Below we've included a written document checklist related to Quality System Assessment for Nonwaived Testing. We hope you find this information helpful as you pursue accreditation.

WRITTEN DOCUMENTATION CHECKLIST

This worksheet lists element of performance (EPs) that require written documentation that a surveyor could ask to see during a survey to show compliance with a standard.

(Note: Documentation can be on paper or in an electronic format)

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.01.01.01, EP 1	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) *Footnote *: For information on current proficiency testing providers, see http://www.cms.hhs.gov/CLIA/14_Proficiency_Testing_Providers.asp.* *Footnote **: 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.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.*	
	QSA.01.02.01, EP 2	The laboratory conducts an investigation of all potential causes, provides evidence of review, and performs corrective action for the following: - Individual unacceptable proficiency testing results - Late submission of proficiency testing results (score is zero) - Nonparticipation in the proficiency testing event (score is zero) - Lack of consensus among all laboratories participating in the proficiency testing event (score is ungradable) These actions are documented. (See also QSA.01.01.01, EP 5) *Note: 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.*	
	QSA.01.02.01, EP 3	The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented.	
	QSA.01.02.01, EP 5	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)	

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Quality System Assessment (QSA)… *continued from page 1*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.01.03.01, EP 1	The laboratory has written policies and procedures for testing proficiency testing samples.	
	QSA.01.03.01, EP 7	The laboratory staff who performed the proficiency testing along with the laboratory director sign attestations documenting that proficiency testing samples were tested in the same manner as patient specimens. *Note: The laboratory director may delegate this responsibility in writing to a technical consultant meeting the qualifications of 42 CFR 493.1409 (for moderate-complexity testing) or a technical supervisor meeting the qualifications of 42 CFR 493.1447 (for high-complexity testing).*	
	QSA.01.05.01, EP 1	The laboratory has written policies and procedures that include acceptability criteria to evaluate the accuracy and reliability of results obtained for both nonregulated analytes that are not included in a formal proficiency testing program and regulated analytes for which compatible proficiency testing samples are not available. *Note: Acceptable methods of evaluating accuracy and reliability include the following:* - *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 evaluate the continuing accuracy and 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 member who performs such testing.* - *Duplicate testing is performed by two different individuals who perform such tests as reticulocyte counts, urine sediments, and crystal identification.*	
	QSA.01.05.01, EP 2	The laboratory performs verification testing at least every six months. The verification is documented.	
	QSA.01.05.01, EP 3	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.	
	QSA.02.01.01, EP 1	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: - Accuracy - Precision - Reportable range The verification is documented.	

Quality System Assessment (QSA)… *continued from page 2*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.01.01, EP 2	When adding or replacing a modified test, method, or instrument, the laboratory establishes written performance specifications that include the following: - Accuracy - Precision - Reportable range - Analytic sensitivity - Analytic specificity, including interfering substances *Note: Modified tests, methods, or instruments include the following:* - *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*	
	QSA.02.01.01, EP 3	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. *Note 1: This element of performance also applies when reference tests are brought in-house.* *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.*	
	QSA.02.01.01, EP 4	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.	
	QSA.02.01.01, EP 5	The laboratory performs verifications for each new test, method, or instrument prior to reporting patient results. These verifications are documented.	
	QSA.02.01.01, EP 6	The laboratory's verification includes the establishment of written quality control procedures for each testing system or methodology.	
	QSA.02.02.01, EP 1	The laboratory has a written procedure for calibration that includes, at a minimum, the following: - 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	
	QSA.02.02.01, EP 4	The laboratory follows its procedure for calibration. The calibration performance is documented.	

Quality System Assessment (QSA)… *continued from page 3*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.02.01, EP 5	The laboratory recalibrates when indicated by evaluation of the following data: - 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)	
	QSA.02.02.01, EP 6	The laboratory has a written procedure for corrective action when calibration or control results fail to meet the laboratory's criteria for acceptability. The corrective action is documented.	
	QSA.02.03.01, EP 1	The laboratory has a written procedure for calibration verification that includes the following, at a minimum: - 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	
	QSA.02.03.01, EP 5	The laboratory follows its procedure for calibration verification. The calibration verification performance is documented.	
	QSA.02.04.01, EP 1	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A complete IQCP that consists of the following three parts that the laboratory director signs and dates prior to implementation: - Risk assessment - Quality control plan - Quality assessment	
	QSA.02.04.01, EP 2	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that is established by the laboratory in its own environment by its own testing personnel. *Note: The risk assessment may include test, method, or instrument verification data; performance specifications; or historical quality control data. Published or manufacturer data may also be included, but cannot be the only data source for the risk assessment.*	

Quality System Assessment (QSA)… *continued from page 4*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.04.01, EP 3	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that contains an evaluation of the following five components: - Specimen - Environment - Reagent - Test system - Testing personnel	
	QSA.02.04.01, EP 4	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that encompasses the following three phases of the entire testing process: - Preanalytic - Analytic - Postanalytic *Note: The risk assessment identifies the sources of potential failures and errors for a testing process, and evaluates the frequency and impact of those failures and sources of error.*	
	QSA.02.04.01, EP 5	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A risk assessment that includes the manufacturer's instructions or other information needed to assess risk in all three phases of the testing process. *Note: The risk assessment includes function and maintenance checks as required by, and not less than, manufacturers' instructions.*	
	QSA.02.04.01, EP 6	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality control plan for devices at each location throughout a facility.	
	QSA.02.04.01, EP 7	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality control plan (or changes in the plan) that the laboratory director signs and dates before implementation. (See also LD.04.05.09, EP 2)	
	QSA.02.04.01, EP 8	Laboratories that develop and implement an individualized quality control plan (IQCP) include the following: A quality assessment that includes documentation of corrective action and preventive action to monitor ongoing effectiveness.	
	QSA.02.06.01, EP 1	A written quality control policy exists for each specialty and subspecialty offered as part of pathology and clinical laboratory services.	
	QSA.02.07.01, EP 1	Before using control material for quality control purposes, the laboratory defines, in writing, control ranges for each lot number.	

Quality System Assessment (QSA)… *continued from page 5*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.07.01, EP 2	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.	
	QSA.02.07.01, EP 5	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. *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.*	
	QSA.02.07.01, EP 6	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.	
	QSA.02.07.01, EP 7	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.	
	QSA.02.07.01, EP 8	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. *Note: Patient controls may be used to supplement the commercial controls if an acceptable level of precision has been defined.*	
	QSA.02.08.01, EP 1	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) *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.*	
	QSA.02.08.01, EP 2	The laboratory performs correlations at least once every six months. The correlations are documented.	

Quality System Assessment (QSA)… *continued from page 6*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.10.01, EP 1	The laboratory uses quality control materials that challenge each step of the testing process. The quality control results are documented.	
	QSA.02.10.01, EP 3	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.	
	QSA.02.10.01, EP 4	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.	
	QSA.02.10.01, EP 5	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.	
	QSA.02.10.01, EP 6	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.	
	QSA.02.10.01, EP 7	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. *Note: For polymer-based immunohistochemical methods, a negative control is not required.*	
	QSA.02.10.01, EP 8	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.	
	QSA.02.10.01, EP 9	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.	
	QSA.02.10.01, EP 10	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.	

Quality System Assessment (QSA)… *continued from page 7*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.10.01, EP 11	If quality control materials are not available, the laboratory performs alternative quality control testing. The alternative quality control results are documented. *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.*	
	QSA.02.10.01, EP 14	The laboratory performs quality control testing before resuming patient testing when the following occurs: - 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 influences test performance. - After calibration in order to verify that the calibration protocol was successful. The quality control results are documented.	
	QSA.02.10.01, EP 16	A qualified * individual assesses the staining quality of stains to determine their ability to correctly stain typical cellular characteristics and facilitate an accurate patient diagnosis. The assessment 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/Regulatory.*	
	QSA.02.10.03, EP 1	The laboratory analyzes positive control material to verify the performance of reagents and staining procedures for flow cytometry methods at the following frequencies: - Each day of analysis for lymphocyte subset and CD34+ hematopoietic stem cell enumeration (single or dual platform) measurements - At least monthly for neoplastic hematolymphoid immunophenotyping The quality control results are documented. (See also DC.02.01.05, EP 3)	
	QSA.02.10.03, EP 2	The laboratory selects the source of positive control material to verify the performance of reagents and staining procedures for flow cytometry methods according to the following criteria: - External positive controls for lymphocyte subset and CD34+ hematopoietic stem cell quantitations - External and/or internal positive controls for neoplastic hematolymphoid cell immunophenotyping The quality control results are documented. Note: External positive controls are normal patient or commercial controls. (See also DC.02.01.05, EP 3)	

Quality System Assessment (QSA)… *continued from page 8*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.10.03, EP 3	The flow cytometry laboratory analyzes positive control material to verify the performance of reagents and staining procedures based on the application and method of analysis as follows: - Two levels of positive control for single platform measurements of CD4+ lymphocytes - Two levels of positive control for single platform measurements of CD34+ stem cell concentrations - Two levels of positive control for dual platform measurements of CD34+ stem cell concentrations - One level of positive control for dual platform measurements of CD4+ lymphocyte The quality control results are documented. (See also DC.02.01.05, EP 3)	
	QSA.02.10.03, EP 4	The laboratory analyzes positive control material for single and dual platform flow cytometry quantitative tests at least daily or each time the flow cytometer is restarted. The quality control results are documented. (See also DC.02.01.05, EP 3)	
	QSA.02.11.01, EP 1	The laboratory has written policies and procedures for surveillance activities that include a coordinated review of the following: - Patient test results - Work records - Equipment performance testing records - Quality control results (See also QSA.02.02.01, EP 5)	
	QSA.02.11.01, EP 3	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)*	
	QSA.02.11.01, EP 5	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.*	

Quality System Assessment (QSA)… *continued from page 9*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.11.01, EP 6	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)	
	QSA.02.11.01, EP 7	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)	
	QSA.02.12.01, EP 1	The laboratory has written policies and procedures to monitor, assess, and correct problems identified in the preanalytic, analytic, and postanalytic processes.	
	QSA.02.12.01, EP 4	The laboratory performs corrective action when the following situations occur: - 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. The corrective action is documented. (See also QSA.02.04.01, EP 8)	
	QSA.02.12.01, EP 5	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)	
	QSA.02.12.01, EP 7	As part of the corrective action, the laboratory documents the following: - Related quality control results - Related repeat patient testing - Related correction of individual results (See also QSA.02.04.01, EP 8)	
	QSA.02.12.01, EP 9	When the laboratory becomes aware of an incorrect test result, it notifies the authorized person ordering the test, and if different, the individual using the test results. The notification is documented. (See also QSA.08.08.01, EP 5)	
	QSA.02.12.01, EP 10	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.	

Quality System Assessment (QSA)… *continued from page 10*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.02.13.01, EP 1	The laboratory has written policies and procedures for storing, preparing, evaluating, and tracking reagents.	
	QSA.02.13.01, EP 4	The laboratory evaluates kits, including reagents, standards, diluents, and other ancillary reagents. The evaluation is documented.	
	QSA.02.13.01, EP 5	The laboratory checks the following opened or prepared items for positive and negative reactivity, as well as graded reactivity, if necessary: - 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 The reactivities are documented.	
	QSA.02.13.01, EP 6	The laboratory documents the lot numbers of reagents in a manner that permits tracking when specific reagents are in use.	
	QSA.02.13.01, EP 9	The laboratory verifies that the water used 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). The verification is documented.	
	QSA.02.14.01, EP 1	The laboratory has written policies and procedures for labeling reagents and solutions.	
	QSA.03.01.01, EP 1	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.)	
	QSA.04.01.01, EP 2	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. The quality control results are documented. *Note: A negative control is not required for the mycology germ tube test.*	

Quality System Assessment (QSA)… *continued from page 11*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.04.01.01, EP 3	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.	
	QSA.04.01.01, EP 4	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.	
	QSA.04.01.01, EP 5	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.	
	QSA.04.01.01, EP 6	The laboratory performs quality controls each time a new batch, shipment, and lot number are prepared or opened or at a frequency consistent with laboratory policy or manufacturer's instructions, if more stringent, for the following: - 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. *Note: If the manufacturer's quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, thelaboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.*	
	QSA.04.01.01, EP 7	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.	

Quality System Assessment (QSA)… *continued from page 12*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.04.02.01, EP 1	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. *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.*	
	QSA.04.02.01, EP 2	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. *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.*	
	QSA.04.02.01, EP 3	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. *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.*	
	QSA.04.02.01, EP 4	The laboratory performs antimycobacterial susceptibility quality control testing on a weekly basis, and on each new batch of media, and on each new lot number and shipment of antimycobacterial agent(s). The quality control results are documented.	
	QSA.04.03.01, EP 1	The laboratory tests staining procedures for intended reactivity by using smears of microorganisms with predictable staining characteristics. The reactivity is documented.	

Quality System Assessment (QSA)… *continued from page 13*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.04.03.01, EP 2	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.	
	QSA.04.03.01, EP 3	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.	
	QSA.04.03.01, EP 4	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.	
	QSA.04.03.01, EP 5	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.	
	QSA.04.04.01, EP 2	The laboratory documents its receipt of each microbiological culture media shipment and the condition of the following: - Cracks in the Petri dishes - Unequal filling of plates - Cracked media - Hemolysis - Freezing - Excessive number of bubbles - Contamination	
	QSA.04.04.01, EP 3	The laboratory or the preparer performs quality control testing on new batches, batches, or shipments 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. *Note: If the manufacturer's quality control recommendations are absent or less stringent than the requirements outlined in Standard QSA.02.10.01, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.*	
	QSA.04.04.01, EP 4	The laboratory maintains documentation of microbiological culture media quality control results performed by the manufacturer if the laboratory does not retest before use.	

Quality System Assessment (QSA)… *continued from page 14*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.04.04.01, EP 5	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.*	
	QSA.04.04.01, EP 6	The laboratory reports deterioration in the microbiological culture media to the manufacturer. This report is documented.	
	QSA.04.06.01, EP 1	The laboratory has written policies and procedures to isolate and identify bacteria, mycobacteria, and fungi from potential sites of infection that address the following: - Name of test(s) used - Type(s) of media required - Reagent(s) needed - Required confirmatory testing	
	QSA.04.07.01, EP 1	The laboratory defines the recommended volume of blood to be drawn for each blood culture. Definition is based on an approved clinical guideline, * manufacturers' requirements, and instrument specifications. *Footnote *: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document M47-A (Principles and Procedures for Blood Cultures).*	
	QSA.04.07.01, EP 2	The laboratory's processing of conventional (manual) blood cultures includes visual inspection for microbial growth (turbidity, growth of microcolonies, hemolysis, color changes, gas production): - After 12 to 24 hours of incubation at 35ºC - Twice daily for days one and two - Daily for days three to seven The results are documented.	
	QSA.04.07.01, EP 3	The laboratory establishes guidelines for the collection, transport, and processing of blood cultures to minimize contamination and support infection prevention and control activities.	
	QSA.05.01.01, EP 1	The laboratory has written policies and procedures for the blood transfusion service.	

Quality System Assessment (QSA)… *continued from page 15*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.05.01.01, EP 4	The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology * conducts a review of the policies and procedures of the blood transfusion service every two years. The review is documented. *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/Regulatory.*	
	QSA.05.01.01, EP 7	The transfusion service obtains written documentation of approval from the medical director when clinical situations warrant an exception to policies, processes, or procedures.	
	QSA.05.01.01, EP 9	The policies and procedures for the blood transfusion service define the staff responsible for the provision of blood, blood components, tissue, derivatives, and services.	
	QSA.05.02.01, EP 1	The laboratory has written policies and procedures for maintaining a minimum inventory of blood and blood components.	
	QSA.05.02.01, EP 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)	
	QSA.05.02.03, EP 1	The laboratory has written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations.	
	QSA.05.02.05, EP 1	The laboratory has written policies and procedures for releasing blood and blood components to the blood supplier or another organization.	
	QSA.05.03.01, EP 1	The laboratory inspects received, stored, or issued blood or blood components for evidence of hemolysis and bacterial contamination. The inspection is documented.	

Quality System Assessment (QSA)… *continued from page 16*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.05.03.03, EP 1	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.	
	QSA.05.04.01, EP 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.	
	QSA.05.04.03, EP 2	The laboratory has written policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.	
	QSA.05.05.01, EP 1	The laboratory defines in writing its criteria for use of sera, antisera, cells, and reagents.	
	QSA.05.05.01, EP 5	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.	
	QSA.05.06.01, EP 1	The laboratory has written policies and procedures for reagent reactivity testing.	
	QSA.05.06.01, EP 2	Each day the procedure is performed, and when a new lot of reagents is first used, the laboratory tests at least one vial from each lot number 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.*	
	QSA.05.06.01, EP 3	The laboratory confirms that each reagent reacts as expected. The confirmation is documented.	
	QSA.05.06.01, EP 4	The laboratory retains a copy of manufacturers' reagent package inserts. The date placed into service is documented.	
	QSA.05.07.01, EP 1	The organization has written policies and procedures addressing specimen collection for typing and crossmatching.	
	QSA.05.07.01, EP 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	

Quality System Assessment (QSA)… *continued from page 17*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.05.08.01, EP 1	The laboratory has written policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type.	
	QSA.05.09.01, EP 1	The laboratory has written policies and procedures for compatibility testing of the donor's blood with the recipient's blood.	
	QSA.05.09.01, EP 4	The laboratory evaluates the compatibility of the donor's blood with the recipient's blood for any blood products containing greater than 2 mL of red blood cells. The results are documented.	
	QSA.05.09.01, EP 5	The laboratory compares current ABO group, Rh type, and antibody screen test results to historical results. Discrepancies are investigated and resolved prior to transfusion. The investigation is documented.	
	QSA.05.09.01, EP 9	The laboratory evaluates the compatibility of the donor's blood with the recipient's blood. The results of this test are documented.	
	QSA.05.09.03, EP 8	The laboratory validates computer systems used for ABO incompatibility testing. The activities are documented.	
	QSA.05.10.01, EP 1	The laboratory has written policies and procedures for identifying donor blood and recipient blood.	
	QSA.05.11.01, EP 1	The laboratory's written policies and procedures for emergent release of blood address selection of blood and blood components when compatibility testing is incomplete.	
	QSA.05.11.01, EP 2	The laboratory obtains documentation justifying the release of uncrossmatched blood in an emergency situation. The clinician responsible for the recipient authenticates the documentation.	
	QSA.05.13.01, EP 1	The laboratory's written policies and procedures for the administration of Rh immune globulin address: - Criteria to identify patients eligible for prophylaxis - Procedure to determine dose of RhIG required - Optimal timing of administration following exposure	
	QSA.05.14.03, EP 1	The laboratory has written policies and procedures that address the processing of plasma components.	

Quality System Assessment (QSA)… *continued from page 18*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.05.14.03, EP 8	The laboratory has written policies and procedures that address the transfusion of plasma components containing a significant amount of incompatible ABO antibodies or unexpected red cell antibodies. * *Footnote *: Additional information can be found in the current editions of the AABB's Standards for Blood Banks and Transfusion Services and Technical Manual.*	
	QSA.05.14.05, EP 1	The laboratory's written policies and procedures for irradiation of blood and blood components address the following: Validation of the target dose of radiation delivered according to the manufacturers' recommendations and the blood or blood component.	
	QSA.05.14.05, EP 2	The laboratory's written policies and procedures for irradiation of blood and blood components address the following: A process to confirm that the target dose of irradiation has occurred. * *Footnote *: For additional information, see U.S. Food and Drug Administration guidance, July 22, 1993, "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products."*	
	QSA.05.14.05, EP 3	The laboratory's written policies and procedures for irradiation of blood and blood components address the following: Assignment of expiration date not to exceed the original expiration date or 28 days from date of irradiation, whichever is sooner.	
	QSA.05.14.05, EP 4	The laboratory's written policies and procedures for irradiation of blood and blood components address the following: Documentation of blood or blood component irradiation, including date and time of irradiation, unit numbers, dose of radiation, duration of radiation, and the staff performing the irradiation.	
	QSA.05.14.07, EP 1	The laboratory's written policies and procedures define methods to leukoreduce blood and blood components.	
	QSA.05.14.07, EP 2	The laboratory's written policies and procedures to leukoreduce blood and blood components address the following: Leukocyte reduction to less than 5 x 10^6 for apheresis platelets and red blood cells.	
	QSA.05.14.07, EP 3	The laboratory's written policies and procedures to leukoreduce blood and blood components address the following: Leukocyte reduction to less than 8.3 x 10^5 for whole blood derived platelets.	
	QSA.05.17.01, EP 1	The laboratory has written policies and procedures for transfusion-related activities.	

Quality System Assessment (QSA)… *continued from page 19*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.05.17.01, EP 3	The laboratory has distinct written policies and procedures for neonatal transfusion-related activities. * *Footnote *: Additional information can be found in the current editions of the AABB's Standards for Blood Banks and Transfusion Services and Technical Manual.*	
	QSA.05.18.01, EP 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.	
	QSA.05.18.01, EP 4	Patient care staff monitor the patient during blood and blood component administration to detect suspected transfusion-related adverse events. The monitoring is documented.	
	QSA.05.18.01, EP 5	The organization provides training for staff who administer and monitor blood and blood component transfusions. The training is documented.	
	QSA.05.18.01, EP 6	The organization assesses competency for staff who administer and monitor blood and blood component transfusions. The competency is documented.	
	QSA.05.19.01, EP 1	The laboratory has written policies and procedures for investigating suspected transfusion-related adverse events.	
	QSA.05.19.03, EP 1	The laboratory has written policies and procedures for investigating a suspected transfusion-related adverse event, including the protocol for a transfusion reaction workup.	
	QSA.05.19.03, EP 2	The transfusion reaction workup protocol includes written criteria to determine if a hemolytic reaction has occurred.	
	QSA.05.19.03, EP 5	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.	
	QSA.05.19.05, EP 1	The transfusion service director interprets the evaluation of test results provided as part of the transfusion reaction workup. The interpretation is documented.	
	QSA.05.20.01, EP 2	The laboratory has written procedures for the notification of blood recipients of potential human immunodeficiency virus (HIV) infection.	
	QSA.05.21.01, EP 2	The laboratory has written procedures for the notification of blood recipients of potential hepatitis C (HCV) infection.	

Quality System Assessment (QSA)… *continued from page 20*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.05.23.01, EP 1	The laboratory's written policies and procedures for blood donation are consistent with U.S. Food and Drug Administration (FDA) regulations.* *Footnote * : The current CFR and blood guidance from the U.S. Food and Drug Administration (FDA) can be found at http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm.*	
	QSA.05.24.03, EP 1	The laboratory has written policies and procedures that address blood donor collection, including handling, processing, testing, dating, labeling, storing, and distributing, according to state and federal regulation.* *Footnote *: Additional practice guidance may be found in the AABB standards or AABB Technical Manual.*	
	QSA.05.24.03, EP 6	The laboratory complies with U.S. Food and Drug Administration (FDA) specifications for donor blood labels. *Note: ISBT 128 is the preferred bar code symbology and should be used in accordance with International Council for Communality in Blood Banking Automation (ICCBBA) standards, whenever possible.*	
	QSA.05.25.01, EP 1	The laboratory's or designated department's written policies and procedures for therapeutic apheresis address: - Documentation of doctor's orders - Patient informed consent process - Acceptance of medical responsibility for the procedure - Treatment of adverse reactions - Patient monitoring - Documentation of procedure	
	QSA.05.25.01, EP 2	The laboratory or the designated department documents the following elements in the patient's therapeutic apheresis record: - Patient identification - Diagnosis - Equipment serial number - Operator - Date and time of procedure start and end - Lot numbers of all fluids used and replaced in the device - Blood volume processed - Amount of fluid removed from patient - Patient assessment - Time out procedure prior to placing venous access device *Note: Equipment serial numbers are not required for therapeutic phlebotomy performed by gravity.*	

Quality System Assessment (QSA)… *continued from page 21*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.06.01.01, EP 1	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.*	
	QSA.06.02.01, EP 1	The laboratory tests at two different levels of quality control materials for blood gas testing each day the procedure is performed. The combination of controls and calibrators used each day of testing are rotated to check normal, alkalosis, and acidosis levels. The quality control results are documented.	
	QSA.06.02.01, EP 2	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.*	
	QSA.06.03.01, EP 1	The laboratory's written quality control and testing procedures for maternal serum marker prenatal screening include the following: Establishment of laboratory specific median values or verification of manufacturer's median values consistent with the population served.	
	QSA.06.03.01, EP 2	The laboratory's written quality control and testing procedures for maternal serum marker prenatal screening include the following: Criteria and frequency for recalculation or reverification of the median values at specifically defined intervals.	
	QSA.06.03.01, EP 3	The laboratory's written quality control and testing procedures for maternal serum marker prenatal screening include the following: Evaluation of new reagent lots against the current median values with adjustments of the median in response to changes in median values that affect clinical interpretation.	
	QSA.06.03.03, EP 1	The laboratory has written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP).	
	QSA.06.04.01, EP 1	The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: The use of calibrators or quality control materials with each batch of patient samples prepared for analysis.	
	QSA.06.04.01, EP 2	The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: Extraction and use of control materials that challenge each step of the testing process.	

Quality System Assessment (QSA)… *continued from page 22*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.06.04.01, EP 3	The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: For procedures that include hydrolysis, the use of a control to assess the efficiency of hydrolysis.	
	QSA.06.04.01, EP 4	The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: The detection and evaluation of carryover.	
	QSA.06.04.01, EP 5	The laboratory has written quality control and testing procedures for high performance liquid chromatography (HPLC) that address the following: The frequency of monitoring column and detector performance.	
	QSA.06.04.03, EP 1	The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: The use of calibrators or quality control materials with each batch of patient samples prepared for analysis.	
	QSA.06.04.03, EP 2	The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: Extraction and use of control materials that challenge each step of the testing process.	
	QSA.06.04.03, EP 3	The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: For procedures that include hydrolysis, the use of a control to assess the efficiency of hydrolysis.	
	QSA.06.04.03, EP 4	The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: The detection and evaluation of carryover.	
	QSA.06.04.03, EP 5	The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: For quantitative tests, an established reportable range and limit of detection.	
	QSA.06.04.05, EP 1	The laboratory has written quality control and testing procedures for mass spectrometry that address the following: The use of calibrators or quality control materials with each batch of patient samples prepared for analysis.	
	QSA.06.04.05, EP 2	The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Extraction and use of control materials that challenge each step of the testing process.	

Quality System Assessment (QSA)… *continued from page 23*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.06.04.05, EP 3	The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Criteria and frequency for establishing mass calibration and optimum performance. *Note: Some organizations refer to mass spectrometer optimum performance as being "in tune." Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods).*	
	QSA.06.04.05, EP 4	The laboratory has written quality control and testing procedures for mass spectrometry that address the following: The detection and evaluation of carryover.	
	QSA.06.04.05, EP 5	The laboratory has written quality control and testing procedures for mass spectrometry that address the following: For quantitative tests, an established reportable range and limit of detection.	
	QSA.06.04.05, EP 6	The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Establishment and validation of identification criteria for the specific technique applied (for example, liquid chromatography–mass spectrometry versus gas chromatography–mass spectrometry). *Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) documents C62 (Liquid Chromatography–Mass Spectrometry Methods) and C43 (Gas Chromatography– Mass Spectrometry Confirmation of Drugs).*	
	QSA.06.04.05, EP 7	The laboratory has written quality control and testing procedures for mass spectrometry that address the following: Liquid chromatography–mass spectrometry includes evaluation, reduction, and monitoring of matrix effects and ion suppression. *Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document C62 (Liquid Chromatography–Mass Spectrometry Methods).*	
	QSA.07.01.01, EP 3	The laboratory establishes guidelines and policies to test pediatric urine specimens for reducing substances.	
	QSA.08.02.01, EP 1	The cytology technical supervisor establishes written policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation.	

Quality System Assessment (QSA)… *continued from page 24*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.08.03.01, EP 1	The cytology technical supervisor establishes, in writing, the quality improvement plan to measure, assess, and improve the cytology services.	
	QSA.08.03.01, EP 7	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.	
	QSA.08.03.01, EP 8	The laboratory annually generates an aggregated statistical report that includes the following: - 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 gynecologic 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 gynecologic cases in which cytology and available histology reports are discrepant - The number of gynecologic 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)	
	QSA.08.04.01, EP 1	The laboratory has written policies and procedures that address cytology workload limits.	
	QSA.08.04.01, EP 2	The cytology technical supervisor establishes in writing a maximum workload limit for each staff member who performs primary screening.	
	QSA.08.04.01, EP 7	Both the laboratory and the cytotechnologist maintain workload records 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.	
	QSA.08.04.01, EP 8	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.	
	QSA.08.04.01, EP 9	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.	

Quality System Assessment (QSA)… *continued from page 25*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.08.04.01, EP 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.	
	QSA.08.05.01, EP 1	The laboratory defines, in writing, cytology stains and staining techniques that are of a quality suitable for evaluation.	
	QSA.08.06.01, EP 1	A qualified * individual reviews a random sample of negative gynecologic slides before reporting patient results. 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/Regulatory.*	
	QSA.08.06.01, EP 4	Records of the review of a random sample of negative gynecologic slides are available and include initial examinations and rescreening results. The results are documented.	
	QSA.08.06.03, EP 1	The laboratory has written policies and procedures to detect and resolve discrepancies between nongynecologic cytologic and histologic findings.	
	QSA.08.07.01, EP 1	An individual qualified as a cytology technical supervisor reviews and confirms all nongynecologic slides. This review is documented.	
	QSA.08.07.01, EP 2	A cytology technical supervisor reviews and confirms all gynecologic 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)	

Quality System Assessment (QSA)… *continued from page 26*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.08.07.01, EP 3	All gynecologic and nongynecologic test reports reviewed by a cytology technical supervisor have a written or secured electronic signature.	
	QSA.08.08.01, EP 1	For all specimen results, cytology reports contain descriptive nomenclature * that facilitates communication between the laboratory and the clinician. *Footnote *: Ali SZ, Cibas ES, editors. The Bethesda System for Reporting Thyroid Cytopathology: Definitions, Criteria and Explanatory Notes. New York: Springer, 2010.*	
	QSA.08.08.01, EP 2	The cytology laboratory communicates results that require urgent patient follow-up to the authorized person ordering the test and, if different, t he individual responsible for using the test results. The communication is documented.	
	QSA.08.08.01, EP 5	When an incorrect cytology result is reported, a corrected report is generated and indicates the basis for the correction.	
	QSA.08.08.01, EP 6	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)	
	QSA.09.01.01, EP 1	The laboratory has written policies and procedures for processing cytogenetic specimens that address the following: - The use of separate incubators equipped with independent electrical circuits or emergency power systems and emergency alarms for amniotic fluid and chorionic villus cultures - Duplicate or independently established cultures for each tissue type whenever possible - Independent harvesting of duplicate amniotic fluid and chorionic villus flasks or plates	
	QSA.09.02.01, EP 1	The laboratory has written policies and procedures to maintain individual sample identification during all phases of cytogenetic testing and reporting.	

Quality System Assessment (QSA)… *continued from page 27*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.09.03.01, EP 2	The laboratory's written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Determination of the number of cells to count and/or analyze and the number karyotyped based on tissue type, culture method, and clinical reason for referral as follows: Cells to count - For peripheral blood samples (non-neoplastic disorders), a minimum of 20 cells *Note: When mosaicism is suspected, a minimum of 30 cells* - *For amniotic fluid (in situ) samples, a minimum of 15 cells from a minimum of 15 colonies* - *For non-amniotic fluid cell cultures, a minimum of 20 cells* - *For chorionic villus cultured preparation samples, a minimum of 20 cells* - *For solid tissue samples, a minimum of 20 cells* *Cells to analyze* - *Minimum of five cells for the following samples: amniotic fluid (in situ), cultured chorionic villus, non-neoplastic blood cells, and non-neoplastic solid tissue* - *Minimum of 20 cells, whenever possible, for neoplastic studies of marrow, blood, or solid tumor specimens* - *Two or more cultures, whenever possible, for neoplastic bone marrow, blood, or solid tumor specimens* *Cells to karyotype* - *Two cells karyotyped for each non-neoplastic case study, with at least one karyogram per cell line for amniotic fluid, chorionic villus, solid tissue, and peripheral blood cell specimens* - *For neoplastic case studies, a minimum of two cells karyotyped, and in addition, one karyogram for each subclone, and one karyogram of a normal cell if observed for solid tumor, blood, or bone marrow specimens*	
	QSA.09.03.01, EP 3	The laboratory's written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Determination of X and Y chromatin counts based on the performance of a full chromosome analysis.	
	QSA.09.03.01, EP 4	The laboratory's written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Level of band resolution necessary for interpretation purposes.	
	QSA.09.03.01, EP 5	The laboratory's written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Confirmatory testing performed for atypical results.	
	QSA.09.03.01, EP 6	The laboratory's written quality control and testing procedures for conventional cytogenetic chromosomal analyses studies include the following: Criteria for clinical circumstances in which an abbreviated chromosome study may be conducted.	

Quality System Assessment (QSA)… *continued from page 28*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.09.03.05, EP 1	The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Validation of each probe.	
	QSA.09.03.05, EP 2	The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Establishment of normal cut off values for each probe.	
	QSA.09.03.05, EP 3	The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Use of a control consistent with hybridization assay based on signal patterns of hybridization and specimen type.	
	QSA.09.03.05, EP 5	The laboratory has written quality control and testing procedures for fluorescence in situ hybridization (FISH) including the following: Criteria for scoring results.	
	QSA.09.03.07, EP 1	The laboratory has written quality control and testing procedures for chromosomal microarray analysis.	
	QSA.09.03.07, EP 2	The laboratory's written quality control and testing procedures for chromosomal microarray analysis include the following: probe specificity.	
	QSA.09.03.07, EP 3	The laboratory's written quality control and testing procedures for chromosomal microarray analysis include the following: assessment of the genomic copy number.	
	QSA.09.03.07, EP 4	The laboratory's written quality control and testing procedures for chromosomal microarray analysis include the following: assay resolution.	
	QSA.09.03.07, EP 5	The laboratory's written quality control and testing procedures for chromosomal microarray analysis include the following: study limitations, including copy number variation.	
	QSA.09.04.01, EP 1	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The media used.	
	QSA.09.04.01, EP 2	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The reactions observed.	
	QSA.09.04.01, EP 3	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of cells counted.	

Quality System Assessment (QSA)… *continued from page 29*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.09.04.01, EP 4	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of cells karyotyped.	
	QSA.09.04.01, EP 5	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The number of chromosomes counted for each metaphase spread.	
	QSA.09.04.01, EP 6	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The quality of the banding.	
	QSA.09.04.01, EP 7	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.	
	QSA.09.04.01, EP 8	The laboratory documents the stages of the cytogenetic testing process and results, including the following: An adequate number of karyotypes prepared for each patient.	
	QSA.09.04.01, EP 9	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The culture conditions.	
	QSA.09.04.01, EP 10	The laboratory documents the stages of the cytogenetic testing process and results, including the following: The incubation times.	
	QSA.09.05.01, EP 1	The laboratory interpretive reports for cytogenetic testing include the following information: A summary and interpretation of the observations.	
	QSA.09.05.01, EP 2	The laboratory interpretive reports for cytogenetic testing include the following information: The number of cells counted and analyzed.	
	QSA.09.05.01, EP 3	The laboratory interpretive reports for cytogenetic testing include the following information: Use of the International System of Cytogenetic Nomenclature.	
	QSA.09.05.01, EP 4	The laboratory interpretive reports for cytogenetic testing include the following information: Documentation of any preliminary report, such as a verbal or telephone report.	
	QSA.09.05.01, EP 5	The laboratory interpretive reports for cytogenetic testing include the following information: All clinical information required for interpretation.	
	QSA.09.05.01, EP 6	The laboratory interpretive reports for cytogenetic testing include the following information: Band resolution for constitutional cases.	

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QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.10.01.01, EP 1	The embryo laboratory has written procedures for each laboratory test performed.	
	QSA.10.02.01, EP 1	The embryo laboratory has written procedures for method validation.	
	QSA.10.04.01, EP 1	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 lymphotrophic virus (HTLV), Type 1; and other diseases that may be deemed appropriate according to the laboratory's written procedures	
	QSA.10.05.01, EP 1	The embryo laboratory labels each cryopreservation container with the date the specimen was frozen and the patient's name or unique identifier.	
	QSA.10.05.01, EP 2	The embryo laboratory maintains documentation in duplicate log books or files for each liquid nitrogen storage tank.	
	QSA.10.06.01, EP 1	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.	
	QSA.10.06.01, EP 3	For transferred specimens, the embryo laboratory documents the following: - Freezing procedure used - Copies of patient release forms - Log sheets that accompany the cryopreserved specimens	

Quality System Assessment (QSA)… *continued from page 31*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.11.01.01, EP 4	Each individual performing manual cell counts performs one level of control for every eight hours of testing. The quality control results are documented.	
	QSA.11.01.01, EP 6	For manual hematology tests, the laboratory defines written criteria for acceptable precision of duplicate samples.	
	QSA.11.01.01, EP 8	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. *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.*	
	QSA.11.02.01, EP 1	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.	
	QSA.11.02.01, EP 2	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.*	
	QSA.11.02.01, EP 3	For automated coagulation testing systems: The laboratory performs two levels of quality control material each time reagents change. The quality control results are documented.	
	QSA.11.02.01, EP 6	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.	
	QSA.11.02.01, EP 7	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.	

Quality System Assessment (QSA)… *continued from page 32*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.11.02.01, EP 10	The laboratory has written policies and procedures based on an approved clinical guideline * to collect specimens for the performance of plasma-based coagulation assays. *Footnote *: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document H21-A (Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays).*	
	QSA.12.01.01, EP 1	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.	
	QSA.12.02.01, EP 1	The laboratory has written criteria for crossmatching, including the following: - 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.	
	QSA.12.02.01, EP 3	The laboratory crossmatches potential recipients and donors before transplantation is performed. This crossmatching is documented. *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.*	
	QSA.12.02.01, EP 4	The laboratory performs crossmatching with the most reactive sample collected within one month of testing. The crossmatching is documented.	
	QSA.12.02.01, EP 6	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.	
	QSA.12.02.01, EP 8	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. *Note: Records of the transplant must reflect any information provided to the laboratory by the patient's physician.*	

Quality System Assessment (QSA)… continued from page 33

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.12.03.01, EP 1	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: - 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 o n 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	
	QSA.12.04.01, EP 1	The laboratory has written procedures for histocompatibility testing, including the following: - 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)	
	QSA.12.06.01, EP 1	The laboratory has written criteria for performing mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens that include the following: - 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.	

Quality System Assessment (QSA)… *continued from page 34*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.12.07.01, EP 1	The laboratory has a written policy to participate in a cell exchange program that does the following: - 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 *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.*	
	QSA.13.01.01, EP 3	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)	
	QSA.13.03.01, EP 1	The laboratory documents its receipt of surgical specimens.	
	QSA.13.03.01, EP 2	The laboratory has written policies and procedures that define how the identity of surgical specimens is maintained throughout processing, evaluation, and storage.	
	QSA.13.03.03, EP 1	The laboratory has written policies and procedures for the safe handling, processing, and disposing of tissues containing radionuclides.	
	QSA.13.04.01, EP 3	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”).	
	QSA.13.04.01, EP 4	When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual’s work is reviewed by a technical supervisor or qualified pathologist within 24 hours. The review is documented.	
	QSA.13.04.01, EP 9	Cancer pathology reports use a synoptic format. * *Footnote *: Additional information can be found in Cancer Program Standards 2012: Ensuring Patient-Centered Care by the Commission on Cancer of the American College of Surgeons at http://www.facs.org/cancer/coc/programstandards2012.pdf.*	

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QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.13.05.01, EP 1	The laboratory has written policies and procedures addressing precautions related to radiation and electrical hazards of an electron microscope.	
	QSA.13.06.01, EP 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. The staining quality assessments are documented. ** 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/Regulatory.*	
	QSA.13.06.01, EP 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. For polymer-based immunohistochemical methods, a negative control is not required.*	
	QSA.13.06.01, EP 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.*	
	QSA.13.08.01, EP 1	The histopathology laboratory has written policies and procedures for surveillance activities that include a review of the correlation of the intraoperative consultation with the final pathology diagnosis report.	
	QSA.13.08.01, EP 2	The histopathology laboratory conducts an investigation and takes corrective action on disparities that exist between an initial intraoperative consultation and a report of pathology diagnosis. The disparities and corrective action are documented.	
	QSA.14.01.01, EP 1	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.	
	QSA.14.01.01, EP 2	The laboratory tests immunology test components for reactivity, if applicable. The reactivity results are documented. *Note: Examples of test components that require a test for reactivity include phosphate buffered saline (PBS), sorbent, buffers, complement, fluorescent reagents, and graded controls.*	

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QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	REQUIRED WRITTEN DOCUMENTATION	DATE LAST VERIFIED
	QSA.14.01.01, EP 3	The laboratory determines, in writing, the reactivity patterns of quality control materials for immunology tests before or concurrently with test performance, if applicable.	
	QSA.14.02.01, EP 2	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.	
	QSA.15.01.01, EP 1	The laboratory has written policies and procedures for molecular testing.	
	QSA.15.01.01, EP 4	The laboratory's policies and procedures for molecular testing address the following: Prevention of sample degradation. (See also DC.01.01.01, EP 1)	
	QSA.15.02.01, EP 3	The laboratory performs verification studies for molecular testing. The verification studies are documented.	
	QSA.15.04.01, EP 1	The laboratory has written quality control procedures for each molecular testing system or methodology, including the frequency of quality control testing.	
	QSA.15.04.01, EP 4	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.	
	QSA.15.05.01, EP 1	The laboratory reports for molecular testing include the following information: The testing methodology used.	
	QSA.15.05.01, EP 2	The laboratory reports for molecular testing include the following information: The limitations of the method used.	
	QSA.15.05.01, EP 3	The laboratory reports for molecular testing include the following information: Any interpretation of findings.	
	QSA.15.05.01, EP 4	The laboratory reports for molecular testing include the following information: Any recommendations for additional testing.	
	QSA.15.05.01, EP 5	For assays developed by the laboratory, the laboratory reports for molecular testing include a statement that the assay was developed by the laboratory.	

Quality System Assessment (QSA)… *continued from page 37*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.15.05.01, EP 6	The laboratory reports for molecular testing include the disclaimer required by federal regulations for analytic specific reagents (ASR). *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)."*	
	QSA.16.01.01, EP 1	The laboratory has written policies and procedures for molecular genetic testing that address recommendations for referral for genetic counseling.	
	QSA.16.01.01, EP 2	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. *Note: Additional information might be required to provide for accurate test interpretation and reporting of results.*	
	QSA.16.01.01, EP 3	The laboratory has written policies and procedures for molecular genetic testing that establish turnaround time requirements, as appropriate (for example, results of certain genetic screening tests require that the laboratory establishes an acceptable turnaround time for immediate diagnosis, so that the clinician can diagnose and provide a critical patient recommendation in a timely manner).	
	QSA.16.02.01, EP 1	The laboratory reports for molecular genetic testing include the following information: Indication for testing.	
	QSA.16.02.01, EP 2	The laboratory reports for molecular genetic testing include the following information: List of mutant genes or alleles tested.	
	QSA.16.02.01, EP 3	The laboratory reports for molecular genetic testing include the following information: Any recommendations for referral to a genetic counselor.	
	QSA.16.02.01, EP 4	The laboratory reports for molecular genetic testing include the following information: Detection rate of the test.	
	QSA.16.02.01, EP 5	The laboratory reports for molecular genetic testing include the following information: Standard nomenclature for genes and mutations.	
	QSA.16.02.01, EP 6	The laboratory reports for molecular genetic testing include the following information: Clinical implications of any detected mutation(s).	
	QSA.17.01.01, EP 1	The laboratory has written procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites.	

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QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	REQUIRED WRITTEN DOCUMENTATION	DATE LAST VERIFIED
	QSA.17.02.01, EP 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.	
	QSA.19.01.01, EP 1	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.*	
	QSA.19.02.01, EP 2	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.	
	QSA.19.02.01, EP 3	For in vivo testing: The laboratory documents in department records the following information for radioactive isotopes: - Identity - Date received - Method of receipt - Activity - Storage - Preparation - Handling - Identity of recipients - Dates administered - Disposal	
	QSA.20.01.01, EP 1	The collection information for semen analysis includes the following: Method of collection. The information is documented.	
	QSA.20.01.01, EP 2	The collection information for semen analysis includes the following: Type of specimen container. The information is documented.	
	QSA.20.01.01, EP 3	The collection information for semen analysis includes the following: Days of abstinence. The information is documented.	
	QSA.20.01.01, EP 4	The sample quality for semen analysis includes the following: Collection or transport problems (for example, exposure to temperatures, incomplete specimen). The information is documented.	
	QSA.20.01.01, EP 5	The sample quality for semen analysis includes the following: Time of specimen receipt and analysis. The information is documented.	
	QSA.20.01.01, EP 6	The sample quality for semen analysis includes the following: Abnormalities of liquefaction. The information is documented.	

Quality System Assessment (QSA)… *continued from page 39*

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.20.01.01, EP 7	Semen analysis information includes the following, as applicable: Characteristics of semen specimens (for example, contaminants, erythrocytes, viscosity, appearance, volume, pH). The information is documented.	
	QSA.20.01.01, EP 8	Semen analysis information includes the following, as applicable: Sperm number, motility, and progression. The information is documented.	
	QSA.20.01.01, EP 9	Semen analysis information includes the following, as applicable: Method for sperm morphology classification, including stains, as required. The information is documented.	
	QSA.20.01.01, EP 10	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.	
	QSA.20.01.01, EP 11	Semen analysis information includes the following, as applicable: The evaluation of semen specimens based on approved clinical guidelines.* The results are documented. *Footnote *: Additional information can be found in the current editions of Clinical and Laboratory Standards Institute (CLSI) document POCT10-A (Physician and Nonphysician Provider-Performed Microscopy Testing) and World Health Organization (WHO) Laboratory Manual for the Examination and Processing of Human Semen. (QSA.20.01.01, EP 11)*	
	QSA.21.02.01, EP 2	The virology laboratory documents the following: Cell lines used for the virus being isolated.	
	QSA.21.02.01, EP 3	The virology laboratory documents the following: Control checks of maintenance media.	
	QSA.21.02.01, EP 4	The virology laboratory documents the following: Sterility checks.	
	QSA.21.02.01, EP 5	The virology laboratory documents the following: Reagent checks for toxicity to cell lines.	
	QSA.21.02.01, EP 6	The virology laboratory documents the following: Controls for neutralization tests.	
	QSA.21.02.01, EP 7	The virology laboratory documents the following: Controls for hemagglutination inhibition tests.	

Quality System Assessment (QSA)... continued from page 39

QUALITY SYSTEM ASSESSMENT (QSA)			
	STANDARD AND EP	**REQUIRED WRITTEN DOCUMENTATION**	**DATE LAST VERIFIED**
	QSA.21.02.01, EP 8	The virology laboratory documents the following: Controls for immunoassays.	
	QSA.21.02.01, EP 9	The virology laboratory documents the following: Controls for direct immunofluorescence tests.	
	QSA.21.02.01, EP 10	The virology laboratory documents the following: Controls for indirect immunofluorescence tests.	
	QSA.21.02.01, EP 11	The laboratory performs daily quality control for virology stains. The quality control results are documented.	
	QSA.21.04.01, EP 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.	
	QSA.21.04.01, EP 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.*	
	QSA.21.04.01, EP 3	For serodiagnostic tests for viral disease, the laboratory performs quality control testing, including internal and external controls. The quality control results are documented.	