The Joint Commission E-dition

Effective Date: January 1, 2019

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

Overview:

The goal of quality systems assessment for nonwaived testing is to guide laboratories in achieving accuracy in testing. The requirements in this chapter address processes and activities that help to produce test results that are meaningful, reproducible, useful, valid, dependable, and specific to the needs of the population served. Because the requirements touch on all aspects of quality systems assessment, everyone who works in the laboratory will have a role in supporting the quality systems and thereby helping to produce the best possible results and outcomes.

Numerous resources are available to provide detailed technical guidance, such as resources from the Clinical and Laboratory Standards Institute (CLSI) and the AABB Technical Manual. Laboratories are encouraged to take advantage of the information that is available from these resources.

About This Chapter:

The standards in this chapter outline policies and procedures that produce quality nonwaived test results. Standards that apply to proficiency testing and general quality control testing appear first, followed by standards that apply to specialties and subspecialties. “Specialty” and “subspecialty,” as used in this chapter, refer to units of the laboratory, whether the unit is called a department, a discipline, an area, a service, or a section. Please see the "Waived Testing" (WT) chapter for standards specific to that classification of tests.

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3. Releasing Blood and Blood Components to the Blood Supplier or Another Organization (QSA.05.02.05)

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2. Returning Unused Blood or Blood Components (QSA.05.03.03)

D. Maintaining and Monitoring Temperature

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2. Alarm Systems (QSA.05.04.03)

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H. ABO Group and Rh Type (QSA.05.08.01)

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2. Plasma Products (QSA.05.14.03)

3. Irradiation of Blood and Blood Components (QSA.05.14.05)

4. Leukoreduced Blood and Blood Components (QSA.05.14.07)

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S. Identification of Recipients Potentially Infected with Human Immunodeficiency Virus (HIV) (QSA.05.20.01)

T. Identification of Recipients Potentially Infected with Hepatitis C Virus (HCV) (QSA.05.21.01)

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V. Blood Donation (QSA.05.23.01)

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VIII. Cytology

A. Staff Qualifications and Number (QSA.08.01.01)

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C. Quality Improvement Process (QSA.08.03.01)

D. Workload Limits (QSA.08.04.01)

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IX. Cytogenetics

A. Specimen Processing (QSA.09.01.01)

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C. Quality Control and Testing Procedures (QSA.09.03.01, QSA.09.03.03, QSA.09.03.05, QSA.09.03.07)

D. Stages of Testing and Results (QSA.09.04.01)

E. Abnormal Case Retention (QSA.09.05.01)

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G. Result Reporting and Performance Monitoring (QSA.09.07.01, QSA.09.07.03)

X. Embryology

A. Testing Procedures (QSA.10.01.01)

B. Method Validation (QSA.10.02.01)

C. Record Maintenance (QSA.10.03.01)

D. Media Quality Controls (QSA.10.04.01)

E. Tracking (QSA.10.05.01)

F. Receipt and Transfer of Specimens (QSA.10.06.01)

G. Record Retention (QSA.10.07.01)

XI. Hematology and Coagulation

A. Procedure and Test Parameter Verification (QSA.11.01.01)

B. Coagulation Quality Control Testing (QSA.11.02.01)

XII. Histocompatibility

A. Quality Control Practices and Method Validation (QSA.12.01.01)

B. Recipient and Donor Crossmatching (QSA.12.02.01)

C. Human Leukocyte Antigen Serologic Typing (QSA.12.03.01)

D. Histocompatibility Testing (QSA.12.04.01)

E. Sera Screening (QSA.12.05.01)

F. Mixed Lymphocyte Cultures (QSA.12.06.01)

G. Interlaboratory Reproducibility Validation (QSA.12.07.01)

XIII. Histopathology

A. Specimen Submission and Exception (QSA.13.01.01)

B. Accompanying Information and Diagnoses (QSA.13.02.01)

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G. Specimen Retention (QSA.13.07.01)

H. Surveillance Activities (QSA.13.08.01)

XIV. Immunology and Serology

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D. Quality Control Testing (QSA.15.04.01)

E. Reporting (QSA.15.05.01)

XVI. Molecular Genetics

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(QSA.17.01.01, QSA.17.01.03)

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XVIII. Provider-Performed Microscopy (PPM) Procedures (QSA.18.01.01)

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XX. Andrology (QSA.20.01.01)

XXI. Virology

A. Testing Methodologies (QSA.21.01.01)

B. Cell Controls and Processes (QSA.21.02.01)

C. Record Maintenance (QSA.21.03.01)

D. Serodiagnostic Tests (QSA.21.04.01)

EP Attributes Icon Legend:

CMS	CMS Crosswalk	**D**	Documentation is required
ESP-1	EP applies to Early Survey Option	**NEW**	EP is new or changed as of the selected effective date.

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.01.01.01: The laboratory participates in Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing programs for all regulated analytes.
Note: This participation in the proficiency testing program includes the specialty of Microbiology, and subspecialties of Bacteriology, Mycobacteriology, Mycology, Parasitology, and Virology; the specialty of Diagnostic Immunology, and subspecialties of Syphilis Serology and general Immunology; the specialty of Chemistry, and subspecialties of routine Chemistry, Endocrinology, and Toxicology; the specialty of Hematology (including routine Hematology and Coagulation); the subspecialty of Cytology (limited to gynecologic examinations); and

the specialty of Immunohematology (ABO group and Rho(D) typing, unexpected antibody detection, compatibility testing, and antibody identification).

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

Introduction: Introduction to Standards QSA.01.01.01 Through QSA.01.03.01

Standards QSA.01.01.01 through QSA.01.03.01 apply to proficiency testing for regulated analytes. * Proficiency testing is not required for nonregulated analytes; however, if the laboratory chooses to participate in a proficiency testing program for nonregulated analytes, these standards will also apply.

Footnote *: For the current list of regulated analytes, refer to 42 CFR 493, Subpart H.

Elements of Performance

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 **: For more information on proficiency testing, see http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.801 §493.821 §493.833 §493.853 §493.843 §493.845 §493.803(a) §493.801(a)(1) §493.1407(e)(4) §493.801(a)(2)(i) §493.839	D	ESP-1

§493.849
§493.857

2 The laboratory authorizes the proficiency testing program to release all data required to determine the laboratory's compliance for proficiency testing and makes proficiency testing results available to the public as required in the Public Health Service Act, Section 353(f)(3)(F).

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.801 §493.803(a) §493.801(a)(4) §493.801(a)(4)(i) §493.801(a)(4)(ii)		ESP-1

3 The laboratory uses a proficiency testing program for each regulated analyte performed.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.803(a)		ESP-1

4 The laboratory participates in the same approved proficiency testing program(s) for a full calendar year before designating a different proficiency testing program. If the laboratory designates a different proficiency testing program before the conclusion of a full calendar year, it notifies the Centers for Medicare & Medicaid Services (CMS) or The Joint Commission before this change is made.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.801 §493.801(a)(3)		ESP-1

5 For each specialty, subspecialty, analyte, or test, the laboratory's proficiency testing results meet satisfactory performance criteria in accordance with law and regulation.
Note 1: Satisfactory performance criteria in the Clinical Laboratory

Improvement Amendments of 1988 (CLIA '88), Subpart H, include the following:
- Participating in a proficiency testing event. Failure to participate in a proficiency testing event results in a score of 0 for the testing event.
- Attaining a score of at least 80% for all specialties, subspecialties, or tests, except ABO group and Rho(D) typing and compatibility testing
- Attaining a score of 100% for ABO group and Rho(D) typing or compatibility testing
- Returning proficiency testing results to the proficiency testing provider within the time frame specified by that provider. Failure to return proficiency testing results to the proficiency testing provider within the time frame specified by that provider results in a score of 0 for the testing event.
- Submitting all results on the proficiency testing form. Omission of results could lead to a failure of attaining the score necessary for satisfactory performance.

Note 2: Most proficiency testing events with fewer than 10 participants automatically result in a score of 100% for the event. These challenges are not sufficient for demonstrating that the laboratory has met satisfactory performance criteria. If this occurs, laboratories must supplement with either interlaboratory comparisons as specified under QSA.01.05.01 or non–Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing provided by the instrument manufacturer.

(For proficiency testing events in which the laboratory achieves satisfactory performance but has unacceptable proficiency testing results, see also QSA.01.02.01, EP 2)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.823(a) §493.823(b) §493.825(a) §493.825(b) §493.823(c) §493.829(a) §493.829(b) §493.827(c) §493.829(c) §493.827(a) §493.827(b) §493.825(c) §493.831(a) §493.831(b) §493.831(c) §493.835(a)		ESP-1

§493.835(b)
§493.835(c)
§493.845(a)
§493.845(b)
§493.845(c)
§493.843(d)
§493.843(a)
§493.843(b)
§493.843(c)
§493.841(d)
§493.837(a)
§493.837(b)
§493.837(c)
§493.837(d)
§493.841(a)
§493.841(b)
§493.841(c)
§493.845(d)
§493.859(a)
§493.859(b)
§493.859(c)
§493.861(a)
§493.861(b)
§493.861(c)
§493.859(d)
§493.865(a)
§493.865(b)
§493.863(a)
§493.863(b)
§493.863(c)
§493.865(c)
§493.1407(e)
(4)(ii)
§493.1445(e)
(4)(ii)
§493.851(a)
§493.851(b)
§493.851(c)
§493.851(d)

6 The laboratory's proficiency test performance is successful for each specialty, subspecialty, analyte, or test, as required by law and regulation. Note: Unsuccessful performance is defined in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart H, as a failure to

achieve satisfactory performance for two consecutive testing events or two out of three consecutive testing events.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.803(a) §493.823(e) §493.825(e) §493.827(e) §493.829(e) §493.831(e) §493.835(e) §493.843(f) §493.843(g) §493.841(f) §493.841(g) §493.837(f) §493.837(g) §493.845(f) §493.845(g) §493.861(e) §493.859(f) §493.859(g) §493.865(e) §493.865(f) §493.863(e) §493.851(f) §493.851(g)		ESP-1

7 Individuals who examine gynecologic preparations participate in a Centers for Medicare & Medicaid Services (CMS)–approved proficiency testing program that meets regulatory requirements for variety and frequency of testing and satisfactory performance criteria.
Note 1: For an individual who fails an annual proficiency testing event (less than 90% on a 10-slide proficiency test), the laboratory schedules a retesting event that takes place not more than 45 days after the receipt of the notification of failure. Steps of retesting include the following:
- A 10-slide retest (event #2), performed within 2 hours, in which a score of 90% is acceptable
- For an individual who fails the 10-slide retest (event #2), the laboratory provides remedial training and education in the area of failure and has evidence that all patient gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide proficiency test (event #3), performed within 4 hours, in which a

score of 90% is acceptable.
- An individual who fails the last 20-slide proficiency test (event #3) ceases examining gynecologic slide preparations immediately upon notification of test failures and may not resume examining gynecologic slides until the laboratory has evidence that the individual obtained at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until the individual is retested with another 20-slide proficiency test and scores at least 90%.
- This final cycle continues until the individual successfully participates in another 20-slide proficiency test.

Note 2: Unexcused absence by an individual for a retest will result in a test failure.

(See also QSA.01.02.01, EP 5)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.855 §493.803(a) §493.803(b) §493.855(a) §493.855(a) §493.855(b) §493.855(b) §493.855(b) §493.855(b) §493.1289(b) §493.1451(c)(5) §493.855(b)(1) §493.855(b)(1) §493.855(b)(2) §493.855(b)(2) §493.855(b)(2) §493.855(b)(2) §493.855(b)(3) §493.855(b)(3) §493.855(b)(3) §493.855(c)		ESP-1

Program: Laboratory

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QSA.01.02.01: The laboratory maintains records of its participation in a proficiency testing program.

Rationale: The laboratory uses results outside acceptable ranges as an opportunity to correct problems, educate staff, prevent recurrence of problems, and improve the quality of services it provides.
Introduction: Introduction to Standards QSA.01.01.01 Through QSA.01.03.01
Standards QSA.01.01.01 through QSA.01.03.01 apply to proficiency testing for regulated analytes. * Proficiency testing is not required for nonregulated analytes; however, if the laboratory chooses to participate in a proficiency testing program for nonregulated analytes, these standards will also apply.

Footnote *: For the current list of regulated analytes, refer to 42 CFR 493, Subpart H.

Elements of Performance

1 The laboratory analyzes and reports results for each testing period during the two years prior to survey for accreditation by The Joint Commission. Note: The laboratory may consider retaining records for a minimum of five years to address potential Centers for Medicare & Medicaid Services (CMS)–required follow-up for repeated unsuccessful proficiency testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1495(b)(2) §493.1425(b)(2) §493.865(d)(2) §493.863(d)(2) §493.859(e)(2) §493.861(d)(2) §493.845(e)(2) §493.837(e)(2) §493.841(e)(2) §493.843(e)(2) §493.835(d)(2) §493.831(d)(2) §493.825(d)(2) §493.829(d)(2) §493.827(d)(2) §493.823(d)(2) §493.1200(c) §493.851(e)(2)		ESP-1

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; see Note 2)
-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 1: 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.
Note 2: Consideration may be given to laboratories failing to participate in a testing event when all the following occur:
- Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results
- The laboratory notifies The Joint Commission and the proficiency testing program provider within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples
- The laboratory participated in the previous two proficiency testing events

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1230 §493.851(c)(1) §493.851(c)(2) §493.851(c)(3) §493.1236(a) §493.1239(b) §493.1239(c) §493.1236(d) §493.1236(b)(2) §493.865(d)(1) §493.865(d)(2) §493.863(d)(1) §493.863(d)(2) §493.863(b)(1) §493.863(b)(2) §493.863(b)(3) §493.865(b)(1) §493.865(b)(2)	D	ESP-1

§493.865(b)(3)
§493.859(e)(1)
§493.859(e)(2)
§493.861(d)(1)
§493.861(d)(2)
§493.861(b)(1)
§493.861(b)(2)
§493.861(b)(3)
§493.859(c)(1)
§493.859(c)(2)
§493.859(c)(3)
§493.845(e)(1)
§493.845(e)(2)
§493.841(c)(1)
§493.841(c)(2)
§493.841(c)(3)
§493.837(e)(1)
§493.837(e)(2)
§493.837(c)(1)
§493.837(c)(2)
§493.837(c)(3)
§493.841(e)(1)
§493.841(e)(2)
§493.843(c)(1)
§493.843(c)(2)
§493.843(c)(3)
§493.843(e)(1)
§493.843(e)(2)
§493.845(c)(1)
§493.845(c)(2)
§493.845(c)(3)
§493.835(d)(1)
§493.835(d)(2)
§493.835(b)(1)
§493.835(b)(2)

3 The laboratory director or technical supervisor reviews each proficiency testing program report, even if testing events are satisfactory. The review is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1230 §493.1236(a)	D	ESP-1

§493.1236(d)
§493.865(d)(2)
§493.863(d)(2)
§493.859(e)(2)
§493.861(d)(2)
§493.845(e)(2)
§493.837(e)(2)
§493.841(e)(2)
§493.843(e)(2)
§493.835(d)(2)
§493.831(d)(2)
§493.825(d)(2)
§493.829(d)(2)
§493.827(d)(2)
§493.823(d)(2)
§493.1407(e)
(4)(iii)
§493.1445(e)
(4)(iii)
§493.1200(c)
§493.851(e)(2)

4 The laboratory retains proficiency testing records for at least two years from the date of participation for the following proficiency testing events:
- Each proficiency testing result
- Test handling
- Preparation
- Processing
- Examination
- Each step in the testing
- Signed attestation statement(s) provided by the proficiency program
- A copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results
- Corrective action taken

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.1230 §493.801(b)(5) §493.1236(d) §493.1495(b)(2) §493.1425(b)(2) §493.1105(a)(4)		ESP-1

§493.865(d)(2)
§493.863(d)(1)
§493.863(d)(2)
§493.859(e)(2)
§493.861(d)(1)
§493.861(d)(2)
§493.845(e)(2)
§493.837(e)(2)
§493.841(e)(2)
§493.843(e)(2)
§493.835(d)(2)
§493.831(d)(2)
§493.825(d)(2)
§493.829(d)(2)
§493.827(d)(2)
§493.823(d)(2)
§493.1407(e)
(4)(iv)
§493.1445(e)
(4)(iv)
§493.851(e)(2)

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1230 §493.855 §493.855(b) §493.1236(d) §493.1451(c)(5) §493.855(b)(2) §493.825(d)(2) §493.827(d)(2) §493.855(c) §493.1200(c)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.01.03.01: The laboratory has a process for handling and testing proficiency testing samples.

Rationale: Not applicable.

Introduction: Introduction to Standards QSA.01.01.01 Through QSA.01.03.01
Standards QSA.01.01.01 through QSA.01.03.01 apply to proficiency testing for regulated analytes. * Proficiency testing is not required for nonregulated analytes; however, if the laboratory chooses to participate in a proficiency testing program for nonregulated analytes, these standards will also apply.

Footnote *: For the current list of regulated analytes, refer to 42 CFR 493, Subpart H.

Elements of Performance

1 The laboratory has written policies and procedures for testing proficiency testing samples.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory tests proficiency testing samples according to its policies and procedures.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The laboratory performs proficiency testing for each test method used as the primary method under each Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate for each regulated analyte. (See also QSA.02.08.01, EP 1)
Note: Proficiency testing for secondary analyzers is not required.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.801(b)(6) §493.1495(b)(2)		ESP-1

		§493.1425(b)(2) §493.1407(e) (4)(i)		

4 Proficiency testing samples are tested along with the laboratory's regular patient testing workload by staff who perform the laboratory's testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.801(b)(1) §493.1495(b)(2) §493.1425(b)(2) §493.1407(e) (4)(i) §493.1445(e) (4)(i)		ESP-1

5 The laboratory rotates proficiency testing samples among the staff who perform patient testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.801(b)(1) §493.1495(b)(2) §493.1425(b)(2) §493.1407(e) (4)(i) §493.1445(e) (4)(i)		ESP-1

6 The laboratory’s staff tests the proficiency testing samples the same number of times that they test patient samples.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.801(b)(2) §493.1495(b)(2) §493.1407(e) (4)(i)		ESP-1

		§493.1445(e) (4)(i)		

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).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.1230 §493.801(b)(1) §493.801(b)(5) §493.1236(a) §493.1236(d) §493.1495(b)(2) §493.1425(b)(2) §493.1105(a)(4) §493.1445(e) (4)(iv) §493.801(b)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.01.04.01: The laboratory performs its proficiency testing independent of other laboratories.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory does not send the proficiency testing samples to another laboratory for analysis. (See also APR.01.02.01, EP 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.1407(e) (4)(i) §493.1445(e) (4)(i) §493.801(b)(4)		ESP-1

2 Communication between laboratories (interlaboratory and laboratories with multiple sites or separate locations) about the results of proficiency testing samples does not occur until after the date by which the laboratory must report proficiency testing results to the program for the testing event.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.801(b)(3) §493.1407(e) (4)(i) §493.1445(e) (4)(i) §493.801(b)(4)		ESP-1

3 The laboratory notifies the Centers for Medicare & Medicaid Services (CMS) and The Joint Commission of proficiency testing samples received from another laboratory for testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.801 §493.1407(e) (4)(i) §493.1445(e) (4)(i) §493.801(b)(4)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.01.05.01: The laboratory evaluates 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.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.801 §493.1230 §493.1236(d) §493.1359(b)(2) §493.1236(c)(1) §493.1236(c)(2) §493.1236(b)(1) §493.801(a)(2)(ii)	D	ESP-1

2 The laboratory performs verification testing at least every six months. The verification is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.801 §493.1230 §493.1236(d) §493.1359(b)(2) §493.1236(c)(1) §493.1236(c)(2) §493.1236(b)(1) §493.801(a)(2)(ii)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1230 §493.1236(d) §493.1359(b)(2) §493.1236(c)(1) §493.1236(c)(2)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.01.01: The laboratory verifies tests, methods, and instruments in order to establish quality control procedures.
Note: This standard also applies to instruments on loan when the original instrument is under repair.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 When adding or replacing an unmodified US 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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1256(a) §493.1253(a) §493.1425(b)(3) §493.1251(b)(6) §493.1253(b)(1)(i) §493.1253(b)(1)(i)(A) §493.1253(b)(1)(i)(B) §493.1253(b)(1)(i)(C) §493.1253(c)	D	ESP-1

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 US 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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1256(a) §493.1253(a) §493.1253(b)(2)	D	ESP-1

		§493.1251(b)(6) §493.1253(b) (2)(i) §493.1253(b) (2)(ii) §493.1253(b) (2)(iii) §493.1253(b) (2)(iv) §493.1253(b) (2)(v) §493.1253(b) (2)(vi) §493.1253(b) (2)(vii) §493.1253(c)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(b)(4)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1253(a) §493.1451(b)(4) §493.1251(b)(10) §493.1253(b) (2)(vi) §493.1253(b) (1)(ii)	D	ESP-1

§493.1282(b)
(1)(iii)
§493.1253(c)

5 The laboratory performs verifications for each new test, method, or instrument prior to reporting patient results. These verifications are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1451(b)(4) §493.1253(c)	D	ESP-1

6 The laboratory's verification includes the establishment of written quality control procedures for each testing system or methodology.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

7 The laboratory's quality control procedure for each testing system or methodology includes the following:
- The range of quality control values used
- The frequency of quality control testing
- Adherence to the manufacturer's recommendations
- The predicted reliability based on history
- The specialty and subspecialty requirements included in this chapter

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(b)		

8 Over time, the laboratory monitors the accuracy and precision of test performance that may be influenced by changes in the following:
- Test system performance
- Environmental conditions
- Variance in operator performance

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1256(c)(2)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.02.01: The laboratory performs calibration and recalibration.

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

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(a) §493.1253(b)(3) §493.1255(a)(1) §493.1251(b)(5) §493.1251(b)(8) §493.1255(a)(2)(ii)	D	ESP-1

2 The laboratory performs calibration using materials traceable to a national reference standard, when available.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(a) §493.1255(a)(1) §493.1255(a)(2) §493.1255(a) (2)(i)		ESP-1

3 If quality control materials are used for calibration, the laboratory uses different lot numbers than those used for routine quality control testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(a) §493.1256(d)(9) §493.1255(a) (2)(i)		ESP-1

4 The laboratory follows its procedure for calibration. The calibration performance is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(a) §493.1495(b)(3) §493.1255(a)(1) §493.1255(a)(2) §493.1253(c)	D	ESP-1

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(a) §493.1255(b) §493.1255(b)(1)	D	ESP-1

§493.1255(b)(2)
§493.1255(a)(1)
§493.1255(a)(2)
§493.1255(a)(3)
§493.1251(b)(8)

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(b)(8)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.03.01: The laboratory performs calibration verification.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1267(a) §493.1255(b) §493.1255(b)(1) §493.1255(b)(2) §493.1255(a)(3)	D	ESP-1

		§493.1251(b)(5) §493.1255(b) (2)(i)		

2 The laboratory tests the reportable range of results during the calibration verification process, including a minimal value, a midpoint value, and a maximum value based on the manufacturer's directions and instrument history.
Note: The Joint Commission does not require the purchase of commercial linearity kits to meet this requirement. Quality control materials, previously tested proficiency testing samples with known results, and calibration materials are acceptable to use for calibration verification.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(b) §493.1255(b)(2) §493.1251(b)(6) §493.1255(b) (2)(ii)		ESP-1

3 Calibration verification is performed every six months.
Note 1: Semiannual calibration verification is not required when the laboratory performs calibration at least once every six months using three or more levels of calibration materials that include a low, mid, and high value.
Note 2: For automated cell counters, calibration verification requirements are met if the laboratory follows manufacturer's instructions for instrument operation and the laboratory tests two levels of quality control materials each day of patient testing, provided the laboratory's quality control criteria are met.
Note 3: Calibration verification is not required on instruments that are manufacturer-calibrated and/or tests that are considered non-quantitative. This exception only applies to those instruments that cannot be calibrated after implementation.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(b) §493.1255(b)(2) §493.1255(b)(3)		

4 Calibration verification is performed whenever the following events occur:
- A complete change of reagents for a procedure is introduced, unless it is demonstrated that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.
- Major preventive maintenance is performed, or critical parts are replaced that may influence test performance.
- Quality control results indicate that there may be a problem with the test system.
- An environmental change occurs, including instrument relocation.
- An instrument has been replaced.
- Quality control materials reflect an unusual trend or shift or are outside the laboratory's acceptable limits, and other means of assessing and correcting unacceptable quality control values fail to identify and correct the problem.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1255(b) §493.1282(b)(2) §493.1255(b)(2) §493.1255(b)(3) §493.1255(a)(3) §493.1251(b)(8) §493.1255(b) (3)(i) §493.1255(b) (3)(ii) §493.1255(b) (3)(iii) §493.1255(b) (3)(iv)		ESP-1

5 The laboratory follows its procedure for calibration verification. The calibration verification performance is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1267(a) §493.1255(b) §493.1425(b)(3) §493.1255(b)(2) §493.1253(c)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.04.01: The laboratory develops and implements an individualized quality control plan (IQCP) in an eligible specialty or subspecialty.

Rationale: Not applicable.

Introduction: Introduction to Standard QSA.02.04.01

The Centers for Medicare & Medicaid Services (CMS) implemented a voluntary quality control option for clinical laboratories on January 1, 2016. The individualized quality control plan (IQCP) allows laboratories to customize quality control policies and procedures based on a risk assessment of their health care setting. IQCP applies to all specialties and subspecialties except pathology, and replaces the previous equivalent quality control (EQC) procedures.

There are additional requirements that are eligible for IQCP located in the QSA chapter of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing. A list of all IQCP-eligible requirements is included in Appendix C: Individualized Quality Control Plan–Eligible Requirements, and the IQCP-eligible requirements can be filtered and displayed in the E-dition. Laboratories that choose to implement IQCP are still required to follow all other non-IQCP-eligible Joint Commission accreditation requirements.

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(1)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.06.01: Each laboratory specialty and subspecialty has a quality control policy.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 A written quality control policy exists for each specialty and subspecialty offered as part of pathology and clinical laboratory services.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1256(b) §493.1451(c)(4) §493.1451(b)(4) §493.1253(b)(3) §493.1256(d)(1) §493.1256(d)(2) §493.1253(c)	D	ESP-1

2 The quality control policy defines the number, type, and frequency of quality control materials according to the following:
- Manufacturers' recommendations
- Performance specifications verified or established by the laboratory
- Specialty and subspecialty requirements found in this chapter for quality control testing

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1256(b) §493.1253(b)(3) §493.1256(d)(2) §493.1271(a)(1) §493.1251(b)(7)		ESP-1

3 The quality control policy includes the quality control criteria for acceptability for each test.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(b) §493.1253(b)(3) §493.1262(b)(1) §493.1263(b)(1) §493.1271(a)(1) §493.1251(b)(7)		ESP-1

4 The quality control policy includes acceptable quality control limits and reportable ranges for each test.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(b) §493.1253(b)(3) §493.1263(b)(1) §493.1251(b)(7)		ESP-1

5 Quality control limits are strict enough to promote precision and accuracy for reliable patient test results.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(b) §493.1253(b)(3)		ESP-1

6 Quality control limits and reportable ranges provide results with meaningful clinical applications.

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

Note 2: For manual tests that do not lend themselves to commercial quality control methods, alternative procedural controls with established limits may be used to verify the results. For example, manual reticulocyte counts could be verified by a specified percentage agreement of the results from two slides.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(b) §493.1253(b)(3)		ESP-1

7 The laboratory's quality control policy is accessible to staff.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.07.01: The laboratory has its own quality control ranges with valid statistical measurements for each procedure.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(10) §493.1261(b)(2) §493.1263(b)(1) §493.1256(d) (10)(i)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(10) §493.1256(d) (10)(i)	D	ESP-1

3 If the laboratory's calculated control ranges reflect variance from previously established ranges, the laboratory investigates, resolves discrepancies, and provides the rationale for its decision.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(10) §493.1256(d)(10)(i)		ESP-1

4 The stated values of an assayed control material may be used as the target values, provided the stated values correspond to the methodology and instrumentation used by the laboratory and are verified by the laboratory through repetitive testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(10) §493.1256(d)(10)(ii)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(10) §493.1256(d)(10)(ii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1256(d)(10) §493.1256(d) (10)(ii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(10) §493.1256(d) (10)(i) §493.1256(d) (10)(iii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(10) §493.1256(d) (10)(i) §493.1256(d) (10)(iii)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.08.01: The laboratory performs correlations to evaluate the results of the same test performed with different methodologies or instruments or at different locations.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1281(a) §493.1281(c)	D	ESP-1

2 The laboratory performs correlations at least once every six months. The correlations are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1281(a) §493.1281(c)	D	

3 The laboratory defines the tolerance limits for agreement when performing comparisons of multiple instruments or different methods of the same test or assay.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1281(a)		ESP-1

4 The laboratory defines the target value and range of analytic values for which the control limits used are acceptable for multiple instrument comparison.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1281(a)		ESP-1

5 The laboratory informs the ordering practitioner of clinically significant differences in correlation results between analytes when the same analytes are tested using different methodologies or instruments or at different locations.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1291(e)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.09.01: The laboratory performs quality control testing in the same manner as it performs patient testing.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 Only staff who perform patient testing perform quality control testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1425(b)(3)		ESP-1

2 Staff who perform patient testing test quality control materials in the same manner as they test patient specimens.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1262(b) §493.1425(b)(3) §493.1256(d)(8)		

3 The laboratory rotates quality control testing among staff who perform patient testing.
Note: Not all staff are required to perform quality control testing each day they perform patient testing, but all staff are included in the quality control testing over time.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1425(b)(3) §493.1256(d)(7)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.10.01: The laboratory performs quality control testing to monitor the accuracy and precision of the analytic process.
Note: This standard is considered in combination with the specialty and subspecialty requirements found in this chapter (for example, blood gas testing requires that the combination of controls and calibrators used each day of testing be rotated to check normal, alkalosis, and acidosis levels).

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory uses quality control materials that challenge each step of the testing process. The quality control results are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(a) §493.1278(g) §493.1276(e) §493.1495(b)(3) §493.1425(b)(3) §493.1445(e)(5) §493.1407(e)(6) §493.1256(d)(2)	D	ESP-1

2 The laboratory uses quality control materials at levels and a frequency consistent with manufacturers' recommendations.
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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1278(g) §493.1256(d)(2)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1267(c) §493.1267(d) §493.1256(g) §493.1278(g) §493.1256(d) (3)(i)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1262(a) §493.1256(g) §493.1278(g) §493.1256(d) (3)(ii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1278(g) §493.1256(d) (3)(iii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1262(a) §493.1256(g) §493.1256(e)(2)	D	ESP-1

7 The laboratory uses a negative and positive reactivity control material to check fluorescent and immunohistochemical stains for intended reactivity each time the procedure is performed. The quality control results are documented. (See also QSA.13.06.01, EP 2)
Note: For polymer-based immunohistochemical methods, a negative control is not required.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(e)(3)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(d) (3)(iv)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(d)(5)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(d)(4) §493.1256(d)(4)(i) §493.1256(d)(4)(ii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(h) §493.1278(g)	D	ESP-1

12 The laboratory does not report individual patient results unless quality control criteria are met.

EP Attributes

New	FSA	CLIA	DOC	ESP

§493.1263(b)
§493.1262(b)
§493.1256(f)
§493.1261(b)
§493.1256(a)
§493.1413(b)
§493.1463(b)(2)
§493.1451(b)(6)
§493.1445(e)(7)
§493.1445(e)(7)
§493.1413(b)(6)
§493.1407(e)(6)
§493.1407(e)(7)
§493.1407(e)(7)
§493.1254(a)(2)
§493.1261(b)(2)
§493.1262(b)(3)
§493.1263(b)(3)
§493.1254(b)
(2)(i)
§493.1200(c)

13 The laboratory does not report individual patient results that exceed the reportable range.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP

§493.1256(g) §493.1495(b)(3) §493.1407(e)(6) §493.1256(d)(6)	D

15 For quantitative tests, the laboratory tests quality control materials across the clinically significant values of the reportable test results during a 24-hour period.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.10.03: The laboratory uses positive control material to verify the performance of flow cytometry analyses.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	

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 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(b)	D	

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 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(2)	D	

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 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(d)(2)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.11.01: The laboratory conducts surveillance of patient results and related records as part of its quality control program.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1239(c) §493.1281(c) §493.1289(a) §493.1289(c) §493.1299(a) §493.1463(a)(4) §493.1445(e)(5) §493.1445(e)(6) §493.1407(e)(5) §493.1407(e)(5) §493.1281(b)(1)	D	ESP-1

§493.1281(b)(2)
§493.1281(b)(3)
§493.1281(b)(4)
§493.1281(b)(5)
§493.1256(c)(1)

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1289(a) §493.1445(e)(6) §493.1407(e)(5) §493.1407(e)(5) §493.1256(c)(1) §493.1251(b)(1)		ESP-1

3 The general supervisor performs or delegates to technical staff the daily supervisory review of patient results. The supervisory review is documented. (See also LD.04.05.01, EP 1; QSA.02.02.01, EP 5)
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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1239(c) §493.1281(c) §493.1289(a) §493.1289(c) §493.1299(a) §493.1463(b) §493.1463(c) §493.1495(c) §493.1495(b)(7)	D	

		§493.1463(a)(3) §493.1463(a)(4) §493.1281(b)(1) §493.1281(b)(2) §493.1281(b)(3) §493.1281(b)(4) §493.1281(b)(5)		

4 For high-complexity testing performed by trained high school graduates qualified under 42 CFR 493.1489(b)(5), the laboratory director, general supervisor, or technical supervisor reviews all results within 24 hours of patient testing. (See also QSA.02.02.01, EP 5)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1289(a) §493.1289(c) §493.1463(c) §493.1495(c) §493.1495(b)(7) §493.1463(a)(3)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1239(c) §493.1289(a) §493.1289(c) §493.1299(a)	D	

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)

EP Attributes

New	FSA	CLIA	DOC	ESP

- Quality System Assessment	§493.1239(c) §493.1289(a) §493.1289(c) §493.1299(a) §493.1291(a)(1) §493.1281(b)(2)	D

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1239(c) §493.1289(a) §493.1289(c)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.12.01: The laboratory investigates and takes corrective action for deficiencies identified through quality control surveillance.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures to monitor, assess, and correct problems identified in the preanalytic, analytic, and postanalytic processes.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1230 §493.1240 §493.1234 §493.1239(a) §493.1249(a)	D	ESP-1

§493.1249(b)
§493.1249(c)
§493.1256(a)
§493.1274(g)
§493.1282(a)
§493.1289(a)
§493.1289(c)
§493.1299(a)
§493.1495(b)(4)
§493.1495(b)(6)
§493.1451(b)(5)
§493.1425(b)(4)
§493.1425(b)(6)
§493.1445(e)(5)
§493.1407(e)(5)
§493.1407(e)(5)
§493.1256(c)(1)
§493.1200(a)

2 The laboratory's policies and procedures include the identification of alternatives for providing patient testing, including backup systems and alternative facilities (for example, reference laboratories).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(b)(14)		ESP-1

3 The laboratory follows its policies and procedures to monitor, assess, and correct problems identified in preanalytic, analytic, and postanalytic processes.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1240		ESP-1
		§493.1239(a)		
		§493.1249(a)		
		§493.1249(b)		
		§493.1249(c)		
		§493.1256(a)		
		§493.1282(a)		
		§493.1289(a)		
		§493.1289(c)		
		§493.1299(a)		

§493.1495(b)(4)
§493.1495(b)(6)
§493.1451(b)(5)
§493.1425(b)(4)
§493.1425(b)(6)
§493.1445(e)(7)
§493.1200(a)

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.
- Communication breaks down between the laboratory and an authorized person who orders or receive the test.
- Other incidents of unsatisfactory specimen collection, testing, or reporting are identified.
The corrective action is documented. (See also PI.01.01.01, EP 17)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1234 §493.1239(b) §493.1239(c) §493.1249(a) §493.1249(b) §493.1249(c) §493.1282(b) §493.1289(a) §493.1289(c) §493.1495(b)(4) §493.1495(b)(6) §493.1425(b)(4) §493.1425(b)(6) §493.1445(e)(7) §493.1282(b)(2) §493.1282(b)(3) §493.1282(b)(1) §493.1251(b)(8)	D	ESP-1

		§493.1282(b)(1)(i) §493.1282(b)(1)(ii) §493.1282(b)(1)(iii)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1239(b) §493.1249(b) §493.1256(a) §493.1289(a) §493.1289(b) §493.1289(c) §493.1299(b) §493.1299(c) §493.1282(b)(2) §493.1251(b)(8)	D	ESP-1

6 For each quality control result outside acceptable limits, the laboratory takes corrective action before patient testing is resumed.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1289(a) §493.1289(c) §493.1413(b) §493.1463(b)(2) §493.1451(b)(6) §493.1413(b)(6) §493.1251(b)(8)		

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1282(b) §493.1289(a) §493.1289(c) §493.1282(b)(2) §493.1282(b)(1) §493.1251(b)(8) §493.1282(b) (1)(i) §493.1282(b) (1)(iii)	D	ESP-1

8 As part of the corrective action, the laboratory performs the following:
- Review of the effectiveness of the corrective action
- Revision of policies and procedures to prevent recurrence
- Discussion of the investigation and corrective action with affected staff

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1239(b) §493.1249(b) §493.1289(a) §493.1289(b) §493.1289(c) §493.1299(b) §493.1299(c) §493.1495(b)(6) §493.1425(b)(6) §493.1407(e)(5) §493.1407(e)(5) §493.1282(b)(2) §493.1251(b)(8)		ESP-1

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, EPs 5 and 6)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1239(b) §493.1249(b) §493.1289(a)	D	

§493.1289(b)
§493.1289(c)
§493.1299(b)
§493.1299(c)
§493.1291(k)
§493.1291(k)(1)
§493.1291(k)(2)
§493.1291(k)(3)
§493.1282(b)(2)
§493.1251(b)(8)

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1289(a) §493.1291(k) §493.1291(k)(2) §493.1282(b)(2)	D	

11 As part of the corrective action, the laboratory retains an exact copy of the original and corrected paper or electronic reports.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1289(a) §493.1291(k) §493.1291(k)(2) §493.1291(k)(3)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.13.01: The laboratory stores, prepares, evaluates, and tracks reagents.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for storing, preparing, evaluating, and tracking reagents.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1252(b) §493.1359(b)(2) §493.1252(c)(2) §493.1271(a)(1) §493.1251(b)(4)	D	ESP-1

2 The laboratory stores reagents as described on the label or by the manufacturer.
Note: Reagents include, but are not limited to, quality control materials, calibration materials, standards, substrates, water, alcohols, diluents, and other test kit components.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1359(b)(2)		ESP-1

3 The laboratory reconstitutes reagents that are not prepackaged as indicated on the label or by the manufacturer.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1359(b)(2) §493.1251(b)(4)		ESP-1

4 The laboratory evaluates kits, including reagents, standards, diluents, and other ancillary reagents. The evaluation is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1359(b)(2) §493.1256(e) (4)(ii) §493.1274(h)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1263(a) §493.1256(g) §493.1273(a) §493.1273(f) §493.1359(b)(2) §493.1256(e)(1) §493.1271(a)(1) §493.1274(h)	D	ESP-1

6 The laboratory documents the lot numbers of reagents in a manner that permits tracking when specific reagents are in use.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1273(f) §493.1359(b)(2) §493.1271(a)(1)	D	ESP-1

7 The laboratory does not interchange components of reagent kits of different lot numbers unless permitted by the manufacturer.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1252(e) §493.1359(b)(2) §493.1274(b)(1)		ESP-1

8 The laboratory uses kits, reagents, media, and supplies according to manufacturers' specifications. (See also QSA.02.14.01, EP 5)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1359(b)(2) §493.1274(b)(1) §493.1256(e)(5) §493.1271(a)(1) §493.1256(e) (4)(iii)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1252(d) §493.1359(b)(2) §493.1252(b)(1)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.02.14.01: The laboratory labels reagents and solutions completely and accurately.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for labeling reagents and solutions.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1252(c) §493.1359(b)(2) §493.1252(c)(3) §493.1252(c)(4)	D	ESP-1

2 The policy for labeling reagents and solutions includes the following:
- Identity
- Strength
- Titer
- Concentration
- Cautionary and accessory information
- Preparation and expiration dates

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1273(f) §493.1359(b)(2) §493.1252(c)(1) §493.1252(c)(3) §493.1252(c)(4)		ESP-1

3 The laboratory identifies reagents that could pose a hazard for staff safety. Note: For more information on hazardous materials and waste, please refer to the "Environment of Care" (EC) chapter, EC.02.02.01.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1359(b)(2)		ESP-1

4 The laboratory does not use deteriorated or substandard reactivity materials.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1252(d) §493.1359(b)(2) §493.1271(a)(1)		ESP-1

5 The laboratory does not use expired reagents or solutions. (See also QSA.02.13.01, EP 8)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1252(d) §493.1273(f) §493.1359(b)(2) §493.1274(b)(1) §493.1271(a)(1)		ESP-1

6 The laboratory follows its policies and procedures for labeling reagents and solutions.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1359(b)(2)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.03.01.01: A pathologist or a qualified physician performs or supervises each autopsy.
Note: This standard does not apply to autopsies conducted for forensic purposes only.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.)

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

2 A pathologist qualified in anatomic pathology makes all microscopic interpretations related to autopsies.

EP Attributes

New	FSA	CLIA	DOC	ESP

3 A pathologist prepares a diagnostic report of each autopsy performed.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.03.02.01: Refrigeration is available for the storage and preservation of cadavers.

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

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.03.03.01: Clinical autopsy results performed within or outside the organization are included in the patient's clinical record.
Note: This standard does not apply to autopsies conducted for forensic purposes only.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP

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

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.04.01.01: The laboratory tests chemical and biological solutions, reagents, and antisera used in bacteriology, mycobacteriology, and mycology for reactivity and deterioration.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory tests and inspects chemical and biological solutions, reagents, and antisera used for identification of bacteria, mycobacteria, and fungi for deterioration.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1262(a) §493.1256(e)(1)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1262(c) §493.1263(c) §493.1262(a) §493.1261(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1262(c) §493.1263(c) §493.1262(a) §493.1256(g)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1263(c) §493.1263(b) §493.1262(b) §493.1256(g) §493.1256(e)(1)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1262(c) §493.1263(c) §493.1262(b) §493.1261(a) §493.1256(g) §493.1256(e)(1) §493.1261(a)(1)	D	

6 The laboratory performs quality controls each time a new batch, shipment, and lot number are prepared or opened 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, the laboratory develops an individualized quality control plan (IQCP) or meets the requirements in Standard QSA.02.10.01.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1263(c) §493.1263(b) §493.1261(a)	D	ESP-1

		§493.1256(g) §493.1256(e)(1)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1263(c) §493.1262(b) §493.1261(a) §493.1256(g) §493.1256(e)(1) §493.1261(a)(3)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.04.02.01: The laboratory verifies antibacterial, antimycobacterial, and antifungal susceptibility testing systems with approved reference organisms.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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 https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1262(c) §493.1263(c) §493.1263(b) §493.1262(b) §493.1256(g) §493.1261(b) §493.1261(b)(1) §493.1261(b)(2) §493.1262(b)(2) §493.1262(b)(3) §493.1263(b)(2) §493.1263(b)(3)	D	ESP-1

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. (For more information on developing an individualized quality control plan, refer to Standard QSA.02.04.01.) The quality control results are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1263(c) §493.1263(b) §493.1256(g) §493.1261(b) §493.1261(b)(1) §493.1263(b)(2)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1263(c) §493.1263(b) §493.1256(g) §493.1261(b) §493.1261(b)(1) §493.1263(b)(2)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1262(c) §493.1262(b) §493.1256(g) §493.1262(b)(2)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.04.03.01: The laboratory uses quality controls to test stains in bacteriology, mycobacteriology, and mycology.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory tests staining procedures for intended reactivity by using smears of microorganisms with predictable staining characteristics. The reactivity is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1261(c) §493.1262(c) §493.1263(a) §493.1262(a) §493.1256(g) §493.1256(e)(2) §493.1256(e)(3)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1256(g) §493.1261(a)(2)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1262(c) §493.1256(g) §493.1256(e)(2)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1261(c) §493.1262(c) §493.1256(g) §493.1256(e)(2) §493.1256(e)(3)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.04.04.01: The laboratory tests each type of microbiological culture media with selected organisms to confirm the required growth characteristics.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(e)(4)(ii)		ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(e)(4)(iii)	D	ESP-1

3 The laboratory or the preparer performs quality control testing on new batches, lot numbers, and 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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(e)(4)(i)	D	ESP-1

4 The laboratory maintains documentation of microbiological culture media quality control results performed by the manufacturer.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(e)(4)(ii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g)	D	ESP-1

6 The laboratory reports deterioration in the microbiological culture media to the manufacturer. This report is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.04.05.01: The laboratory uses equipment that supports the recovery of bacteria, mycobacteria, and fungi.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 The laboratory uses aerosol-free centrifuge equipment (for example, tubes, carriers, cups) for mycobacteriology procedures that require centrifugation.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(d)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.04.06.01: The laboratory has methods for the identification of bacteria, mycobacteria, and fungi.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)	D	ESP-1

2 The laboratory collaborates with the medical staff to develop policies and procedures for reporting antibiotic susceptibility patterns in organisms from potential sites of infection.

EP Attributes

New	FSA	CLIA	DOC	ESP

3 The laboratory reports the results of acid-fast stains, both positive and negative, within 24 hours of specimen receipt.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1291(g)		

4 The laboratory maintains stock cultures of reference organisms.

EP Attributes

New	FSA	CLIA	DOC	ESP

5 The laboratory follows its policies and procedures to isolate and identify bacteria, mycobacteria, and fungi.

EP Attributes

New	FSA	CLIA	DOC	ESP

§493.1251(a)

6 All stool specimens from patients diagnosed with acute community-acquired diarrhea are simultaneously cultured for O157 Shiga toxin-producing Escherichia coli (STEC) on selective and differential agar and assayed for non-O157 STEC with a test that detects Shiga toxins or the genes encoding these toxins.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.04.07.01: The laboratory has written policies and procedures for the collection, transport, processing, and interpretation of blood cultures.

Rationale: A blood culture is a specimen of blood submitted to the laboratory to detect the presence of microorganisms. A blood culture is the fundamental laboratory test used to diagnose sepsis or systemic inflammatory response syndrome (SIRS) plus infection. Rapid, accurate diagnosis of sepsis optimizes antimicrobial therapy, improves clinical outcomes, and reduces health care costs.

Introduction: Not applicable

Elements of Performance

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 (Principles and Procedures for Blood Cultures).

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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 35°C
- Twice daily for days one and two
- Daily for days three to seven
The results are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

3 The laboratory establishes guidelines for the collection, transport, and processing of blood cultures to minimize contamination and support infection prevention and control activities.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.01.01: The laboratory has written policies and procedures for the blood transfusion service.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(a) §493.1271(b)	D	ESP-1

2 The policies and procedures for the blood transfusion service are current and are revised whenever standards of practice change.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

3 The policies and procedures for the blood transfusion service are available to staff involved in transfusion services.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion		D	ESP-1

5 The transfusion service director has oversight of policies, processes, and procedures related to the blood transfusion service, including blood administration.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1407		ESP-1

6 The laboratory's written policies and procedures for administration of outpatient transfusions include instructions for monitoring adverse patient reactions after release from direct medical observation.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d)		ESP-1

7 The transfusion service obtains written documentation of approval from the medical director when clinical situations warrant an exception to policies, processes, or procedures.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion		D	

8 The laboratory follows its policies and procedures for the blood transfusion service.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(a)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.02.01: A supply of blood and blood components that meets the needs of the patients, the services provided by the organization, and the clinical staff is available at all times to the organization.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for maintaining a minimum inventory of blood and blood components.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion		D	ESP-1

2 The laboratory establishes a minimum inventory of blood and blood components based on the needs of the patients, the services provided by the organization, and the clinical staff.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(a)	D	ESP-1

4 Transportation for the blood and blood components from the supplier is available.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

5 The laboratory follows its policies and procedures for maintaining a minimum inventory of blood and blood components.

EP Attributes

New	FSA	CLIA	DOC	ESP

	- Transfusion	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.02.03: The laboratory has policies and procedures for maintaining blood and blood components for emergencies.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for obtaining blood or blood components needed in urgent or emergent situations.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion		D	ESP-1

2 Policies and procedures for obtaining blood or blood components needed in urgent or emergent situations address the following:
- The minimum inventory of blood and blood components to be maintained by the blood bank
- The arrangements for obtaining blood and blood components from community blood sources within a time frame defined by the organization

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

3 The laboratory follows its policies and procedures for obtaining blood or blood components needed in urgent or emergent situations.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.02.05: For blood and blood components that will not be used within the organization, the laboratory has policies and procedures for releasing it to the blood supplier or another organization.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for releasing blood and blood components to the blood supplier or another organization.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 Policies and procedures for releasing blood and blood components to the blood supplier or another organization address the following:
- How to determine the availability of blood and blood components for release
- The agreement between the laboratory and the blood supplier for return and transfer of blood and blood components
- The safe transport of blood and blood components
- Record maintenance

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The laboratory follows its policies and procedures for releasing blood and blood components to the blood supplier or another organization.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.03.01: The laboratory inspects received, stored, or issued blood or blood components for any abnormality in appearance.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory inspects received, stored, or issued blood or blood components for evidence of hemolysis and bacterial contamination. The inspection is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b) §493.1105(a)(3)(ii)	D	ESP-1

2 If an abnormality is found, the blood or blood component is not used unless authorized by the transfusion service director.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.03.03: The laboratory has policies and procedures for returning unused blood and blood components previously issued for transfusion to the blood bank.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b)	D	ESP-1

2 Policies and procedures for returning unused blood previously issued for transfusion to the blood bank address the following:
- Temperature and time restriction
- Requirements for intact labeling and intact ports on the blood unit
- Storage, transport, and expiration of blood or blood components
- Retention of documentation *

Footnote *: Additional information on storage and transportation can be found in the current edition of the AABB's Standards for Blood Banks and Transfusion Services, Table 5.1.8A.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b) §493.1103(c)(1)		ESP-1

3 The laboratory follows its policies and procedures for controlling transport, storage, or return of unused blood.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b) §493.1103(c)(1)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.04.01: The laboratory maintains temperature ranges for the safe storage and transport of blood and blood components.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has procedures on temperature ranges for blood and blood components that include the following:
- Whole blood and packed red cells: 1°C to 6°C
- Frozen plasma: less than or equal to -18°C
- Cryoprecipitated AHF: less than or equal to -18°C
- Red cells frozen in 40% glycerol: less than or equal to -65°C
- Red cells frozen in 20% glycerol: less than or equal to -120°C
- Platelets: 20°C to 24°C
- Granulocytes: 20°C to 24°C *

Footnote *: Additional information on storage and transportation can be found in the current edition of the AABB's Standards for Blood Banks and Transfusion Services, Table 5.1.8A.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1103(c) §493.1271(c) §493.1271(c)(1) §493.1103(c)(1)		ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1271(c)(1) §493.1103(c)(1)		ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1271(c)(1) §493.1103(c)(1)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1271(c)(1) §493.1103(c)(1)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.04.03: The laboratory uses alarm systems for refrigerators and freezers to monitor storage temperatures for blood and blood components.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has alarm systems for each refrigerator or freezer that meet the following requirements:
- Alarms are audible.
- Remote alarms are present for use when staff are not in the immediate area.
- Alarms, including remote alarms, are monitored continuously.
- The alarm system is battery operated or powered by a different circuit than the refrigerator(s) and freezer(s).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1252(b)(2) §493.1254(a)(2) §493.1271(c)(1) §493.1103(c)(1)		ESP-1

2 The laboratory has written policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1271(c)(1) §493.1103(c)(1)	D	ESP-1

3 Policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers include the following:
- A list of staff to notify, in order of priority
- Backup or alternative provisions for blood storage
- A process for maintaining records

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1271(c)(1) §493.1103(c)(1)		ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1271(c)(1)		ESP-1

5 The laboratory follows its policies and procedures for responding to the activation of the blood-storage alarm for refrigerators and freezers.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c) §493.1271(c)(1) §493.1103(c)(1)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.05.01: The laboratory uses sera, antisera, cells, and reagents of the same quality as federally licensed equivalents.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory defines in writing its criteria for use of sera, antisera, cells, and reagents.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory uses sera that meet federal licensing requirements or that are approved by the US Food and Drug Administration (FDA).

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The laboratory uses antisera and reagent products that are licensed by the US Food and Drug Administration (FDA).

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

4 The laboratory uses other prepared reagents that meet or exceed US Food and Drug Administration (FDA) requirements.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g)	D	ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.06.01: The laboratory conducts reactivity testing on the potency and reliability of reagents used for ABO grouping, Rh typing, antibody detection, and compatibility determinations.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for reagent reactivity testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a) §493.1271(a)(1)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1256(g) §493.1256(e)(1) §493.1256(d)(3)(ii)	D	ESP-1

3 The laboratory confirms that each reagent reacts as expected. The confirmation is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1271(a)(1)	D	ESP-1

4 The laboratory retains a copy of manufacturers' reagent package inserts. The date placed into service is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

5 The laboratory reviews manufacturers' package inserts of reagent lots for changes in instructions for use prior to using reagent. The laboratory then updates procedures when instructions change.

EP Attributes

New	FSA	CLIA	DOC	ESP

6 The laboratory follows its policies and procedures for reactivity testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(a)(1)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.07.01: The organization labels blood specimens drawn from a recipient for typing and crossmatching.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The organization has written policies and procedures addressing specimen collection for typing and crossmatching.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(b)(1)	D	ESP-1

2 Policies and procedures addressing specimen collection for typing and crossmatching include the requirement that the recipient be positively identified at the time of collection using two unique identifiers (neither of which is the patient room number).

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(b)(1)		ESP-1

3 Policies and procedures addressing specimen collection for typing and crossmatching include the requirement to label specimens legibly and immediately upon collection, in the presence of the recipient.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(b)(1)		ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(b)(1)	D	ESP-1

5 Policies and procedures addressing specimen collection for typing and crossmatching include a consistent approach to identify recipients who are unknown, incoherent, or unconscious.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(b)(1)		ESP-1

6 The organization identifies the individuals who draw blood for typing and crossmatching.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

7 The organization follows its policies and procedures addressing specimen collection for typing and crossmatching.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.08.01: The laboratory tests donor blood and recipient blood with potent typing sera and reactive cells of a known type to determine the correct ABO blood group and Rh type.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(b) §493.1271(a)(2) §493.1271(a)(3)	D	ESP-1

2 According to its policies and procedures, the transfusion service performing the crossmatch confirms the following: The ABO group of all units of whole blood and red blood cell components.
Note: The laboratory determines the ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(b) §493.1271(a)(2)		ESP-1

3 According to its policies and procedures, the transfusion service performing the crossmatch confirms the following: The Rh type of units labeled as Rh negative.
Note: The laboratory determines the Rho(D) type by testing unknown red cells with anti-Rho (anti-D) blood typing reagent.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(b)		ESP-1

4 According to its policies and procedures, the transfusion service performing the crossmatch confirms the following: The ABO group and Rh type of the recipient.
Note: For confirmation of the ABO group, the unknown serum is tested with known A1 and B red cells.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(b)		ESP-1

5 According to its policies and procedures, the transfusion service performing the crossmatch confirms the following: The Rho(D) negative donor cells are tested for the Du variant.
Note 1: This test is performed by the donor center.
Note 2: Confirmatory testing for the Du variant does not have to be completed by the transfusion service.

EP Attributes

New	FSA	CLIA	DOC	ESP

- Transfusion	§493.1103(b)		ESP-1

6 The laboratory follows its policies and procedures addressing donor and recipient blood testing to determine ABO blood group and Rh type.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(b) §493.1271(a)(2) §493.1271(a)(3)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.09.01: The laboratory has policies and procedures for serologic and computer (if performed) compatibility testing of donor blood with recipient blood.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for compatibility testing of the donor's blood with the recipient's blood.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1251(a) §493.1271(b)	D	ESP-1

2 Policies and procedures for compatibility testing include the following:
- A determination of recipient ABO Group and Rh type
- A serologic and computer (if performed) crossmatch protocol
- An antibody screening protocol
- Actions to be taken in cases of positive antibody screens and direct antiglobulin tests
- Actions to be taken in cases of incompatible crossmatches
- A time frame during which a sample may be used for crossmatching before obtaining a new sample

- A time frame not to exceed three days for recipient serum or plasma samples if the recipient has been pregnant or transfused within the previous three months or if history is unknown or unavailable. The day the sample is drawn is day zero.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(a) §493.1271(b) §493.1271(a)(1)		ESP-1

3 Before administration of blood to a patient, the following occurs (unless the physician responsible for the recipient determines that the blood administration is needed for an emergency): Tests on recipient blood, including ABO group, Rh type, screening for unexpected antibodies, antibody identification, and a compatibility test major crossmatch between donor red cells and recipient serum.
Note: When the screen and transfusion history for detection of unexpected antibodies is negative, the antiglobulin phase of testing is optional. Testing to detect ABO incompatibility (serologic or computer crossmatch) is required.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(b) §493.1271(a) §493.1271(b) §493.1271(a)(1)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion		D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP

- Transfusion	§493.1281(b)	D	

6 The laboratory's method to screen for unexpected red cell alloantibodies includes the use of non-pooled reagent red cells and incubation at 37°C, followed by an antiglobulin (or equivalent) test.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(a) §493.1271(a)(1)		ESP-1

7 The laboratory has a process in place to identify patients who require specially selected products based on both current admission orders and transfusion history (for example, irradiated, leukoreduced, antigen-negative units).

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

8 The laboratory employs a direct antiglobulin technique (DAT) capable of detecting immunoglobulin G (IgG) and complement components bound to red blood cells.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			

9 The laboratory evaluates the compatibility of the donor’s blood with the recipient’s blood. The results of this test are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion		D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.09.03: The laboratory validates computer systems used to detect ABO blood group incompatibility.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory defines system requirements before the validation of computer systems to detect ABO incompatibility.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

2 If the laboratory uses a computer system to detect ABO incompatibility, system requirements meet the following: On-site validation of selection limited to ABO compatible whole blood or red blood cells for transfusion.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			

3 If the laboratory uses a computer system to detect ABO incompatibility, system requirements meet the following: Confirmation of recipient ABO group by retesting the current sample, testing a second sample, or comparing results of current first drawn sample with previous records.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1281(b)		

4 If the laboratory uses a computer system to detect ABO incompatibility, system requirements meet the following: The computer system record contains donor unit information including the identification number, component name, ABO group, and Rh type of the component.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1291(c)(1) §493.1291(c)(6)		

5 If the laboratory uses a computer system to detect ABO incompatibility, system requirements meet the following: The computer system record contains recipient information including two patient identifiers, ABO group, Rh type, antibody screen results, and interpretation of compatibility.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1291(c)(1) §493.1291(c)(6)		

6 If the laboratory uses a computer system to detect ABO incompatibility, system requirements meet the following: Verification of manual data entered into the computer system prior to release of blood or blood components.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1281(b) §493.1281(c)		

7 If the laboratory uses a computer system to detect ABO incompatibility, system requirements meet the following: Generation of system alerts to notify user of discrepant serologic, labeling, or compatibility results of the donor unit or the recipient.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1281(b) §493.1281(c)		

8 The laboratory validates computer systems used for ABO incompatibility testing. The activities are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1253(b)(1) §493.1253(c)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.10.01: The laboratory has policies and procedures for identifying donor blood and recipient blood.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(c)(2)	D	ESP-1

2 Policies and procedures for identifying donor blood and recipient blood include the following:
- The blood recipient's full name
- An additional patient identifier (for example, a clinical record number, health care account number)
- A protocol for labeling of donor blood and recipient blood, including securely affixing the label to the units after crossmatching and retention of the label on the units until the transfusion is completed

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(c)(2)		ESP-1

3 The laboratory follows its policies and procedures for identifying donor blood and recipient blood.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(c)(2)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.11.01: The laboratory has written policies and procedures for emergent release of blood.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(a) §493.1271(a)(1)	D	ESP-1

2 The laboratory obtains documentation justifying the release of uncrossmatched blood in an emergency situation. The clinician responsible for the recipient authenticates the documentation.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(b) §493.1105(a) (3)(ii)	D	

3 The laboratory completes tests on recipient blood, including ABO group, Rh type, screening for unexpected antibodies, antibody identification, and a major crossmatch between donor red cells and recipient serum as soon as possible. Abnormal results that may affect the patient's safety are reported immediately by staff to the medical director and the clinician responsible for the patient's care.
Note: When the screen and transfusion history for detection of unexpected antibodies is negative, the antiglobulin phase of testing is optional. Testing to detect ABO incompatibility (serologic or computer crossmatch) is required. (For more information, refer to Standard QSA.05.09.01.)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(a) §493.1271(a)(1)		

4 The laboratory follows its procedures for emergent release of blood and components.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(a) §493.1271(a)(1)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.12.01: The laboratory retains samples of each unit of transfused blood and a sample of recipient blood.

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

Introduction: Not applicable

Elements of Performance

1 The laboratory retains samples of transfused blood and a sample of recipient blood for at least 7 days following a transfusion and 10 days following a crossmatch.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(d)		

2 The laboratory disposes of expired blood not needed for further testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(d)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.13.01: The laboratory has written policies and procedures that address Rh immune globulin (RhIG) administration.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion		D	ESP-1

2 The laboratory follows its policies and procedures for RhIG administration.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.14.01: The laboratory has written policies and procedures for modifying blood and blood components.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The policies and procedures for modification of blood and blood components follow good manufacturing practice and address the following:
- Maintaining sterility
- Using US Food and Drug Administration (FDA) approved additives
- Pooling of multiple blood products

- Thawing procedures
- Storing and processing
- Assigning expiration date and time
- Labeling requirements
- Tracing blood or blood component from source to final disposition
- Documenting reports of unacceptable products and the corrective action and disposition taken
- Varying from established procedures is reviewed and affected products are approved prior to administration *

Footnote *: The AABB Technical Manual is a resource for component preparation procedures.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 The laboratory assigns expiration dates to blood components in compliance with US Food and Drug Administration (FDA) regulation 21 CFR 610.53.

EP Attributes

New	FSA	CLIA	DOC	ESP

3 The laboratory label affixed to blood or blood components contains all information required by the US Food and Drug Administration (FDA) and is displayed in a format supported by ISBT 128 standards.
Note: If a transfusing facility receives a unit with a Codabar label, the facility may relabel the unit in Codabar format after any manipulation to the product.

EP Attributes

New	FSA	CLIA	DOC	ESP

4 The laboratory reviews labels for accuracy, adulteration, and legibility after application.

EP Attributes

New	FSA	CLIA	DOC	ESP

5 The laboratory system allows tracking of blood component numbers from source to final disposition.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1105(a)(3)(ii) §493.1105(a)(6)(i)		

6 The laboratory maintains records of the individual donor unit numbers for each unit in a pooled product.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1105(a)(3)(ii) §493.1105(a)(6)(i)		

7 All containers, additives, and solutions meet or exceed US Food and Drug Administration (FDA) criteria for collection, preservation, and storage of blood and blood components.

EP Attributes

New	FSA	CLIA	DOC	ESP

9 If a closed system is not maintained during aliquot preparation of blood components, the expiration date of the product is changed to reflect that of an open system. *
Footnote *: For information on assigning expiration dates to blood components, refer to US Food and Drug Administration (FDA) regulation 21 CFR 610.53.

EP Attributes

New	FSA	CLIA	DOC	ESP

10 A quality control program is in place to verify that components modified by the laboratory meet US Food and Drug Administration (FDA) requirements for human blood and blood products.

EP Attributes

New	FSA	CLIA	DOC	ESP

11 The laboratory follows its policies and procedures for modification of blood and blood components.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.14.03: The laboratory provides plasma products to its patients.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures that address the processing of plasma components.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory thaws frozen plasma or cryoprecipitate between 30°C and 37°C and protects outlet ports from water contamination.

EP Attributes

New	FSA	CLIA	DOC	ESP

3 The laboratory stores thawed fresh frozen plasma products between 1°C and 6°C.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c)		

4 The laboratory relabels thawed plasma products or byproducts as “thawed plasma.” *

Footnote *: For information on thawed plasma, refer to US Food and Drug Administration (FDA) regulation 21 CFR 606.122(m).

EP Attributes

New	FSA	CLIA	DOC	ESP

5 The laboratory prepares cryoprecipitate according to US Food and Drug Administration (FDA) regulation 21 CFR 640.54.

EP Attributes

New	FSA	CLIA	DOC	ESP

6 The laboratory stores thawed cryoprecipitate between 20°C and 24°C.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c)		

7 The laboratory follows its policies and procedures for modifying plasma products.

EP Attributes

New	FSA	CLIA	DOC	ESP

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.14.05: The laboratory irradiates blood and blood components according to law and regulation.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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 US Food and Drug Administration guidance, July 22, 1993, "Recommendations Regarding License Amendments and Procedures for Gamma Irradiation of Blood Products."

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1105(a)(6)(i)	D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.14.07: The laboratory provides leukoreduced blood and components to its patients.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory's written policies and procedures define methods to leukoreduce blood and blood components.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

4 The laboratory follows its policies and procedures for leukoreduction of blood and blood components.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.16.01: The laboratory safeguards the quality and integrity of platelet products it provides to its patients.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory gently agitates and maintains platelet components at temperatures between 20°C and 24°C.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(c)		ESP-1

2 The laboratory has a system in place to limit and detect, or inactivate bacteria in platelet components.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.17.01: The laboratory has policies and procedures for transfusion-related activities.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(b) §493.1103(c)(2)	D	ESP-1

2 Policies and procedures for transfusion-related activities address the following:
- Positive identification of the blood recipient and the blood container, including matching the recipient information to the blood or blood component being transfused
- Use of filters, warming devices, and cell salvage processes, including the transfusion service director's responsibilities for these activities
- Special or urgent situations (for example, life-threatening emergencies)
Note: Additional practice guidance on transfusion-related activities can be found in current AABB standards.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1271(b) §493.1103(c)(2)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

4 The laboratory follows its policies and procedures for transfusion-related activities.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion			ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.18.01: The organization has policies and procedures to monitor and evaluate the patient and report suspected transfusion-related adverse events.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)	D	ESP-1

2 Policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration address the following:
- The protocol for monitoring patients during blood and blood component administration
- The criteria for recognizing a suspected transfusion-related adverse event
- The protocol to follow if a suspected transfusion-related adverse event occurs
- The requirement that suspected transfusion-related adverse events are reported immediately to the physician responsible for the patient
- The requirement that suspected transfusion-related adverse events are reported immediately to the laboratory, whether or not the physician responsible for the patient deems it necessary to report the event

EP Attributes

New	FSA	CLIA	DOC	ESP

	- Transfusion	§493.1103(d) §493.1103(b)		ESP-1

3 Policies and procedures for nursing services related to blood and blood component administration do not conflict with the laboratory's policies and procedures.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)		ESP-1

4 Patient care staff monitor the patient during blood and blood component administration to detect suspected transfusion-related adverse events. The monitoring is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)	D	

5 The organization provides training for staff who administer and monitor blood and blood component transfusions. The training is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Human Resources	§493.1103(d) §493.1103(b)	D	ESP-1

6 The organization assesses competency for staff who administer and monitor blood and blood component transfusions. The competency is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Human Resources		D	ESP-1

7 The organization follows its policies and procedures that guide the monitoring of the patient and the reporting of suspected transfusion-related adverse events during blood and blood component administration.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.19.01: The laboratory has policies and procedures for reporting and investigating suspected transfusion-related adverse events.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)	D	ESP-1

2 Policies and procedures for investigating suspected transfusion-related adverse events address the following:
- Laboratory responsibility for investigation
- The transfusion service director’s review and interpretation
- Record maintenance
- Nursing responsibility for monitoring and reporting events to the laboratory
- Nursing responsibility for monitoring and reporting events to a physician responsible for the patient

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)		ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)		ESP-1

4 The laboratory follows its policies and procedures for investigating suspected transfusion-related adverse events.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.19.03: The laboratory investigates the cause of suspected transfusion-related adverse events immediately upon notification.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for investigating a suspected transfusion-related adverse event, including the protocol for a transfusion reaction workup.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b) §493.1271(e)(1)	D	ESP-1

2 The transfusion reaction workup protocol includes written criteria to determine if a hemolytic reaction has occurred.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b) §493.1271(e)(1)	D	ESP-1

3 The laboratory evaluates the suspected transfusion-related adverse event immediately upon notification and to the extent determined by the transfusion service director.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b) §493.1271(e)(1)		

4 When a transfusion-related adverse event has been confirmed by the transfusion service director, the laboratory reviews all policies and procedures to prevent recurrence and provide for the safety of individuals being transfused.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b) §493.1271(e)(1) §493.1271(e)(2)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b) §493.1271(e)(1) §493.1271(e)(2)	D	

6 The laboratory reports all confirmed fatal transfusion reactions to the US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER). * (Refer to the "Sentinel Events" [SE] chapter.)
Footnote *: For information on how and when to report information to the FDA, see http://www.fda.gov/biologicsbloodvaccines/safetyavailability/reportaproblem/transfusiondonationfatalities/default.htm.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b) §493.1271(e)(1)		

7 Per federal regulation, the laboratory notifies the US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research when a biological product deviation occurs.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(b)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.19.05: The transfusion service director interprets each suspected transfusion-related adverse event.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The transfusion service director interprets the evaluation of test results provided as part of the transfusion reaction workup. The interpretation is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b)	D	

§493.1271(f)

2 The interpretation of the transfusion reaction workup provided by the transfusion service director is documented in the patient's clinical record.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Transfusion	§493.1103(d) §493.1103(b) §493.1271(f)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.20.01: If blood or blood components have been administered that are potentially infected with human immunodeficiency virus (HIV), the laboratory identifies recipients and informs them of the risk of infection.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 Blood suppliers notify the transfusing facility of receipt of units from blood donors subsequently confirmed as positive for human immunodeficiency virus (HIV).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b)		ESP-1

2 The laboratory has written procedures for the notification of blood recipients of potential human immunodeficiency virus (HIV) infection.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

3 The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to make several attempts to notify the blood recipient's attending licensed independent practitioner (physician of record) of the recipient's potential for HIV infection and ask him or her to inform the recipient or, as needed, another authorized person of the need for HIV testing and counseling.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

4 The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to make several attempts to notify the blood recipient or, as needed, another authorized person, of the potential for HIV infection and to inform him or her of the need for HIV testing and counseling, if the physician is unavailable or declines to notify the recipient.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

5 The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to document the attempts to notify the blood recipient of the potential for HIV infection, including whether the recipient was located.
Note: Documentation of notification attempts are in accordance with federal guidelines.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

6 The laboratory's human immunodeficiency virus (HIV) procedures require the transfusing facility to maintain strict confidentiality of records related to recipient health and donor suitability.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

7 The laboratory follows its procedures for notification of blood recipients of potential human immunodeficiency virus (HIV) infection.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.21.01: If blood or blood components have been administered that are potentially infected with hepatitis C (HCV), the laboratory identifies recipients and informs them of the risk of infection.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 Blood suppliers notify the transfusing facility of receipt of units from blood donors subsequently confirmed as positive for hepatitis C (HCV).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b) §493.1271(a)(1)		ESP-1

2 The laboratory has written procedures for the notification of blood recipients of potential hepatitis C (HCV) infection.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

3 The laboratory's hepatitis C (HCV) procedures require the transfusing facility to make several attempts to contact the blood recipient's attending licensed independent practitioner (physician of record) of the recipient's potential for HCV infection and ask him or her to inform the recipient or, as needed, another authorized person of the need for HCV testing and counseling.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

4 The laboratory's hepatitis C (HCV) procedures require the transfusing facility to make several attempts to notify the blood recipient or, as needed, another authorized person of the potential for HCV infection and inform him or her of the need for HCV testing and counseling, if the physician is unavailable or declines to notify the recipient.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

5 The laboratory's hepatitis C (HCV) procedures require the transfusing facility to document the attempts to notify the blood recipient of the potential for HCV infection, including whether the recipient was located.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

6 The laboratory's hepatitis C (HCV) procedures require the transfusing facility to maintain strict confidentiality of records related to recipient health and donor suitability.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(a)(1)		ESP-1

7 The laboratory follows its procedures for notification of blood recipients of potential hepatitis C (HCV) infection.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.22.01: The laboratory retains records on the receipt, testing, and disposition of blood and blood components.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory retains an audit trail detailing the receipt and disposition of all blood and blood components for 10 years.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(f) §493.1271(a)(1)		

2 The documentation of testing of blood and blood components is retained for at least five years.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(f) §493.1271(a)(1)		

3 For blood and blood components issued by the facility that collected and processed the unit, the identification of the recipient is retained for 10 years.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(f) §493.1271(a)(1)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.24.03: The laboratory safely collects, stores, handles, processes, tests, and labels blood or blood components.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

5 The laboratory does not use blood or blood components that test reactive for an infectious agent unless allowed by US Food and Drug Administration (FDA).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1271(b)		

8 The laboratory establishes procedures to prevent inadvertent release of unsuitable units (for example, an organized grouping of components and blood in temperature-controlled places and the use of computer alerts).

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.05.25.01: The laboratory, or designated department, monitors therapeutic phlebotomy, plasmapheresis, and apheresis procedures.

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

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

3 The laboratory or designated department uses equipment and fluids approved by the US Food and Drug Administration (FDA) for apheresis procedures. Manufacturers' instructions are followed.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

4 Blood collected from therapeutic phlebotomy is not used for transfusion unless specifically approved by the US Food and Drug Administration (FDA).

EP Attributes

New	FSA	CLIA	DOC	ESP

5 A qualified physician accepts medical responsibility for all therapeutic blood collection and exchange procedures, including those performed perioperatively.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

6 Therapeutic apheresis procedures are ordered by the patient's physician with instructions regarding frequency, volume, and number of procedures to perform.

EP Attributes

New	FSA	CLIA	DOC	ESP

8 Staff follow the laboratory's or designated department's policies and procedures for apheresis.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.06.01.01: The laboratory verifies each clinical chemistry test system through the use of quality control materials.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.06.02.01: The laboratory verifies the operation of each blood gas testing instrument through the use of quality control materials.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory tests at least 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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1267(b) §493.1267(c) §493.1267(d) §493.1256(g)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1267(b) §493.1267(c) §493.1267(d) §493.1256(g)	D	

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1267(c) §493.1256(g)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.06.03.01: The laboratory's procedures for maternal serum marker prenatal screening provide for accurate results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1253(b)(1)(ii)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(f)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(f)	D	ESP-1

4 The laboratory follows its quality control and testing procedures for maternal serum marker prenatal screening.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.06.03.03: The laboratory procedures for maternal amniotic fluid alpha fetal protein (AFAFP) provide for accurate results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP).

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1251(a) §493.1256(a)	D	ESP-1

2 The laboratory's written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP) include the following: Establishment of laboratory-specific median values or verification of a manufacturer's median values consistent with the population served.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1253(b)(1)(ii)		ESP-1

3 The laboratory's written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP) include the following: Criteria and frequency for recalculation or reverification of the median values at specific intervals.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(f)		ESP-1

4 The laboratory's written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP) include the following: Inclusion of a minimum of one amniotic fluid dilution control with each run.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)		ESP-1

5 The laboratory's written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP) include the following: Determination of presence or absence of fetal blood contamination in fluids visibly contaminated with blood.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1253(b)(2)(iv)		ESP-1

6 The laboratory's written quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP) include the following: Criteria for confirmatory testing requirements for abnormal amniotic alpha fetal protein results.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(b)(3)		ESP-1

7 The laboratory follows its quality control and testing procedures for maternal amniotic fluid alpha fetal protein (AFAFP).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.06.04.01: The laboratory's procedures for high performance liquid chromatography (HPLC) provide for accurate results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1256(d)(3)(iv)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1254(b)(1)(i)	D	ESP-1

6 The laboratory follows its procedures for high performance liquid chromatography (HPLC).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.06.04.03: The laboratory's procedures for gas chromatography (GC) provide for accurate results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1256(d) (3)(iv)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

4 The laboratory has written quality control and testing procedures for gas chromatography (GC) that address the following: The detection and evaluation of carryover.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1253(b)(1)(i)(C)	D	ESP-1

6 The laboratory follows its procedures for gas chromatography (GC).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.06.04.05: The laboratory's procedures for mass spectrometry provide for accurate results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP

§493.1256(a)	D	ESP-1	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1256(d)(3)(iv)	D	ESP-1

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).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a) §493.1255(a)(2)	D	ESP-1

4 The laboratory has written quality control and testing procedures for mass spectrometry that address the following: The detection and evaluation of carryover.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1253(b)(1)(i)(C)	D	ESP-1

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).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

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).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)	D	ESP-1

8 The laboratory follows its procedures for mass spectrometry.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(a)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.07.01.01: The laboratory follows an approved clinical guideline * when performing urine tests on specimens that meet acceptability criteria.
Footnote *: Additional information can be found in the current edition

of Clinical and Laboratory Standards Institute (CLSI) document GP16 (Urinalysis).

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

Introduction: Not applicable

Elements of Performance

1 The laboratory performs urine tests only on fresh or preserved specimens.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(b)(1)		

2 The laboratory establishes and follows a defined system for handling, testing, and reporting urine specimens that exceed stability requirements (for example, room temperature urine more than two hours old and refrigerated urine more than four hours old).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(b)(1)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.07.02.01: The laboratory makes reference materials available for microscopic examination of urine sediment.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.01.01: The laboratory director or the cytology technical supervisor determines qualifications and number of cytology staff.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory director or cytology technical supervisor determines cytology staff qualifications. *
Footnote *: Qualifications for cytology staff are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/Regulatory.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 The laboratory complies with federal and state personnel qualification and licensure requirements. *
Footnote *: Qualifications for cytology personnel are described in Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/Regulatory.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment			ESP-1

3 The laboratory director or cytology technical supervisor provides a number of cytotechnologists sufficient to review the volume and variety of cytology cases.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.02.01: The cytology technical supervisor establishes policies and procedures for the testing of cytology specimens.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The cytology technical supervisor establishes written policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 Policies and procedures for cytology specimen collection include the criteria for unacceptable cytology specimens.
Note 1: The following list of common criteria may be used to define an unacceptable cytology specimen:
- The name on the slide or specimen container is different from the name on the requisition.
- The slide or container is not labeled according to the laboratory's procedure regarding specimen collection.
- The submitted slide is broken or crushed and cannot be repaired for processing.
- The specimen is improperly fixed.
Note 2: For more information on specimen collection procedures, please refer to the "Document and Process Control" (DC) chapter, Standard DC.01.01.01.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(4) §493.1274(e)(4) §493.1251(b)(2) §493.1241(c)(7)		ESP-1

3 Policies and procedures for cytology specimen evaluation include the criteria for unsatisfactory specimens that do not allow for a definitive diagnosis.
Note: The following list of common criteria may be used to define an unsatisfactory cytology specimen. Slides containing or showing signs of:
- Too few cells
- Obscuring of cells
- Obscuring inflammation
- Obscuring red blood cells
- Obscuring lubricant
- Excessive air drying
- Excessive cellular degeneration

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(4) §493.1274(e)(4) §493.1242(a)(7)		ESP-1

4 The laboratory communicates the policies and procedures for cytology specimen collection, identification, preservation, and transport to clinical staff and other clients who collect cytology specimens.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

5 The laboratory rejects unacceptable cytology specimens.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(4) §493.1274(e)(4) §493.1251(b)(1)		

		§493.1241(c)(7)		

6 The laboratory notifies the sender when unacceptable cytology specimens are received.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1242(a)(7)		

7 The laboratory follows its policies and procedures for cytology specimen collection, identification, preservation, transport, and evaluation.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1485(a)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.03.01: The cytology technical supervisor uses quality improvement processes to measure, assess, and improve the cytology service.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The cytology technical supervisor establishes, in writing, the quality improvement plan to measure, assess, and improve the cytology services.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(e)	D	ESP-1

2 The quality improvement plan includes a system to detect errors in the cytologic examination process and a process to report results.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(e) §493.1274(c)		ESP-1

3 The laboratory reviews all gynecologic and nongynecologic cytology reports with available patient clinical information and compares the results of the review for discrepancies.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(c)(2)		

4 The laboratory reviews all gynecologic cytology reports of a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with available histopathology reports and compares the results of the review for discrepancies.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(c)(2)		

5 For all gynecologic slides with current high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasm, the laboratory reviews all normal or negative gynecologic specimens received within the previous five years, if available to the laboratory (on site or in storage), documents discrepancies, and issues a corrected report for any discrepancies that would affect patient care.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(c)(2) §493.1274(c)(3)		

6 The laboratory determines the causes of any cytology discrepancies when comparing the following:
- Gynecologic and nongynecologic reports with available patient clinical information
- Gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report
-A current HSIL, adenocarcinoma, or other malignant neoplasm with previous (normal or negative) gynecologic specimens from the previous

five years

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(c)(2)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1289(c)	D	

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1289(c) §493.1274(c)(5) §493.1274(c)(5)(i) §493.1274(c)(5)(ii) §493.1274(c)(5)(iii)	D	

§493.1274(c)(5)(iv)
§493.1274(c)(5)(v)
§493.1274(c)(5)(vi)

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(c)(3)		

10 The laboratory measures, assesses, and improves the quality of cytology services.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1289(c)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.04.01: The laboratory establishes workload limits for staff who perform primary cytology screening.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures that address cytology workload limits.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The cytology technical supervisor establishes in writing a maximum workload limit for each staff member who performs primary screening.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(d) §493.1451(c)(2) §493.1451(c)(4) §493.1274(d)(1)	D	ESP-1

3 The cytology workload limit is based on each staff member's performance using evaluations of the following:
- Review of 10% of the cases interpreted as negative (See also QSA.08.06.01, EP 2)
- Comparison of the primary screener's initial cytologic interpretation with the pathologist's final interpretation (See also QSA.08.07.01, EP 2)
- Other measures as established by the cytology technical supervisor

Note 1: Staff members include individuals who perform primary screening and individuals who perform quality control re-examinations.
Note 2: Individuals that qualify under CFR §493.1449(k) are not required to perform the 10% rescreen of negative cases on their own cases. This requirement applies exclusively to the cytology general supervisor and cytotechnologist.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(d) §493.1451(c)(4) §493.1274(d) (1)(i) §493.1274(d) (1)(i)(A) §493.1274(d) (1)(i)(B)		ESP-1

4 Workload requirements apply to all cytotechnologists, pathologists, and pathology residents in the final year of training leading to board certification.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

5 For individuals who perform primary screening, the maximum total number of cytology slides staff may screen is 100 slides (or full slide equivalents) per 24-hour period for either gynecologic or nongynecologic specimens or both.

For gynecologic specimens screened by automated or semiautomated screening devices, workload limits must comply with those specified by the manufacturer as approved by the US Food and Drug Administration (FDA).

Note 1: For manual screening, liquid-based gynecologic preparations cannot be counted as a half slide. All gynecologic slide preparations (liquid-based or conventional) are counted as one full slide.

Note 2: The workload limit for staff reading slides requiring 100% manual review may not exceed 100 slides, as a result of automated or semiautomated analysis or in the routine workload. When performing evaluations using automated and semiautomated screening devices, the laboratory conforms to current manufacturer's instructions.

Note 3: Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one half or less of the total available slide may be counted as one half slide.

Note 4: The 100-slide limit includes previously unevaluated gynecologic slides and nongynecologic slides, 10% rescreen slides, and review slides. Cytology technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100-slide workload limit.

Note 5: The 100-slide limit does not include previously examined negative, reactive, atypical, premalignant, or malignant gynecologic cases; previously examined nongynecologic cytology preparations; or tissue pathology slides examined by a cytology technical supervisor.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(g) §493.1451(c)(2) §493.1451(c)(4) §493.1274(d)(2) §493.1274(d)		ESP-1

(2)(ii)
§493.1274(d)
(2)(iii)
§493.1274(d)
(2)(iv)

6 The maximum number of cytology slides is examined in no less than an eight-hour workday.
Note 1: For the purposes of establishing workload limits for staff examining slides by nonautomated microscopic technique on other than an eight-hour workday basis (including full-time employees with duties other than slide examination and part-time employees), a period of eight hours must be used to prorate the number of slides that may be examined. Use the following formula: (number of hours examining slides x 100) ÷ 8 = maximum slide volume to be examined.
Note 2: For both nonautomated microscopic techniques and automated/semiautomated microscopic techniques, laboratories must consider the time spent reading each slide to achieve consistent quality results without exceeding the maximum workload requirements. For information on how laboratorians can safely calculate workload for semi-automated gynecologic cytology screening devices approved by the US Food and Drug Administration (FDA), refer to https://www.mdtmag.com/news/2010/07/safety-tips-laboratorians-how-laboratorians-can-safely-calculate-workload-fda-approved-semi.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1485(b) §493.1485(c) §493.1471(b)(3) §493.1471(b)(4) §493.1451(c)(2) §493.1451(c)(4) §493.1274(d)(2) §493.1274(d) (2)(i) §493.1274(d) (2)(ii)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1485(a) §493.1485(b) §493.1485(c) §493.1471(b)(2) §493.1471(b)(3) §493.1471(b)(4) §493.1451(c)(4) §493.1451(c)(6) §493.1274(d)(2) §493.1274(d)(3) §493.1274(d)(4) §493.1274(d) (2)(i) §493.1274(h)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(2) §493.1451(c)(3) §493.1451(c)(4) §493.1274(d) (1)(ii)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(4) §493.1274(c)(6)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(4) §493.1274(c)(6)	D	

11 The cytology technical supervisor makes adjustments in each staff member's workload, if needed, based on the results of the workload assessment.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(2) §493.1451(c)(3) §493.1451(c)(4)		

12 The laboratory follows its policies and procedures for cytology workload limits.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(d)(2)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.05.01: Cytology slide staining provides acceptable quality.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory defines, in writing, cytology stains and staining techniques that are of a quality suitable for evaluation.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1274(b) §493.1274(h)	D	ESP-1

2 All gynecologic specimens are stained using a Papanicolaou or modified Papanicolaou staining method.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(b) §493.1274(b)(1)		ESP-1

3 The laboratory takes measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the cytology staining process.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(b)(2)		ESP-1

4 The laboratory separately stains nongynecologic specimens that have a high potential for cross-contamination from other nongynecologic specimens.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(b)(3) §493.1101(a)(2)		ESP-1

5 The laboratory filters or changes the cytology stains following the staining of nongynecologic specimens with a high potential for cross-contamination.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(b)(3)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.06.01: The cytology quality system includes review of a random sample of negative gynecologic slides.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(d) §493.1471(b)(2) §493.1451(c)(4) §493.1274(c)(1) §493.1274(c) (1)(i)(A) §493.1274(c) (1)(i)(B) §493.1274(c) (1)(i)(C)	D	

2 The review of a minimum of 10% of negative gynecologic slides includes the following:
- A random sample of 10% of all gynecologic cases read by each primary screener and interpreted to be negative for epithelial cell abnormalities and malignant or premalignant conditions
- Patients identified as having a higher-than-average probability for developing cervical cancer
- Slides from each primary screener
(See also QSA.08.04.01, EP 3)
Note 1: During the initial screening process, primary screeners are not made aware of which slides will be reexamined.
Note 2: The 10% review of negative cases is not required for a one-person laboratory consisting of a cytology technical supervisor or for a laboratory that only employs pathologists qualified as cytology technical supervisors. However, all laboratories must establish and follow a program to detect

errors.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1485 §493.1274(d) §493.1471(b)(2) §493.1451(c)(4) §493.1274(c)(1) §493.1274(c) (1)(ii) §493.1274(d) (1)(i)(A)		

3 A qualified * individual completes the review of a random sample of negative gynecologic slides before reporting patient results.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov /clia/Regulatory.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(c)(1) §493.1274(c) (1)(iii)		

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1485 §493.1471(b)(2) §493.1274(c)(4) §493.1274(c)(1) §493.1274(c) (1)(iii) §493.1274(d) (1)(i)(B) §493.1274(h)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.06.03: The cytology laboratory has a process to correlate cytologic interpretations with the corresponding histologic finding.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures to detect and resolve discrepancies between nongynecologic cytologic and histologic findings.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(c)(2)	D	ESP-1

2 The laboratory follows its policies and procedures to detect and resolve discrepancies between nongynecologic cytologic and histologic findings. The discrepancies and their resolutions are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1281(b)(3)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.07.01: The cytology technical supervisor reviews cytology slides.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 An individual qualified as a cytology technical supervisor reviews and confirms all nongynecologic slides. This review is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment		D	

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1274(d) §493.1451(c)(4) §493.1274(e)(1) §493.1274(e)(1)(ii) §493.1274(e)(1)(i) §493.1274(e)(1)(iii) §493.1274(e)(1)(i)(A) §493.1274(e)	D	

(1)(i)(B)
§493.1274(e)
(1)(i)(C)
§493.1274(e)
(1)(i)(D)
§493.1274(e)
(1)(ii)(A)
§493.1274(e)
(1)(ii)(B)
§493.1274(e)
(1)(ii)(C)
§493.1274(e)
(1)(ii)(D)

3 All gynecologic and nongynecologic test reports reviewed by a cytology technical supervisor have a written or secured electronic signature.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(e)(2) §493.1274(e)(3)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.08.01: Cytology reporting includes processes to communicate with the authorized person ordering the test and, if different, the individual responsible for using the test results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 For all specimen results, cytology reports contain descriptive nomenclature * that facilitates communication between the laboratory and the clinician. Footnote *: Ali SZ, Cibas ES, eds. The Bethesda System for Reporting Thyroid Cytopathology: Definitions, Criteria and Explanatory Notes. New York: Springer, 2010.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(4) §493.1274(e)(5)	D	

2 The cytology laboratory communicates results that require urgent patient follow-up to the authorized person ordering the test and, if different, the individual responsible for using the test results. The communication is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1291(g)	D	

3 Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(e)(4)		

4 Diagnostic interpretations are not reported on unsatisfactory specimens.

EP Attributes

New	FSA	CLIA	DOC	ESP

5 When an incorrect cytology result is reported, a corrected report is generated and indicates the basis for the correction. (See also QSA.02.12.01, EP 9)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1451(c)(4) §493.1274(e)(6)	D	

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)

EP Attributes

New	FSA	CLIA	DOC	ESP

D

7 When a gynecologic cytology examination method is automated, the cytology report includes the automated instrument used.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.08.09.01: Cytology slides are maintained, stored, and retrieved.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory maintains and stores cytology slide preparations under conditions that allow preservation.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(e) §493.1274(f)(1)		

2 The laboratory retains cytology slide preparations for at least five years from the examination date, or longer as required by state law or regulation.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(e) §493.1274(f)(1) §493.1105(a)(3) §493.1105(a) (7)(i)(A)		

3 The laboratory retrieves cytology slide preparations on request.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1274(f)(4)		

4 The laboratory maintains documentation for cytology slides loaned or referred for purposes other than proficiency testing.
Note: Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgement of the receipt of slides by the proficiency testing program and maintains the acknowledgement to document the loan of these slides.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(e) §493.1274(f)(1) §493.1274(f)(2) §493.1274(f)(3) §493.1105(a) (7)(i)(A)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.11.01.01: On each day of patient testing, the laboratory verifies each hematology procedure and test parameter against known standards or controls within the range of clinically significant values.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

4 Each individual performing manual cell counts performs one level of control for every eight hours of testing. The quality control results are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1269(a) §493.1256(g) §493.1269(a)(1)	D	

5 Cell counts are tested in duplicate when performed using a hemocytometer.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1269(a) §493.1269(a)(2)		

6 For manual hematology tests, the laboratory defines written criteria for acceptable precision of duplicate samples.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

7 For manual hematology tests, the laboratory adheres to criteria for acceptable precision of duplicate samples.

EP Attributes

New	FSA	CLIA	DOC	ESP

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.11.02.01: The laboratory's coagulation testing provides accurate results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1269(d)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1269(b) §493.1256(g)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP

§493.1269(b) §493.1256(g)	D	ESP-1	

4 For manual coagulation testing systems (any coagulation test with a manual pipetting step): The laboratory runs patient samples and quality control materials in duplicate.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1269(c)(1) §493.1269(c)(2)		

5 For manual coagulation testing systems (any coagulation test with a manual pipetting step): The laboratory has predetermined limits of precision for the results of patient samples and quality control materials performed in duplicate.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1269(c)(2)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1269(c)(1)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1269(c)(1)	D	ESP-1

8 For each new lot number of thromboplastin reagent, the laboratory establishes the normal patient prothrombin time mean.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1269(c)(1) §493.1269(c)(2)		

9 The laboratory reports results based on the current reagent lot number specifications.
Note: For prothrombin time results, the international normalized ratio (INR) calculation incorporates the normal patient prothrombin time mean and the international sensitivity index (ISI) value specific to the lot of thromboplastin reagent in use.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1269(c)(1) §493.1269(c)(2)		

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 (Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays).

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.01.01: Surgical specimens are sent to a pathologist for evaluation.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 Surgical specimens are sent to a pathologist for evaluation unless exceptions are identified by the clinical staff.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 The clinical staff, in consultation with a pathologist, decides when an exception to the submission of surgical specimens to pathology should be made using the following criteria:
- The quality of care has not been compromised.
- The surgical specimen removal is routinely verified by another clinically acceptable means.
- The removal of the specimen is documented in an authenticated operative or other official report.
- The exception is authorized by law, the requirements of a training program, or the clinical staff laws or rules and regulations.
(See also QSA.13.04.01, EP 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.02.01: Surgical specimens are accompanied by supporting clinical information and preoperative and postoperative diagnoses to the degree known.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 Requests for examining surgical specimens are accompanied by preoperative and postoperative diagnoses to the degree known.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 Requests for examining surgical specimens are accompanied by supporting clinical information as indicated by patient history and laboratory policy.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.03.01: The laboratory documents its receipt of surgical specimens and maintains the identity of the specimens throughout processing and storage.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory documents its receipt of surgical specimens.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory has written policies and procedures that define how the identity of surgical specimens is maintained throughout processing,

evaluation, and storage.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

3 The laboratory maintains the identity of the surgical specimens throughout processing, evaluation, and storage.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.03.03: The laboratory manages risks associated with tissues containing radionuclides.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for the safe handling, processing, and disposing of tissues containing radionuclides.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(d)	D	ESP-1

2 The laboratory follows its policies and procedures for the safe handling, processing, and disposing of tissues containing radionuclides.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(d)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.04.01: Surgical specimens sent to the laboratory are examined by or under the supervision of a qualified individual.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 Every surgical specimen receives a gross and microscopic evaluation and a diagnostic report, unless identified as an exemption. (See also QSA.13.01.01, EPs 2 and 3)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment			ESP-1

2 When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: He or she meets the qualifications for high-complexity testing personnel. *
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov /clia/Regulatory.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment			ESP-1

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”).

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment		D	ESP-1

4 When a nonpathologist performs gross analysis under the supervision of a qualified pathologist: The individual's work is reviewed by the technical supervisor or qualified pathologist within 24 hours. The review is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment		D	ESP-1

5 An individual qualified * in anatomic pathology evaluates each microscopic section.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov /clia/Regulatory.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment			ESP-1

6 For Mohs testing, an individual qualified * in anatomic pathology or a qualified dermatologist evaluates each microscopic section.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov /clia/Regulatory.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment			ESP-1

7 The diagnosis for each surgical specimen is made by or under the supervision of a qualified * individual.
Footnote *: Qualifications are described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) under Subpart M: "Personnel for Nonwaived Testing," §493.1351 - §493.1495. A complete description of the requirement is located at http://wwwn.cdc.gov/clia/Regulatory.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment			ESP-1

8 The laboratory uses terminology for diagnoses from a nationally recognized, professionally accepted disease nomenclature (for example, the Systematized Nomenclature of Medicine-Clinical Terms [SNOMED-CT]).

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Quality System Assessment	§493.1273(e)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.05.01: The laboratory manages hazards associated with the use of an electron microscope.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory uses precautions related to radiation and electrical hazards of an electron microscope.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.06.01: The equipment, methods, and stains used in producing microscopic slides provide tissue sections that facilitate a diagnosis.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.
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.

EP Attributes

New	FSA	CLIA	DOC	ESP

		§493.1273(f)		ESP-1

2 The laboratory performs quality controls on histologic stains for intended reactivity. The quality control results are documented. (See also QSA.02.10.01, EP 7)
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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1273(a) §493.1273(f) §493.1256(e)(3)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1273(a) §493.1273(f) §493.1256(e)(3)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.07.01: The laboratory retains histological specimens for patient care purposes.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(e) §493.1273(b)		

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(e) §493.1273(b) §493.1105(a)(7)(ii) §493.1105(a)(7)(iii) §493.1105(a)(7)(i)(B)		

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.13.08.01: The histopathology laboratory conducts surveillance of patient results and related records as part of its quality management plan.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1281(b)(1) §493.1281(b)(2) §493.1281(b)(3) §493.1281(b)(4) §493.1281(b)(5)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1299(a) §493.1299(b) §493.1299(c)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.14.01.01: The laboratory provides for the accuracy of immunology tests, including syphilis serology, through the use of quality controls and tests for antigen reactivity.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(d)(3)(iv)	D	

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g)	D	

3 The laboratory determines, in writing, the reactivity patterns of quality control materials for immunology tests before or concurrently with test performance, if applicable.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.14.02.01: The laboratory performs syphilis testing with equipment, reagents, quality control materials, and techniques.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory's syphilis testing conforms to manufacturers' specifications, including techniques, equipment (for example, rotator speed), room temperature, quality control materials, and reagent drop size.

EP Attributes

New	FSA	CLIA	DOC	ESP

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(d)(3)(iii)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.15.01.01: The laboratory uses written policies and procedures for molecular testing.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a) §493.1101(a)(3)	D	ESP-1

2 The laboratory's policies and procedures for molecular testing address the following: Appropriateness of testing.
Note: For genetic testing, additional information might be required to select tests and to provide for accurate test interpretation and reporting of results (for example, a pedigree may be required to show genetic relationships).

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The laboratory's policies and procedures for molecular testing address the following: Prevention of nucleic acid contamination, including work areas, equipment, personal protective equipment, and reagents, during specimen preparation, aliquoting, and testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1101(a)(2) §493.1101(a)(3) §493.1256(e) (4)(i)		ESP-1

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)

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1232	D	ESP-1

5 The laboratory's policies and procedures for molecular testing address the following: Documentation of all nucleic acid reagents, including probes and primers, used in a particular test.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

6 The laboratory's policies and procedures for molecular testing address the following: The quality and quantity of nucleic acid required for a particular test.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

7 The laboratory's policies and procedures for molecular testing address the following: Investigation and corrective action for internal controls that fail to amplify.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

8 The laboratory's policies and procedures for molecular testing address the following: Competition between target and internal controls (for example, false negatives or the presence of a strong target signal with a negative internal control signal).

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

9 The laboratory's policies and procedures for molecular testing address the following: Investigation of discrepant results between different methods.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

10 The laboratory's policies and procedures for molecular testing address the following: Reuse of patient specimens for quality control purposes.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

11 The laboratory's policies and procedures for molecular testing address the following: Confirmation of restriction endonuclease activity (for example, complete digestion, accurate fragment production).

EP Attributes

New	FSA	CLIA	DOC	ESP

ESP-1

12 The laboratory's policies and procedures for molecular testing address the following: The criteria for analysis of autoradiographs, membranes, and electrophoretic gels (for example, the presence of a strong target signal, minimal background signal).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(b)(3)		ESP-1

13 The laboratory's policies and procedures for molecular testing address the following: Verification of patient nucleic acid integrity and labeling.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

14 The laboratory's policies and procedures for molecular testing address the following: Validation of the nucleic acid extraction and purification method, including elimination of inhibitory factors.
Note: Additional information can be found in the current edition of Clinical and Laboratory Standards Institute (CLSI) document MM19 (Establishing Molecular Testing in Clinical Laboratory Environments).

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

15 The laboratory follows its policies and procedures for molecular testing.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.15.02.01: The laboratory's verification studies for molecular testing include representatives from each specimen type expected to be tested in the assay and specimens representing the scope of reportable results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory's verification studies for molecular testing include positive and negative representatives from each specimen type expected to be tested in the assay.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 The laboratory's verification studies for molecular testing include specimens representing the scope of reportable results.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The laboratory performs verification studies for molecular testing. The verification studies are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.15.03.01: The laboratory establishes quality control limits, reference ranges, and reportable ranges for molecular testing.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory establishes quality control limits, reference ranges, and reportable ranges to provide molecular test results with meaningful clinical applications.

EP Attributes

New	FSA	CLIA	DOC	ESP

2 The laboratory establishes quality control limits for quantitative molecular tests that are strict enough to promote precision and accuracy for reliable patient test results.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 For qualitative tests, the laboratory establishes a threshold value to distinguish positive from negative results prior to patient testing; threshold values are then verified for each new lot and every six months thereafter, or at a frequency consistent with laboratory policy or manufacturers' instructions, if more stringent.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.15.04.01: The laboratory uses quality control materials to verify each test run of patient samples for molecular testing.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written quality control procedures for each molecular testing system or methodology, including the frequency of quality control testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 Molecular testing procedures are consistent with current practice standards for this or similar methodologies, and are at least as rigorous as those required or recommended by the manufacturer.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The laboratory follows its quality control procedures for molecular testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1256(d)(3)(v)	D	ESP-1

5 For each electrophoretic run, the laboratory uses the following markers:
- Molecular weight markers of known size that span the expected range of band distribution
- Visual or fluorescent markers to establish the endpoint of electrophoresis

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.15.05.01: The laboratory's molecular testing reports include specific testing information.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory reports for molecular testing include the following information: The testing methodology used.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory reports for molecular testing include the following information: The limitations of the method used.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

3 The laboratory reports for molecular testing include the following information: Any interpretation of findings.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

4 The laboratory reports for molecular testing include the following information: Any recommendations for additional testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

5 For assays developed by the laboratory, the laboratory reports for molecular testing include a statement that the assay was developed by the laboratory.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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 US Food and Drug Administration (FDA).”

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

7 Molecular testing reports filed in the patient’s clinical record that require specific interpretation are authenticated by the individual qualified * by the Clinical Laboratory Improvement Amendments (CLIA ’88) to make the interpretation.
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.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.16.01.01: The laboratory uses policies and procedures for molecular genetic testing.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written policies and procedures for molecular genetic testing that address recommendations for referral for genetic counseling.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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).

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

4 The laboratory follows its policies and procedures for molecular genetic testing.

EP Attributes

New	FSA	CLIA	DOC	ESP

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.16.02.01: Molecular genetic testing reports include specific testing information.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory reports for molecular genetic testing include the following information: Indication for testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory reports for molecular genetic testing include the following information: List of genes or alleles tested.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

3 The laboratory reports for molecular genetic testing include the following information: Any recommendations for referral to a genetic counselor.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

4 The laboratory reports for molecular genetic testing include the following information: Detection rate of the test.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

5 The laboratory reports for molecular genetic testing include the following information: Standard nomenclature for genes and mutations.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

6 The laboratory reports for molecular genetic testing include the following information: Clinical implications of any detected mutation(s).

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.17.01.01: The laboratory uses parasitology reference materials and a calibrated measuring device for determining the size of ova or parasites.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory has written procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

2 The laboratory makes a calibrated ocular lens for ova and parasite size measurement available to staff performing testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites are available for staff performing testing.

EP Attributes

New	FSA	CLIA	DOC	ESP

ESP-1

4 The laboratory follows its procedures for calibrating and using the ocular micrometer for size measurements of ova and parasites.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1264(b)		ESP-1

5 The laboratory makes parasitology reference materials available to staff performing testing.
Note: Examples of reference materials include textbooks with photographs, collections of previously stained slides, preserved gross specimens of identified parasites, and slides for proficiency testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1264(a)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.17.01.03: The laboratory stores and evaluates reagents for parasitology.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory determines the specific gravity of zinc sulfate solutions used for the concentration of fecal specimens (1.18 for fresh specimens and 1.20 for formalin-fixed specimens).

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1252(d)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.17.02.01: The laboratory performs quality control testing for parasitology permanent stains.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory uses quality control materials to verify parasitology permanent stains that demonstrate typical staining characteristics.
Note: Quality control materials can consist of fecal samples with parasites or added leukocytes to demonstrate staining characteristics.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1264(c) §493.1256(e)(3)		ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1264(c) §493.1264(d) §493.1256(g) §493.1256(e)(3)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.18.01.01: Provider-performed microscopy (PPM) procedures are performed using a brightfield or a phase/contrast microscope.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory performs provider-performed microscopy (PPM) * procedures using a microscope limited to a brightfield or a phase/contrast microscope.
Footnote *: For more information on competency regarding provider-performed microscopy (PPM) procedures, please refer to the "Human Resources" (HR) chapter, Standard HR.01.06.01.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1365(b) §493.1365		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.20.01.01: The laboratory obtains and maintains information and records of complete semen analysis.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The collection information for semen analysis includes the following: Method of collection. The information is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(b)(1)	D	ESP-1

2 The collection information for semen analysis includes the following: Type of specimen container. The information is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

3 The collection information for semen analysis includes the following: Days of abstinence. The information is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

5 The sample quality for semen analysis includes the following: Time of specimen receipt and analysis. The information is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

6 The sample quality for semen analysis includes the following: Abnormalities of liquefaction. The information is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

8 Semen analysis information includes the following, as applicable: Sperm number, motility, and progression. The information is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

9 Semen analysis information includes the following, as applicable: Method for sperm morphology classification, including stains, as required. The information is documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g)	D	

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 (Physician and Nonphysician Provider-Performed Microscopy Testing) and World Health Organization (WHO) Laboratory Manual for the Examination and Processing of Human Semen.

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.21.01.01: The laboratory has methods for virology testing.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1251(a)		ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.21.02.01: The laboratory uses cell controls and processes to assess the accuracy of virology testing results.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory simultaneously incubates either a cell substrate control or uninoculated cells as a negative control material with patient testing.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1265(a)		

2 The virology laboratory documents the following: Cell lines used for the virus being isolated.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

3 The virology laboratory documents the following: Control checks of maintenance media.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

4 The virology laboratory documents the following: Sterility checks.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b) §493.1256(e) (4)(i)	D	ESP-1

5 The virology laboratory documents the following: Reagent checks for toxicity to cell lines.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

6 The virology laboratory documents the following: Controls for neutralization tests.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

7 The virology laboratory documents the following: Controls for hemagglutination inhibition tests.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

8 The virology laboratory documents the following: Controls for immunoassays.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

9 The virology laboratory documents the following: Controls for direct immunofluorescence tests.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

10 The virology laboratory documents the following: Controls for indirect immunofluorescence tests.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1265(a) §493.1265(b)	D	ESP-1

11 The laboratory performs daily quality control for virology stains. The quality control results are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1265(a) §493.1265(b)	D	

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.21.03.01: The laboratory maintains records of virology testing processes.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The laboratory maintains records on the following: Cell lines used to isolate viruses.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 The laboratory maintains records on the following: Test methods used to detect or identify viruses.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

3 The laboratory maintains records on the following: Reactions observed as part of the virology testing processes (for example, cytopathic effects [CPE]).

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

Program: Laboratory

Chapter: Quality System Assessment for Nonwaived Testing

QSA.21.04.01: For serodiagnostic tests for viral disease, the laboratory tests components for reactivity.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1265(a)	D	ESP-1

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.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1265(a)	D	ESP-1

3 For serodiagnostic tests for viral disease, the laboratory performs quality control testing, including internal and external controls. The quality control results are documented.

EP Attributes

New	FSA	CLIA	DOC	ESP
		§493.1256(g) §493.1265(a)	D	ESP-1