratory determines the ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. | A |
| 3. | According to its policies and procedure(s), the transfusion service performing the crossmatch confirms the following: The Rh type of units labeled as Rh negative.
Note: The laboratory determines the Rho(D) type by testing unknown red cells with anti-Rho (anti-D) blood typing reagent. | A |

KEY: A indicates scoring category A; C indicates scoring category C; △₂ indicates situational decision rules apply; △₃ indicates direct impact requirements apply; M indicates Measure of Success if needed; ⓓ indicates that documentation is required

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| 4. | According to its policies and procedure(s), the transfusion service performing the crossmatch confirms the following: The ABO group and Rh type of the recipient.
Note: For confirmation of the ABO group, the unknown serum is tested with known A ¹ and B red cells. | A |
| 5. | According to its policies and procedure(s), the transfusion service performing the crossmatch confirms the following: The Rho(D) negative donor cells are tested for the Du variant.
Note 1: This test is performed by the donor center.
Note 2: Confirmatory testing for the Du variant does not have to be completed by the transfusion service. | A |
| 6. | The laboratory follows its policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type. | A |

Standard QSA.05.22.01

The laboratory conducts reactivity testing on the potency and reliability of reagents used for ABO grouping, Rh typing, antibody detection, and compatibility determinations.

Elements of Performance for QSA.05.22.01

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| 1. | D The laboratory has written policies and procedures for reactivity testing. | A |
| 2. | D Each day the procedure is performed, and when a new lot of reagents is first used, the laboratory tests each opened vial of antisera, reactive cells, and reagents for reactivity. The reactivity results are documented.
Note: This testing includes positive and negative reactivity when recommended by the manufacturer. | A |
| 3. | D The laboratory confirms that each reagent reacts as expected. The confirmation is documented. | A |
| 4. | The laboratory follows its policies and procedures for reactivity testing. | A |

Standard QSA.05.23.01

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

Elements of Performance for QSA.05.23.01

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| 1. | D The laboratory defines in writing its criteria for use of sera, antisera, cells, and reagents. | A |
| 2. | The laboratory uses sera that meet federal licensing requirements or that are approved by the U.S. Food and Drug Administration (FDA). | A |
| 3. | The laboratory uses antisera and reagent products that are licensed by the U.S. Food and Drug Administration (FDA). | A |
| 4. | The laboratory uses other prepared reagents that meet or exceed U.S. Food and Drug Administration (FDA) requirements. | A |
| 5. | D If IgG-coated red cells and A and B cells used for reverse grouping are prepared locally, the laboratory tests for reactivity and specificity of those cells. The reactivity results and specificity are documented. | A |




KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

6. The laboratory follows its criteria for use of sera, antisera, cells, and reagents. **A**

Standard QSA.05.24.01

Before blood is administered, the laboratory performs compatibility and antibody testing (except in an emergency).

Elements of Performance for QSA.05.24.01

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| 1. | Before administration of blood to a patient, the following occurs (unless the physician responsible for the recipient determines that the blood administration is needed for an emergency): Tests on recipient blood, including ABO, Rh, screening for unexpected antibodies, antibody identification, compatibility, and a major crossmatch between donor red cells and recipient serum. |  A |
| 2. | Before administration of blood to a patient, the following occurs (unless the physician responsible for the recipient determines that the blood administration is needed for an emergency): When the screen for unexpected antibodies is negative, serologic testing to detect ABO incompatibility or a validated electronic crossmatch is required. |  A |
| 3. | Before administration of blood to a patient, the following occurs (unless the physician responsible for the recipient determines that the blood administration is needed for an emergency): The transfusion service director approves the decision to omit the antiglobulin phase of the crossmatch. | A |
| 4. |  The laboratory provides documentation justifying the release of uncrossmatched blood in an emergency situation. The clinician responsible for the recipient authenticates the documentation. | A |

Standard QSA.05.25.01





The laboratory retains samples of each unit of transfused blood and a sample of recipient blood.

Rationale for QSA.05.25.01

The samples of each transfused unit and recipient blood are retained for further testing in the event of an adverse reaction.

Elements of Performance for QSA.05.25.01

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| 1. | The laboratory retains samples of transfused blood and a sample of recipient blood for at least 7 days following a transfusion and 10 days following a crossmatch. | A |
| 2. | The laboratory disposes of expired blood not needed for further testing. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

Standard QSA.05.26.01

The laboratory retains records on the receipt, testing, and disposition of blood and blood components.

Rationale for QSA.05.26.01

It is essential to maintain a history of the disposition of blood and blood components and recipient information to establish an audit trail for look-back purposes.

Elements of Performance for QSA.05.26.01

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| 1. | The laboratory retains an audit trail detailing the receipt and disposition of all blood and blood components for 10 years. | A |
| 2. | The documentation of testing of blood and blood components is retained for at least five years. | A |
| 3. | For blood and blood components issued by the facility that collected and processed the unit, the identification of the recipient is retained for 10 years. | A |

Standard QSA.06.01.01

The laboratory verifies each clinical chemistry test system through the use of quality control materials.

Elements of Performance for QSA.06.01.01

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| 1. | D The laboratory performs at least one level of quality control material with each clinical chemistry run of patient specimens. The quality control results for each run are documented.
Note: The laboratory defines a "run" for each test system. Within each 24-hour period, the laboratory tests each level of quality control material at least once. | A |
| 2. | During a 24-hour period, the laboratory tests quality control materials used in clinical chemistry across a range of clinically significant values of reportable test results. | A |

Standard QSA.06.02.01

The laboratory verifies the operation of each blood gas testing instrument through the use of quality control materials.

Elements of Performance for QSA.06.02.01

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| 1. | D The laboratory tests at least three levels of quality control materials (acid, normal, alkalosis) for blood gas testing each day the procedure is performed. The quality control results are documented. | A |
| 2. | D The laboratory tests at least one level of quality control material for each eight hours of patient blood gas testing. The quality control results are documented.
Note: The laboratory should attempt to perform quality control testing as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before or after the 8-hour mark, providing a 30-minute window. Ranges in excess of +/- 30 minutes that produce a window of more than an hour do not meet the intent of this element of performance. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

3. The laboratory tests at least one level of quality control material each time patients are tested unless automated instrumentation verifies calibration internally every 30 minutes. **A**

Standard QSA.07.01.01

The laboratory performs urine tests on specimens that meet acceptability criteria.

Rationale for QSA.07.01.01

Unless a urine specimen is fresh or properly preserved, it will not yield accurate results. This applies to most of its analyzed constituents, including the microscopic examination.

Elements of Performance for QSA.07.01.01

1. The laboratory performs urine tests only on fresh or preserved specimens. **A**
2. The laboratory has a defined system for handling urine specimens that are not acceptable because of age or storage. **A**

Standard QSA.07.02.01

The laboratory makes reference materials available for microscopic examination of urine sediment.

Elements of Performance for QSA.07.02.01

1. For microscopic examination of urine sediment, the laboratory makes reference materials available to help with identification. **A**

Standard QSA.08.01.01

The laboratory director or the cytology technical supervisor determines qualifications and number of cytology staff.

Elements of Performance for QSA.08.01.01

1. The laboratory director or cytology technical supervisor determines cytology staff qualifications. **A**
Footnote: Qualifications for cytology staff are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.
2. The laboratory complies with federal and state personnel qualification and licensure requirements. **3 A**
Footnote: Qualifications for cytology personnel are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.
3. The laboratory director or cytology technical supervisor provides a number of cytotechnologists sufficient to review the volume and variety of cytology cases. **A**

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.08.02.01

The cytology technical supervisor establishes policies and procedures for the testing of cytology specimens.

Elements of Performance for QSA.08.02.01

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| 1. | <p>D The cytology technical supervisor establishes written policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation.</p> | A |
| 2. | <p>Policies and procedures for cytology specimen collection include the criteria for unacceptable cytology specimens.
 Note 1: The following list of common criteria may be used to define an unacceptable cytology specimen:
 - The name on the slide or specimen container is different from the name on the requisition.
 - The slide or container is not labeled according to the laboratory's procedure regarding specimen collection.
 - The submitted slide is broken or crushed and cannot be repaired for processing.
 - The specimen is improperly fixed.
 Note 2: For more information on specimen collection procedures, please refer to the "Document and Process Control" (DC) chapter, Standard DC.01.01.01.</p> | A |
| 3. | <p>Policies and procedures for cytology specimen evaluation include the criteria for unsatisfactory specimens that do not allow for a definitive diagnosis.
 Note: The following list of common criteria may be used to define an unsatisfactory cytology specimen:
 - Too few cells or obscured cells on slide
 - Obscuring inflammation
 - Obscuring red blood cells
 - Obscuring lubricant
 - Excessive air drying
 - Excessive cellular degeneration
 - Absence of endocervical components
 - Smears containing too few epithelial cells</p> | A |
| 4. | <p>The laboratory communicates the policies and procedures for cytology specimen collection, identification, preservation, and transport to clinical staff and other clients who collect cytology specimens.</p> | A |
| 5. | <p>The laboratory rejects unacceptable cytology specimens.</p> | A |
| 6. | <p>The laboratory follows its policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation.</p> | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.08.03.01

The cytology technical supervisor uses quality improvement processes to measure, assess, and improve the cytology service.

Elements of Performance for QSA.08.03.01

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| 1. | <p>D The cytology technical supervisor establishes, in writing, the quality improvement plan to measure, assess, and improve the cytology services.</p> | A |
| 2. | <p>The quality improvement plan includes a system to detect errors in the cytological examination process and a process to report results.</p> | A |
| 3. | <p>The laboratory reviews all gynecological and nongynecological cytology reports with available patient clinical information and compares the results of the review for discrepancies.</p> | A |
| 4. | <p>The laboratory reviews all gynecological cytology reports of a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology reports and compares the results of the review for discrepancies.</p> | A |
| 5. | <p>The laboratory reviews all gynecological and nongynecological slides with current high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm with all normal or negative gynecological specimens received within the previous five years, if available in the laboratory (on site or in storage), and compares the results of the review for discrepancies.</p> | A |
| 6. | <p>The laboratory determines the causes of any cytology discrepancies when comparing the following:</p> <ul style="list-style-type: none"> - Gynecological and nongynecological reports with available patient clinical information - Gynecological cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report - A current HSIL, adenocarcinoma, or other malignant neoplasm with the histopathology report | A |
| 7. | <p>D The laboratory performs reeducation and other corrective actions (for example, adjusting workload, if indicated) for significant cytology discrepancies as defined by the cytology technical supervisor. Reeducation and other corrective actions occur within a time frame that prevents recurrence. The performance is documented.</p> | A |
| 8. | <p>D The laboratory annually generates an aggregated statistical report that includes the following:</p> <ul style="list-style-type: none"> - The number of cytology cases examined - The number of specimens processed by specimen type - The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) - The number of gynecological cases with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm for which the histology results were available for comparison - The number of gynecological cases in which cytology and available histology reports are discrepant - The number of gynecological cases in which a rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm(s) | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 9. | The laboratory assesses communications with the clinical staff and makes improvements so that the following can be maintained at an acceptable level:
- Collection and identification of specimens
- Completion of the cytology requisition with the required information, such as date of birth, date of the last menstrual period, previous abnormal findings for Pap smears, and other abnormal findings from previous Pap smears or other specimens
- Follow-up on abnormal findings with clinical consultation, when indicated
- Notification of the patient’s physician and issuance of an amended report for significant cytology discrepancies | A |
| 10. | The laboratory measures, assesses, and improves the quality of cytology services. | A |

Standard QSA.08.04.01

The laboratory establishes workload limits for staff who perform primary cytology screening.

Elements of Performance for QSA.08.04.01

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| 1. | (D) The laboratory has written policies and procedures that address cytology workload limits. | A |
| 2. | (D) The cytology technical supervisor establishes in writing a maximum workload limit for each staff member who performs primary screening. | A |
| 3. | The cytology workload limit is based on the staff member's performance using evaluations of the following:
- Review of 10% of the cases interpreted as negative (See also QSA.08.06.01, EP 2)
- Comparison of the staff’s interpretation of the primary cytology screening with the technical supervisor’s confirmation of patient smears (See also QSA.08.07.01, EP 2) | A |
| 4. | Workload requirements apply to all cytotechnologists, pathologists, and fifth-year pathology residents who perform primary cytology screening. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

5. The maximum total number of cytology slides staff may screen is as follows: **A**
- For gynecological specimens:
- 100 slides (manual screening)
- For nongynecological specimens:
- 100 “full” slides (manual screening)
 - 200 “half” slides (manual screening: one half of the slide or less)
 - A combination of full and half slides (based on prorated time, not to exceed the preceding limits)
- For both gynecological and nongynecological specimens:
- As specified by the manufacturer for automated or semiautomated screening devices
- Note 1: Liquid-based preparations cannot be counted as a half slide.
- Note 2: The workload limit for staff reading slides requiring 100% manual review may not exceed 100 slides, as a result of automated or semiautomated analysis or in the routine workload.
- Note 3: Nongynecological slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one half or less of the total available slide may be counted as one half slide. All gynecological slide preparations (liquid-based or conventional) are counted as one full slide.
- Note 4: The 100-slide limit includes gynecological slides, nongynecological slides, previously unevaluated slides, 10% rescreen slides, and review slides. The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecological cases; previously examined nongynecological cytology preparations; or tissue pathology slides examined by a technical supervisor.
- Note 5: Pathologists' review of the following slides is not included in the workload limit:
- Previously screened reactive/repairative, atypical, premalignant, and malignant gynecological slides
 - Previously screened nongynecological slides
 - Slides prepared for determination of specimen adequacy
6. The maximum number of cytology slides is examined in no less than an eight-hour workday. **A**
- Note: For the purposes of establishing workload limits for staff examining slides by nonautomated microscopic technique on other than an eight-hour workday basis (including full-time employees with duties other than slide examination and part-time employees), a period of eight hours must be used to prorate the number of slides that may be examined. Use the following formula: $(\text{number of hours examining slides} \times 100) \div 8 = \text{maximum slide volume to be examined}$.
7. **D** The laboratory maintains records for each staff member of the total number of cytology slides examined, regardless of the site or laboratory, and the number of hours spent examining slides for each 24-hour period. **A**
8. **D** The cytology technical supervisor reassesses the workload limits for each staff member every six months, or more frequently as specified in the laboratory's policy. The reassessment is documented. **A**
9. **D** The cytology technical supervisor reestablishes, in writing, workload limits for each staff member through a documented assessment of case reviews based on each staff member's performance against the laboratory's overall statistical values. **A**

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| 10. | Ⓓ The cytology technical supervisor investigates any discrepancies with the assessment of staff performance, including reasons for deviation and any corrective actions taken. The investigation is documented. | A |
| 11. | The cytology technical supervisor makes adjustments in each staff member's workload, if needed, based on the results of the workload assessment. | A |
| 12. | The laboratory follows its policies and procedures for cytology workload limits. | A |

Standard QSA.08.05.01

Cytology slide staining provides acceptable quality.

Elements of Performance for QSA.08.05.01

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| 1. | Ⓓ The laboratory defines, in writing, cytology stains and staining techniques that are of a quality suitable for evaluation. | A |
| 2. | All gynecological smears are stained using a Papanicolaou, modified Papanicolaou, or another approved alternative staining method. | A |
| 3. | The laboratory takes measures to prevent cross-contamination between gynecological and nongynecological specimens during the cytology staining process. | A |
| 4. | The laboratory separately stains nongynecological specimens that have a high potential for cross-contamination from other nongynecological specimens. | A |
| 5. | The laboratory filters or changes the cytology stains following the staining process. | A |

Standard QSA.08.06.01

The cytology quality assurance system includes review of a random sample of negative gynecological slides.

Elements of Performance for QSA.08.06.01

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| 1. | Ⓓ A qualified individual reviews a random sample of negative gynecological slides. The review is documented.
Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . | A |
| 2. | The review of a random sample of negative gynecological slides includes the following:
- A random sample of 10% of all gynecological cases read by the cytotechnologists and interpreted to be negative for epithelial cell abnormalities and malignant or premalignant conditions
- Low-risk and high-risk patients
- Slides from all cytotechnologists
(See also QSA.08.04.01, EP 3)
Note: During the initial screening process, the cytotechnologist does not know which slides will be reexamined. | A |



KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 3. | A qualified individual completes the review of a random sample of negative gynecological slides before reporting patient results.
Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . | A |
| 4. | Records of the review of a random sample of negative gynecological slides are available and include initial examinations and rescreening results. | A |

Standard QSA.08.07.01

The cytology technical supervisor reviews cytology slides.



Elements of Performance for QSA.08.07.01





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| 1. | ⓓ A cytology technical supervisor reviews and confirms all nongynecological slides. This review is documented. |  A |
| 2. | ⓓ A cytology technical supervisor reviews and confirms all gynecological slides interpreted as reactive or reparative, premalignant or malignant, or any of the following epithelial cell abnormalities:
- Squamous cell
- Atypical squamous cells of undetermined significance (ASC-US) or high-grade squamous intraepithelial lesion (HSIL) (ASC-H)
- LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1)
- HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion
- Squamous cell carcinoma
- Glandular cell
- Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, glandular)
- Atypical cells favor neoplastic (endocervical or glandular)
- Endocervical adenocarcinoma in situ
- Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS
- Other malignant neoplasms
This review is documented. (See also QSA.08.04.01, EP 3) |  A |

Standard QSA.08.08.01

Cytology reporting includes processes to communicate with the ordering physician.

Elements of Performance for QSA.08.08.01

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| 1. | ⓓ Cytology reports contain descriptive nomenclature for all results. | A |
| 2. | ⓓ In the event that atypical, premalignant, or malignant cells are identified on an unsatisfactory smear or specimen, the laboratory communicates this information to the ordering physician. The communication is documented. |  A |
| 3. | Diagnostic interpretations are not reported on unsatisfactory specimens. | A |
| 4. | ⓓ When an incorrect cytology result is reported, a corrected report is generated and indicates the basis for the correction. |  A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

5. **D** When an incorrect cytology result is reported, the laboratory communicates directly with the ordering physician or other authorized individual qualified to follow up with the patient. The communication is documented. (See also QSA.02.12.01, EP 9)

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Standard QSA.08.09.01

Cytology slides are maintained, stored, and retrieved.

Elements of Performance for QSA.08.09.01

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| | 1. | The laboratory maintains and stores cytology slide preparations under conditions that allow preservation. | A |
| | 2. | The laboratory retains cytology slide preparations for at least five years from the examination date, or longer as required by state law or regulation. | A |
| | 3. | The laboratory retrieves cytology slide preparations on request. | A |
| M | 4. | The laboratory maintains documentation for cytology slides loaned or referred for purposes other than proficiency testing.
Note: Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of these slides. | C |

Standard QSA.09.01.01

The laboratory's cytogenetic procedures provide for accurate results.

Elements of Performance for QSA.09.01.01

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| | 1. | 1. D The laboratory has written quality control and testing procedures for cytogenetics. | A |
| | 2. | The laboratory's quality control and testing procedures for cytogenetics include the following: The use of duplicate or independently established cultures for specimen types. | A |
| | 3. | The laboratory's quality control and testing procedures for cytogenetics include the following: Determination of sex, performed by X and Y chromatin counts based on the performance of a full chromosome analysis. | A |
| | 4. | The laboratory's quality control and testing procedures for cytogenetics include the following: Confirmatory testing performed for atypical results. | A |
| | 5. | The laboratory's quality control and testing procedures for cytogenetics include the following: Two cells karyotyped for each case or clone. | A |
| | 6. | The laboratory's quality control and testing procedures for cytogenetics include the following: The level of band resolution necessary for interpretation purposes. | A |
| | 7. | The laboratory follows its quality control and testing procedures for cytogenetics. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.09.02.01

The laboratory maintains individual sample identification during all phases of cytogenetic testing and reporting.

Elements of Performance for QSA.09.02.01

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| 1. | (D) The laboratory has written policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting. | 3 A |
| 2. | The policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting include the following: Specimen collection and accessioning. | 3 A |
| 3. | The policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting include the following: Cultures. | 3 A |
| 4. | The policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting include the following: Cell preparation. | 3 A |
| 5. | The policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting include the following: Photography or another image reproduction technique. | 3 A |
| 6. | The policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting include the following: Photographic printing and storage. | 3 A |
| 7. | The policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting include the following: Karyotypes and photographs. | 3 A |
| 8. | The laboratory follows its policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting. | 3 A |

Standard QSA.09.03.01

The laboratory documents the stages of the cytogenetic testing process and the results.

Elements of Performance for QSA.09.03.01

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| (M) | 1. (D) The laboratory documents the stages of the cytogenetic testing process and results, including the following: The media used. | C |
| (M) | 2. (D) The laboratory documents the stages of the cytogenetic testing process and results, including the following: The reactions observed. | C |
| (M) | 3. (D) The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of cells counted. | C |
| (M) | 4. (D) The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of cells karyotyped. | C |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **(M)** indicates Measure of Success if needed; **(D)** indicates that documentation is required

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| M | | 5. | D | The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of chromosomes counted for each metaphase spread. | C |
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| M | | 6. | D | The laboratory documents the stages of the cytogenetic testing process and results, including the following: The quality of the banding. | C |
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| M | | 7. | D | The laboratory documents the stages of the cytogenetic testing process and results, including the following: The resolution, based on the clinical information provided to the laboratory for the type of tissue or specimen and the type of study required. | C |
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| M | | 8. | D | The laboratory documents the stages of the cytogenetic testing process and results, including the following: An adequate number of karyotypes prepared for each patient. | C |
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Standard QSA.09.04.01

The laboratory's cytogenetic interpretive reports include specific testing information.

Elements of Performance for QSA.09.04.01

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| | | 1. | D | The laboratory interpretive reports for cytogenetic testing include the following information: A summary and interpretation of the observations. | A |
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| | | 2. | D | The laboratory interpretive reports for cytogenetic testing include the following information: The number of cells counted and analyzed. | A |
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| | | 3. | D | The laboratory interpretive reports for cytogenetic testing include the following information: Use of the International System of Cytogenetic Nomenclature. | A |
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| M | | 4. | D | The laboratory interpretive reports for cytogenetic testing include the following information: Documentation of any preliminary report, such as a verbal or telephone report. | C |
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| | | 5. | D | The laboratory interpretive reports for cytogenetic testing include the following information: All clinical information required for interpretation. | A |
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Standard QSA.09.05.01

The laboratory retains abnormal cases identified by cytogenetic testing.

Elements of Performance for QSA.09.05.01

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| | | 1. | The laboratory permanently retains slides, negatives, prints, or magnetic media of abnormal cases identified by cytogenetic testing. | A |
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
KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.10.01.01

Embryo laboratory procedures provide for accurate results.

Note: Embryos are examples of a tissue. For more information on tissue storage and issuance, see the "Transplant Safety" (TS) chapter.

Elements of Performance for QSA.10.01.01



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| 1. | Ⓓ The embryo laboratory has written procedures for each laboratory test performed. | A |
| 2. | The embryo laboratory's procedures address the following:
- Infectious disease assessments
- Evaluation and assessment of oocyte morphology and maturity, fertilization, and embryo quality
- Insemination schedule relative to oocyte maturity
- Volume, numbers, and quality of sperm used for insemination of each oocyte
- Disposition of oocytes with an abnormal number of pronuclei
- Disposition of excess oocytes
- The time period following insemination for examination of oocytes to determine fertilization
- Micromanipulation of oocytes and embryos, such as intracytoplasmic sperm injection, oocyte and embryo biopsy, and assisted hatching
- Cryopreservation of specimens
- Embryo transfer procedures, which include the following: the length of time embryos are cultured before transfer, the media and protein supplementation used for transfer (as applicable), disposition of excess embryos, types of catheters available (with circumstances for use of each), methods of transfer, and technique for posttransfer catheter check
- Confirmation of patient identity and the identification of gametes and embryo samples
- Obtaining informed consent | A |
| 3. | The embryo laboratory maintains a system that provides for patient identification and preparation; specimen collection, identification, and handling (transportation, processing, storage, preservation); and accurate recording and reporting of laboratory procedural outcomes. |  A |
| 4. | The embryo laboratory follows its procedures for each laboratory test it performs. | A |

Standard QSA.10.02.01

The embryo laboratory has a process for method validation.

Elements of Performance for QSA.10.02.01

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| 1. | Ⓓ The embryo laboratory has written procedures for method validation. | A |
| 2. | The embryo laboratory determines performance measures and demonstrates that the procedures meet or exceed acceptable levels of performance. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 3. | The embryo laboratory verifies through its performance improvement activities each procedure's continued acceptable level of performance. | A |
| 4. | The embryo laboratory validates all assisted reproductive technology procedures selected or established by the embryo laboratory before routine patient use. | A |

Standard QSA.10.03.01

The embryo laboratory maintains records during all phases of testing and reporting.

Rationale for QSA.10.03.01

A well-designed record system helps ensure reliable identification and control of the patient's specimens as they are received and the laboratory procedures are performed.

Elements of Performance for QSA.10.03.01

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| 1. | The embryo laboratory maintains records and dates of laboratory testing and reporting. | A |
| M 2. | The embryo laboratory records include the following: <ul style="list-style-type: none"> - Each patient's assisted reproductive technology cycle - Semen assessment before and after processing and concentration for insemination - Outcome of insemination or micromanipulation procedures (for example, fertilization) - Outcome of any culture (for example, cleavage) - Relative timing of protocol events (for example, incubation hours) - Assessment of the developmental status and quality of all embryos at transfer - Verification that no embryos remain in the catheter following completion of transfer - The identity and lot numbers of media and media supplements used in each phase of the procedure - The identity of the laboratory staff who handled the specimens and performed the procedures | C |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.10.04.01

The embryo laboratory documents quality control methods for the media it uses.

Elements of Performance for QSA.10.04.01

1. **D** The embryo laboratory documents the following for the media it uses:
 - Procedures for the quality control of culture media
 - Completion of a visual check for physical damage to the media container and evidence of media contamination before its use
 - For each batch of culture media prepared in-house, the pH, osmolality, and culture suitability using a bioassay system appropriate for performing these activities
 - The lot number, the date prepared, the method of sterilization, and the expiration date for each batch of media
 - For each batch of commercially prepared culture media, evidence that media undergo a quality control process using a bioassay system appropriate for performing these activities, unless documentation of quality control performed by the manufacturer meets this requirement
 - Evidence that manufacturers' specifications for using media are followed
 - Any media supplementation testing (for example, protein) using a bioassay system, when needed, unless documentation of quality control performed by the manufacturer meets this requirement
 - Blood-based media supplements (for example, human fetal cord serum) prepared in-house and used in testing for human immunodeficiency virus (HIV), Type 1; human immunodeficiency virus (HIV), Type 2; hepatitis B virus (HBV); hepatitis C virus (HCV); human T-cell lymphotropic virus (HTLV), Type 1; and other diseases that may be deemed appropriate according to the laboratory's written procedures

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Standard QSA.10.05.01

The embryo laboratory has a method of tracking cryopreserved specimens.

Rationale for QSA.10.05.01

The embryo laboratory has an accurate and reliable method of tracking cryopreserved specimens ensuring positive identification of each cryopreservation container.

Elements of Performance for QSA.10.05.01

1. **D** The embryo laboratory labels each cryopreservation container with the date the specimen was frozen and the patient's name or unique identifier.
2. **D** The embryo laboratory maintains documentation in duplicate log books or files for each liquid nitrogen storage tank.

3 A

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KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

3. The documentation for each liquid nitrogen storage tank used in the embryo laboratory includes the following: A
- The patient name or unique identifier
 - A description of each cryopreservation container's contents
 - The freezing procedure used
 - The date each cryopreservation container was frozen
 - The type and location of the cryopreservation container
 - Final disposition or disposal of the cryopreserved specimen(s)

Standard QSA.10.06.01

The embryo laboratory uses policies and procedures for the receipt or transfer of cryopreserved specimens that maintain specimen identification and integrity.

Elements of Performance for QSA.10.06.01



1. **D** If cryopreserved specimens are received or transferred to other facilities, the embryo laboratory has written policies and procedures for the receipt or transfer of cryopreserved specimens.  A
2. The embryo laboratory policies and procedures for the receipt or transfer of cryopreserved specimens include the following:  A
- Methods to maintain specimen identification and specimen integrity
 - Methods of transportation
 - Method for verifying the identification and number of cryopreservation containers received or transferred
- M** 3. **D** For transferred specimens, the embryo laboratory documents the following: C
- Freezing procedure used
 - Copies of patient release forms
 - Log sheets that accompany the cryopreserved specimens
4. The embryo laboratory follows its policies and procedures for the receipt or transfer of cryopreserved specimens. A

Standard QSA.10.07.01

The embryo laboratory retains its records.

Elements of Performance for QSA.10.07.01

1. The embryo laboratory retains its records for 10 years beyond the date of final disposition or disposal of all specimens obtained during each patient's assisted reproductive technology cycle, or longer if required by federal, state, or local laws. A
2. The embryo laboratory retains its records on site for two years. A
3. In the event of closure, the embryo laboratory makes provisions for records to be maintained for the time frames required. A
 Note: Transfer of cryopreserved specimens to another facility constitutes final disposition or disposal for the transferring facility.

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.11.01.01

On each day of patient testing, the laboratory verifies each hematology procedure and test parameter against known standards or controls within the range of clinically significant values.

Elements of Performance for QSA.11.01.01

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| 1. | <p>(D) For each automated hematology test system, the laboratory tests at least one level of control for every eight hours of patient testing. The quality control results are documented.</p> <p>Note 1: Patient controls may be used to supplement the commercial controls if an acceptable level of precision has been defined.</p> <p>Note 2: Laboratories perform quality control as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before performing the test or after the 8-hour mark, which provides a 30-minute window. Ranges in excess of +/-30 minutes, producing a window of more than an hour, do not meet the intent of this element of performance.</p> | A |
| (M) 2. | <p>(D) For each automated hematology test system, the laboratory tests at least two levels of commercial control for every 24 hours of patient testing. The quality control results are documented.</p> | C |
| 3. | <p>For each automated hematology test system, the controls used during a 24-hour period test a range of clinically significant values of reportable test results.</p> | A |
| (M) 4. | <p>(D) Each individual performing manual cell counts performs one level of control for every eight hours of testing. The quality control results are documented.</p> | C |
| 5. | <p>Cell counts are tested in duplicate when performed using a hemocytometer.</p> | A |
| 6. | <p>(D) For manual hematology tests, the laboratory defines written criteria for acceptable precision of duplicate samples.</p> | A |
| 7. | <p>For manual hematology tests, the laboratory adheres to criteria for acceptable precision of duplicate samples.</p> | A |
| (M) 8. | <p>(D) For manual determination of hemoglobin, the laboratory uses two levels of control for every eight hours of patient testing. The quality control results are documented.</p> <p>Note: Laboratories perform quality control as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before performing the test or after the 8-hour mark, which provides a 30-minute window. Ranges in excess of +/-30 minutes, producing a window of more than an hour, do not meet the intent of this element of performance.</p> | C |

Standard QSA.11.02.01

The laboratory's coagulation testing provides accurate results.

Elements of Performance for QSA.11.02.01

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|----|---|----------|
| 1. | <p>(D) The laboratory performs quality control testing across a range of clinically significant values on each day that it performs coagulation testing. The quality control results are documented.</p> | A |
|----|---|----------|

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **(M)** indicates Measure of Success if needed; **(D)** indicates that documentation is required

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|---|-----------------|
| <p>M 2. D For automated coagulation testing systems: The laboratory performs two levels of quality control material each eight hours of patient testing. The quality control results are documented.
 Note: Laboratories perform quality control as close to 8-hour intervals as possible. A range may be specified in written policy, such as within 15 minutes before performing the test or after the 8-hour mark, which provides a 30-minute window. Ranges in excess of +/-30 minutes, producing a window of more than an hour, do not meet the intent of this element of performance.</p> | <p>C</p> |
| <p>M 3. D For automated coagulation testing systems: The laboratory performs two levels of quality control material each time reagents change. The quality control results are documented.</p> | <p>C</p> |
| <p>4. For manual coagulation testing systems (any coagulation test with a manual pipetting step): The laboratory runs patient samples and quality control materials in duplicate.</p> | <p>A</p> |
| <p>5. For manual coagulation testing systems (any coagulation test with a manual pipetting step): The laboratory has predetermined limits of precision for the results of patient samples and quality control materials performed in duplicate.</p> | <p>A</p> |
| <p>6. D For manual coagulation testing systems (any coagulation test with a manual pipetting step): Each staff who performs a test analyzes two levels of quality control materials before testing individual patient samples. The quality control results are documented.</p> | <p>A</p> |
| <p>M 7. D For manual coagulation testing systems (any coagulation test with a manual pipetting step): Each staff who performs a test analyzes two levels of quality control materials each time reagents change. The quality control results are documented.</p> | <p>C</p> |
| <p>8. For each new lot number of thromboplastin reagent, the laboratory establishes the normal patient prothrombin time mean.</p> | <p>A</p> |
| <p>9. The laboratory reports results based on the current reagent lot number specifications.
 Note: For prothrombin time results, the international normalized ratio (INR) calculation incorporates the normal patient prothrombin time mean and the international sensitivity index (ISI) value specific to the lot of thromboplastin reagent in use.</p> | <p>A</p> |

Standard QSA.12.01.01



The laboratory uses quality control practices and validation methods for histocompatibility testing.

Elements of Performance for QSA.12.01.01

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|--|-----------------|
| <p>1. D The laboratory has written quality control practices and validation methods for histocompatibility, including clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed human leukocyte antigen (HLA)-specific antibodies.</p> | <p>A</p> |
| <p>2. The laboratory's quality control practices and validation methods for histocompatibility are current.</p> | <p>A</p> |
| <p>3. The laboratory follows its quality control practices and validation methods for histocompatibility.</p> | <p>A</p> |
| <p>4. The laboratory assigns separate and unique identifiers to donor and recipient samples that clearly distinguish the donor from the recipient.</p> | <p>A</p> |





KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- 5. The laboratory screens and tests donors and recipients. Screens and tests include the following: **A**
 - Human leukocyte antigen (HLA) typing on all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection
 - HLA typing on cells from organ donors referred to the laboratory

Note: The laboratory makes a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch.
- 6. For immunologic reagents (for example, antibodies, antibody-coated particles, complement) that facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the laboratory monitors the efficacy of the methods with quality control procedures. **A**
- 7. The laboratory checks each typing for disease-associated human leukocyte antigen (HLA) antigens using quality control materials to monitor the test components and each phase of the test system for acceptable performance.  **A**
-  8. The laboratory has a system in place for proper storage and maintenance of both recipient sera and reagents at an acceptable temperature range for sera and components, including a temperature alarm system and an emergency plan for alternative storage. **C**
- 9. After compatibility is established between donor and recipient, a system exists to link the donor to the recipient. **A**

Note: Acceptable sources for histocompatibility testing practices include the current editions of the standards manuals for the American Society for Histocompatibility and Immunogenetics (ASHI) and federal regulations.
- 10. Reagent typing sera prepared in-house indicates source, bleeding date, identification number, reagent specificity, and volume remaining. **A**
- 11. The laboratory uses human leukocyte antigen (HLA) antigen terminology that conforms to the most recent report of the World Health Organization (WHO) Committee on Nomenclature. **A**
- 12. The laboratory uses a technique(s) that is established to define human leukocyte antigen (HLA) Class I and II specificities. **A**
- 13. Each human leukocyte antigen (HLA) typing is checked by testing the following: **A**
 - A positive quality control material
 - A negative quality control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results
 - Positive quality control materials for specific cell types (that is, T cells, B cells, and monocytes), when applicable

Note: In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results.
- 14. Each antibody screening is checked by testing the following: **A**
 - A positive quality control material containing antibodies of the appropriate isotype for the assay
 - A negative quality control material

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

Standard QSA.12.02.01

Before transplantation is performed, the laboratory crossmatches potential recipients and donors using the most reactive and recent sera appropriate to the study or individual procedure performed.

Note: The laboratory makes every effort to screen out donors with any incompatibility potential.

Elements of Performance for QSA.12.02.01

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|--|--------------------------|
| <p>1. D The laboratory has written criteria for crossmatching, including the following:</p> <ul style="list-style-type: none"> - Selecting patient serum samples for crossmatching - The preparation of donor cells or cellular extracts (for example, solubilized antigens, nucleic acids), appropriate to the crossmatch technique(s) performed | <p>A</p> |
| <p>2. The laboratory follows its criteria for crossmatching.</p> | <p>A</p> |
| <p>3. D The laboratory crossmatches potential recipients and donors before transplantation is performed. This crossmatching is documented.</p> <p>Note: For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, the laboratory has available results of final crossmatches before the kidney is transplanted.</p> | <p>3 A</p> |
| <p>4. D The laboratory performs crossmatching with the most reactive sample collected within one month of testing. The crossmatching is documented.</p> | <p>A</p> |
| <p>5. The laboratory uses a technique(s) documented to have increased sensitivity when compared to the basic complement-dependent microlymphocytotoxicity assay for crossmatching.</p> | <p>A</p> |
| <p>6. D The laboratory checks each crossmatch and compatibility test for human leukocyte antigen (HLA) Class II antigenic differences using quality control materials to monitor the test components and each phase of the test system for acceptable performance. The quality control results are documented.</p> | <p>A</p> |
| <p>7. If the recipient has had a sensitizing event, or his or her history is uncertain, the crossmatch is done with a serum sample collected within two days of the transplant.</p> | <p>A</p> |
| <p>8. D For nonrenal transplantation, if human leukocyte antigen (HLA) testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances under which the emergency transplant was performed, if known.</p> <p>Note: Records of the transplant must reflect any information provided to the laboratory by the patient's physician.</p> | <p>A</p> |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.12.03.01

The laboratory performs human leukocyte antigen (HLA) serologic typing of both donor and recipient appropriate to the study or individual procedure performed.

Elements of Performance for QSA.12.03.01

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| 1. | <p>D The laboratory has written procedures for human leukocyte antigen (HLA) serologic typing of both donor and recipient appropriate to the study or individual procedure performed, which include the following:</p> <ul style="list-style-type: none"> - Each HLA-A, -B, -C antigen is defined by using at least two or three different sera depending on whether monospecific or multispecific sera are used. - Each HLA-DR antigen is defined by using five antisera or three operationally monospecific antisera. - Using a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay - The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed - The selection of typing reagents, whether prepared in-house or commercially - Reagents used for histocompatibility typing that are adequate to define HLA-A,-B, and-DR specificities that are officially recognized by the most recent World Health Organization (WHO) Committee on Nomenclature - The assignment of HLA antigens - Antigen redefinition and retyping - Using a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens | A |
| 2. | The laboratory follows its procedures for human leukocyte antigen (HLA) serologic typing of both donor and recipient. | A |

Standard QSA.12.04.01

The laboratory uses procedures for histocompatibility testing.

Elements of Performance for QSA.12.04.01

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|----|--|----------|
| 1. | <p>D The laboratory has written procedures for histocompatibility testing, including the following:</p> <ul style="list-style-type: none"> - Human leukocyte antigen (HLA) typing, antibody screening, compatibility testing, and crossmatching, to be performed for each type of cell, tissue, or organ to be transfused or transplanted - Testing protocols for deceased donor, living, living-related, and combined organ and tissue transplants - Testing protocols for patients at high risk for allograft rejection - The level of testing required to support clinical transplant protocols (for example, antigen or allele level) | A |
| 2. | The laboratory follows its procedures for histocompatibility testing. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.12.05.01

The laboratory uses procedures to screen individual sera from potential organ or tissue graft recipients through characterization of antibodies against histocompatibility antigens.

Elements of Performance for QSA.12.05.01

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|----|--|----------|
| 1. | Appropriate to the study or individual procedure performed, the laboratory uses a panel for screening individual sera from potential organ or tissue graft recipients for characterization of antibodies against histocompatibility antigens to the level necessary to support clinical transplant protocol. | A |
| 2. | Appropriate to the study or individual procedure performed, the laboratory uses a panel that includes the major human leukocyte antigen (HLA) specificities and common splits. | A |

Standard QSA.12.06.01

The laboratory performs mixed lymphocyte cultures or uses other recognized methods to detect cellular-defined antigens.

Elements of Performance for QSA.12.06.01

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|----|---|----------|
| 1. | <p>D The laboratory has written criteria for performing mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens that include the following:</p> <ul style="list-style-type: none"> - Viability of all suspensions exceeding 80% at the start of culture - A demonstrated lack of cytotoxic antibodies for sera used in media - Each mixed lymphocytic culture test includes an autologous control and unrelated control responders and stimulators. - Incubating and labeling techniques discriminate between positive and negative responses. | A |
| 2. | The laboratory follows its criteria for performing mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens. | A |

Standard QSA.12.07.01

The laboratory validates interlaboratory reproducibility.

Elements of Performance for QSA.12.07.01

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|----|--|----------|
| 1. | <p>D The laboratory has a written policy to participate in a cell exchange program that does the following:</p> <ul style="list-style-type: none"> - Establishes valid interlaboratory reproducibility criteria - Documents performance levels - Takes and documents corrective action when indicated - Maintains a cumulative record for at least two years before survey - Provides that the director or supervisor performs and documents each review <p>Note: The laboratory participates in at least one national or regional cell exchange program, if available, or develops an exchange system with another laboratory in order to validate interlaboratory reproducibility.</p> | A |
|----|--|----------|

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

2. The laboratory follows its policy for participating in a cell exchange program. **A**

Standard QSA.13.01.01

Surgical specimens are sent to a pathologist for evaluation.

Elements of Performance for QSA.13.01.01

1. Surgical specimens are sent to a pathologist for evaluation unless exceptions are identified by the clinical staff. **A**
2. The clinical staff, in consultation with a pathologist, decides when an exception to the submission of surgical specimens to pathology should be made using the following criteria: **A**
 - The quality of care has not been compromised.
 - The surgical specimen removal is routinely verified by another clinically acceptable means.
 - The removal of the specimen is documented in an authenticated operative or other official report.
 - The exception is authorized by law, the requirements of a training program, or the clinical staff laws or rules and regulations. (See also QSA.13.04.01, EP 1)
3. **D** The pathologist and the clinical staff jointly determine and document, in writing, the categories of surgical specimens that require only a gross description and diagnosis. (See also QSA.13.04.01, EP 1) **A**

Standard QSA.13.02.01

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

Elements of Performance for QSA.13.02.01

- M** 1. Requests for examining surgical specimens are accompanied by preoperative and postoperative diagnoses to the degree known. **C**
- M** 2. Requests for examining surgical specimens are accompanied by supporting clinical information as indicated by patient history and laboratory policy. **C**

Standard QSA.13.03.01

The laboratory documents its receipt of surgical specimens and maintains the identity of the specimens throughout processing and storage.

Elements of Performance for QSA.13.03.01



- M** 1. **D** The laboratory documents its receipt of surgical specimens. **C**
2. **D** The laboratory has written policies and procedures that define how the identity of surgical specimens is maintained throughout processing, evaluation, and storage. **A**
3. The laboratory maintains the identity of the surgical specimens throughout processing, evaluation, and storage. **A**





KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.13.04.01

Surgical specimens sent to the laboratory are examined by or under the supervision of a qualified individual.

Elements of Performance for QSA.13.04.01

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|----|---|---|
| 1. | Every surgical specimen receives a gross and microscopic evaluation and a diagnostic report, unless identified as an exemption. (See also QSA.13.01.01, EPs 2 and 3) | A |
| 2. | When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: He or she meets the qualifications for high-complexity testing personnel.
Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . | A |
| 3. | D When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The laboratory delineates in writing the portions of the gross analysis that the individual is permitted to perform (for example, "May weigh, measure, and describe these types of tissue, but not section," or "May only perform gross analysis of skin biopsies"). | A |
| 4. | D When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual's work is reviewed by a qualified pathologist. The review is documented. | A |
| 5. | D When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual's work is reviewed within 24 hours. The review is documented. | A |
| 6. | An individual qualified in anatomic pathology evaluates each microscopic section.
Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . |  A |
| 7. | For Mohs testing, an individual qualified in anatomic pathology or a qualified dermatologist evaluates each microscopic section.
Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . |  A |
| 8. | The diagnosis for each surgical specimen is made by or under the supervision of a qualified individual.
Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . | A |
| 9. | The laboratory uses terminology for diagnoses from a nationally recognized, professionally accepted disease nomenclature (for example, the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT)). | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

Standard QSA.13.05.01

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

Elements of Performance for QSA.13.05.01

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| 1. | ⓓ The laboratory has written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope. | A |
| 2. | The laboratory uses precautions related to radiation and electrical hazards of an electron microscope. | A |

Standard QSA.13.06.01

The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

Elements of Performance for QSA.13.06.01

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| 1. | A pathologist qualified in anatomic pathology assesses the staining quality (for example, equipment, methods, stains) of microscopic tissue sections to determine the stain's ability to facilitate a diagnosis.
Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/regs/toc.aspx . | A |
| Ⓜ 2. | ⓓ The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented.
Note: For example, immunohistochemical (IHC) stains have positive and negative controls, and for periodic acid-Schiff (PAS) stains, documentation of typical cellular staining characteristics is acceptable. | C |
| Ⓜ 3. | ⓓ Each time of use for patient testing, the laboratory performs quality controls for each type of histologic stain used. The quality control results are documented.
Note: Documentation may be contained in a dictated report or on a separate log. | C |

Standard QSA.13.07.01

The laboratory retains histological specimens for patient care purposes.

Elements of Performance for QSA.13.07.01

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| 1. | Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are permanently identified, stored for preservation purposes, and organized for retrieval. | A |
|----|--|----------|

2. Microscopic slides, paraffin blocks, bone marrow aspirates, needle biopsy specimens, and gross tissue specimens are retained in accordance with law and regulation and as defined by organization policy. **A**
- Note 1: Minimum retention requirements in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) regulations are defined as follows:
- Microscopic slides, including stained slides, are retained for at least 10 years.
 - Paraffin blocks are stored for at least two years from the date of the examination.
 - Gross tissue specimens are retained for at least seven days after required microscopic sections are examined and reports are reviewed and signed.
- Note 2: Individual state law and regulation for retention requirements may vary. The most stringent guidelines should be followed.

Standard QSA.14.01.01

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

Elements of Performance for QSA.14.01.01

1. **D** For immunology tests, including syphilis serology, the laboratory uses quality control materials that include a challenge of the extraction phase of the test, if applicable. The quality control results are documented. **A**
- M** 2. **D** The laboratory tests immunology test components for reactivity, if applicable. The reactivity results are documented. **C**
 Note: Examples of test components that require a test for reactivity include phosphate buffered saline (PBS), sorbent, buffers, complement, fluorescent reagents, and graded controls.
3. **D** The laboratory determines, in writing, the reactivity patterns of quality control materials for immunology tests before or concurrently with test performance, if applicable. **A**

Standard QSA.14.02.01

The laboratory performs syphilis testing with equipment, reagents, quality control materials, and techniques.

Elements of Performance for QSA.14.02.01

1. The laboratory's syphilis testing conforms to manufacturers' specifications, including techniques, equipment (for example, rotator speed), room temperature, quality control materials, and reagent drop size. **A**
2. **D** If required by the manufacturer, the laboratory tests a weak reactive quality control material for syphilis testing. The quality control result for weak reactive is documented. **A**

Standard QSA.15.01.01

The laboratory uses written policies and procedures for molecular testing.

Elements of Performance for QSA.15.01.01

1. **D** The laboratory has written policies and procedures for molecular testing. **A**

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| 2. | The laboratory's policies and procedures for molecular testing address the following: Appropriateness of testing.
Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results. | A |
| 3. | The laboratory's policies and procedures for molecular testing address the following: Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation and testing. | A |
| 4. | The laboratory's policies and procedures for molecular testing address the following: Documentation of all nucleic acid reagents, including probes and primers, used in a particular test. | A |
| 5. | The laboratory's policies and procedures for molecular testing address the following: The quality and quantity of nucleic acid required for a particular test. | A |
| 6. | The laboratory's policies and procedures for molecular testing address the following: Investigation and corrective action for internal controls that fail to amplify. | A |
| 7. | The laboratory's policies and procedures for molecular testing address the following: Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal). | A |
| 8. | The laboratory's policies and procedures for molecular testing address the following: Investigation of discrepant results between different methods. | A |
| 9. | The laboratory's policies and procedures for molecular testing address the following: Reuse of patient specimens for quality control purposes. | A |
| 10. | The laboratory follows its policies and procedures for molecular testing. | A |

Standard QSA.15.02.01

The laboratory's verification studies for molecular testing include representatives from each specimen type expected to be tested in the assay and specimens representing the scope of reportable results.

Elements of Performance for QSA.15.02.01

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| 1. | The laboratory's verification studies for molecular testing include positive and negative representatives from each specimen type expected to be tested in the assay. | A |
| 2. | The laboratory's verification studies for molecular testing include specimens representing the scope of reportable results. | A |
| 3. | D The laboratory performs verification studies for molecular testing. The verification studies are documented. | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.15.03.01

The laboratory establishes quality control limits, reference ranges, and reportable ranges for molecular testing.

Elements of Performance for QSA.15.03.01

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| 1. | The laboratory establishes quality control limits, reference ranges, and reportable ranges to provide molecular test results with meaningful clinical applications. | A |
| 2. | The laboratory establishes quality control limits for quantitative molecular tests that are strict enough to promote precision and accuracy for reliable patient test results. | A |

Standard QSA.15.04.01

The laboratory uses quality control materials to verify each test run of patient samples for molecular testing.

Elements of Performance for QSA.15.04.01

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| 1. | (D) The laboratory has written quality control procedures for each molecular testing system or methodology, including the frequency of quality control testing. | A |
| 2. | Molecular testing procedures are consistent with current practice standards for this or similar methodologies, and are at least as rigorous as those required or recommended by the manufacturer. | A |
| 3. | The laboratory follows its quality control procedures for molecular testing. | A |
| (M) 4. | (D) For each molecular amplification procedure, the laboratory uses two control materials. If reaction inhibition is a source of false negative results, the laboratory uses a control material capable of detecting the inhibition. The quality control results are documented. | C |

Standard QSA.15.05.01

The laboratory's molecular testing reports include specific testing information.

Elements of Performance for QSA.15.05.01

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| (M) 1. | (D) The laboratory reports for molecular testing include the following information: The testing methodology used. | C |
| (M) 2. | (D) The laboratory reports for molecular testing include the following information: The limitations of the method used. | C |
| (M) 3. | (D) The laboratory reports for molecular testing include the following information: Any interpretation of findings. | C |
| (M) 4. | (D) The laboratory reports for molecular testing include the following information: Any recommendations for additional testing. | C |
| (M) 5. | (D) For assays developed by the laboratory, the laboratory reports for molecular testing include a statement that the assay was developed by the laboratory. | C |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **(M)** indicates Measure of Success if needed; **(D)** indicates that documentation is required

- 6. **D** The laboratory reports for molecular testing include the disclaimer required by federal regulations for analytic specific reagents (ASR). **A**
 Note: Federal regulations require that the following disclaimer accompany the test result on the report: "This test was developed and its performance characteristics determined by (laboratory name). It has not been cleared or approved by the U.S. Food and Drug Administration (FDA)."
- 7. Molecular testing reports filed in the patient's clinical record that require specific interpretation are authenticated by the individual qualified by the Clinical Laboratory Improvement Amendments (CLIA '88) to make the interpretation. **A**
 Footnote: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at <http://wwwn.cdc.gov/clia/regs/toc.aspx>.

Standard QSA.16.01.01

The laboratory uses policies and procedures for molecular genetic testing.

Elements of Performance for QSA.16.01.01

- 1. **D** The laboratory has written policies and procedures for molecular genetic testing that address recommendations for referral for genetic counseling. **A**
- 2. **D** The laboratory has written policies and procedures for molecular genetic testing that address the reporting of results when additional information necessary for interpreting test results is not received by the laboratory. **A**
 Note: Additional information might be required to provide for accurate test interpretation and reporting of results.
- 3. The laboratory follows its policies and procedures for molecular genetic testing. **A**

Standard QSA.16.02.01

Molecular genetic testing reports include specific testing information.

Elements of Performance for QSA.16.02.01


- 1. **D** The laboratory reports for molecular genetic testing include the following information: List of mutant genes or alleles tested. **C**
- 2. **D** The laboratory reports for molecular genetic testing include the following information: Any recommendations for referral to a genetic counselor. **C**
- 3. **D** The laboratory reports for molecular genetic testing include the following information: Detection rate of the test. **C**
- 4. **D** The laboratory reports for molecular genetic testing include the following information: Standard nomenclature for genes and mutations. **C**
- 5. **D** The laboratory reports for molecular genetic testing include the following information: Clinical implications of any detected mutation(s). **C**

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.17.01.01

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


Elements of Performance for QSA.17.01.01

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| 1. |  The laboratory has written procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites. | A |
| 2. | The laboratory makes a calibrated ocular lens for ova and parasite size measurement available to staff performing testing. | A |
| 3. | The procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites are available for staff performing testing. | A |
| 4. | The laboratory follows its procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites. | A |
| 5. | The laboratory makes parasitology reference materials available to staff performing testing.
Note: Examples of reference materials include textbooks with photographs, collections of previously stained slides, preserved gross specimens of identified parasites, and slides for proficiency testing. | A |

Standard QSA.17.02.01

The laboratory performs quality control testing for parasitology permanent stains.

Elements of Performance for QSA.17.02.01





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| 1. | The laboratory uses quality control materials to verify parasitology permanent stains that demonstrate typical staining characteristics.
Note: Quality control materials can consist of fecal samples with parasites or added leukocytes to demonstrate staining characteristics. | A |
| 2. |  The laboratory performs quality control testing on parasitology permanent stains each month of use, or according to laboratory policy if more stringent. The quality control results are documented. | A |

Standard QSA.18.01.01

Provider-performed microscopy (PPM) procedures are performed using a brightfield or a phase/contrast microscope.

Elements of Performance for QSA.18.01.01

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| 1. | The laboratory performs provider-performed microscopy (PPM) procedures using a microscope limited to a brightfield or a phase/contrast microscope.
Footnote: For more information on competency regarding provider-performed microscopy (PPM) procedures, please refer to the "Human Resources" (HR) chapter, Standard HR.01.06.01. | A |
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KEY: **A** indicates scoring category A; **C** indicates scoring category C;  indicates situational decision rules apply;  indicates direct impact requirements apply;  indicates Measure of Success if needed;  indicates that documentation is required

Standard QSA.19.01.01

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.

Elements of Performance for QSA.19.01.01

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| 1. | <p>D The laboratory has written procedures for quality control, reagent handling, and specimen handling for radiobioassay tests.
 Note: For quality control requirements, please refer to the clinical chemistry section of this chapter, Standard QSA.06.01.01.</p> | A |
| 2. | <p>The laboratory addresses the following related to radiobioassay tests:</p> <ul style="list-style-type: none"> - 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) <p>(See also EC.02.02.01, EP 6)
 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.</p> | A |
| 3. | <p>The laboratory follows its procedures for quality control, reagent handling, and specimen handling for radiobioassay tests.</p> | A |

Standard QSA.19.02.01

The laboratory uses a quality control system for in vivo testing.

Elements of Performance for QSA.19.02.01

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| 1. | <p>For in vivo testing: The laboratory has a quality control system that addresses safety and proper equipment performance.</p> | A |
| 2. | <p>D For in vivo testing: The laboratory maintains records on radioactive isotopes and radiopharmaceuticals from the point of entry into the laboratory to administration and final disposal.</p> | A |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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|---|-----------------|
| <p>3. D For in vivo testing: The laboratory documents in department records the following information for radioactive isotopes:</p> <ul style="list-style-type: none"> - Identity - Date received - Method of receipt - Activity - Storage - Preparation - Handling - Identity of recipients - Dates administered - Disposal | <p>A</p> |
| <p>4. For in vivo testing: The laboratory identifies radioactive isotopes and dose verification before administration.</p> | <p>A</p> |
| <p>5. For in vivo testing: The laboratory prepares radiopharmaceuticals according to manufacturers' specifications.</p> | <p>A</p> |
| <p>6. For in vivo testing: The laboratory standardizes equipment performance by using radiation standard sources with energies equivalent to those radioactive isotopes used in patient studies.</p> | <p>A</p> |

Standard QSA.20.01.01

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

Elements of Performance for QSA.20.01.01

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| <p>M 1. D The collection information for semen analysis includes the following: Method of collection. The information is documented.</p> | <p>C</p> |
| <p>M 2. D The collection information for semen analysis includes the following: Type of specimen container. The information is documented.</p> | <p>C</p> |
| <p>M 3. D The collection information for semen analysis includes the following: Days of abstinence. The information is documented.</p> | <p>C</p> |
| <p>M 4. D The sample quality for semen analysis includes the following: Collection or transport problems (for example, exposure to temperatures, incomplete specimen). The information is documented.</p> | <p>C</p> |
| <p>M 5. D The sample quality for semen analysis includes the following: Time of specimen receipt and analysis. The information is documented.</p> | <p>C</p> |
| <p>6. D The sample quality for semen analysis includes the following: Abnormalities of liquefaction. The information is documented.</p> | <p>A</p> |
| <p>7. D Semen analysis information includes the following, as applicable: Characteristics of semen specimens (for example, contaminants, erythrocytes, viscosity, appearance, volume, pH). The information is documented.</p> | <p>A</p> |
| <p>8. D Semen analysis information includes the following, as applicable: Sperm number, motility, and progression. The information is documented.</p> | <p>A</p> |

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

- 9. **D** Semen analysis information includes the following, as applicable: Method for sperm morphology classification, including stains, as required. The information is documented. **A**
- 10. **D** Semen analysis information includes the following, as applicable: Positive and negative controls with each assay for quantitative biochemical tests performed on the semen. The quality control results are documented. **A**

Standard QSA.21.01.01

The laboratory has methods for virology testing.

Elements of Performance for QSA.21.01.01

- 1. The laboratory has methodologies that are designed to isolate and/or identify viruses. **A**

Standard QSA.21.02.01

The laboratory uses cell controls and processes to assess the accuracy of virology testing results.

Elements of Performance for QSA.21.02.01

- 1. The laboratory simultaneously incubates either a cell substrate control or uninoculated cells as a negative control material with patient testing. **A**
- M** 2. **D** The virology laboratory documents the following: Cell lines used for the virus being isolated. **C**
- M** 3. **D** The virology laboratory documents the following: Control checks of maintenance media. **C**
- M** 4. **D** The virology laboratory documents the following: Sterility checks. **C**
- M** 5. **D** The virology laboratory documents the following: Reagent checks for toxicity to cell lines. **C**
- M** 6. **D** The virology laboratory documents the following: Controls for neutralization tests. **C**
- M** 7. **D** The virology laboratory documents the following: Controls for hemagglutination inhibition tests. **C**
- M** 8. **D** The virology laboratory documents the following: Controls for immunoassays. **C**
- M** 9. **D** The virology laboratory documents the following: Controls for direct immunofluorescence tests. **C**
- M** 10. **D** The virology laboratory documents the following: Controls for indirect immunofluorescence tests. **C**
- M** 11. **D** The laboratory performs daily quality control for virology stains. The quality control results are documented. **C**

KEY: **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

Standard QSA.21.03.01

The laboratory maintains records of virology testing processes.

Elements of Performance for QSA.21.03.01

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| 1. | The laboratory maintains records on the following: Cell lines used to isolate viruses. | A |
| 2. | The laboratory maintains records on the following: Test methods used to detect or identify viruses. | A |
| 3. | The laboratory maintains records on the following: Reactions observed as part of the virology testing processes (for example, cytopathic effects (CPE)). | A |
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Standard QSA.21.04.01

For serodiagnostic tests for viral disease, the laboratory tests components for reactivity.

Elements of Performance for QSA.21.04.01

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| 1. | ⓓ For serodiagnostic tests for viral disease, the laboratory determines the reactivity patterns of the quality control materials before or concurrent with performance of the test and before the reporting of individual patient test results. The reactivity patterns are documented. | A |
| 2. | ⓓ For serodiagnostic tests for viral disease, the laboratory tests components for reactivity. The reactivity patterns are documented.
Note: Examples of such components include phosphate buffered saline (PBS), sorbent, buffers, complement, fluorescent reagents, and graded quality control materials. | A |
| 3. | ⓓ For serodiagnostic tests for viral disease, the laboratory performs quality control testing, including internal and external controls. The quality control results are documented. | A |