The Joint Commission E-dition

Effective Date: July 1, 2022

Program: Hospital

Chapter: Waived Testing

Overview:

A laboratory test is an activity that evaluates a substance(s) removed from a human body and translates the evaluation into a result. A result can be stated as a number, presence or absence of a cell or reaction, or an interpretation. Tests that produce a result measured as a discrete number are termed "quantitative." Tests that produce a negative or positive result, such as occult bloods and urine pregnancy screens, are termed "qualitative." A test that is more precise than a qualitative test (pos/neg), but less precise than a quantitative test (numerical), is usually scored on a graded scale (1+, 2+, 3+) and is termed "semiquantitative." Tests with analysis steps that rely on the use of an instrument to produce a result are instrument-based tests. These can be qualitative, semiquantitative, or quantitative.

Test results that are used to assess a patient condition or make a clinical decision about a patient are governed by the federal regulations known as the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). CLIA '88 classifies testing into four complexity levels: high complexity, moderate complexity, provider-performed microscopy (PPM) procedures (a subset of moderate complexity), and waived testing. The high, moderate, and PPM levels, otherwise called nonwaived testing, have specific and detailed requirements regarding personnel qualifications, quality assurance, quality control, and other systems. Waived testing, on the other hand, has few requirements and is less stringent than the requirements for nonwaived testing.

The waived testing requirements are supported by the Morbidity and Mortality Weekly Report (November 11, 2005, on "Good Laboratory Practices for Waived Testing Sites"). This report indicates quality and safety concerns related to waived testing. Although by law waived tests should have insignificant risk of erroneous results, these tests are not completely error proof; some waived tests have potential for serious health impacts if performed incorrectly. This report draws attention to these pertinent risks:
- Lack of current manufacturers' instructions, including manufacturers' updates
- Failure to follow manufacturers' instructions, including performing quality control
- Reporting of incorrect results
- Lack of adherence to expiration dates
- Inappropriate storage requirements
- Not performing test system function checks or calibration checks
- Lack of documentation, including quality control and tests performed
- Inadequate training
- Lack of understanding about good laboratory practices

These errors could cause inaccurate results that could lead to inaccurate diagnoses, inappropriate or unnecessary medical treatment, and poor patient outcomes.

Waived testing is the most common complexity level performed by caregivers at the patient bedside or point of care. The list of methods that are approved as waived is under constant revision, so it is advisable to check the US Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), or Centers for Medicare & Medicaid Services (CMS) websites for the most up-to-date information regarding test categorization and complete CLIA '88 requirements such as the following:
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm
- https://www.cdc.gov/labquality/waived-tests.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fclia%2Fwaived-tests.html
- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

About This Chapter:

When a patient performs their own test (for example, whole blood glucose testing by a patient on their own meter cleared by the FDA for home use), the action is not regulated. Only testing performed by staff on patients is an activity regulated by CLIA '88. The Joint Commission standards apply to staff using instruments owned by staff, owned by the organization, or owned by the patient in performing waived laboratory tests. If staff are providing only instruction or cueing the patient, then these standards do not apply. This distinction is important when caring for patients who monitor their own health care (for example, testing of glucose or prothrombin times with home devices).

Currently, The Joint Commission allows for an organization to use the patient's results for treatment decisions. When using a patient's results from self-testing, health care providers do not have the same types of assurance about quality as they would if they conducted the testing themselves. The following processes are not specific Joint Commission requirements and are provided only as examples of how organizations have dealt with these concerns in practice:
- Verification of competency by either confirming the patient has been previously trained or observing the patient perform their first test
- Requiring the patient to perform quality control, if available for the meter, each day results are used
- Correlation of the patient's first glucose result with testing by a main laboratory
- Confirmation of all critical and nonlinear instrument values with testing by the main laboratory
- Demonstration of proper equipment maintenance

Note: The Joint Commission requirements for laboratories or sites that perform nonwaived testing are located in the "Quality System Assessment for Nonwaived Testing" (QSA) chapter of the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing.

Chapter Outline:

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.

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WT.01.01.01: Policies and procedures for waived tests are established, current, approved, and readily available.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The director named on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate approves a consistent approach for when waived test results can be used for diagnosis and treatment and when follow-up testing is required.

EP Attributes

New	FSA	CMS	DOC	ESP
				ESP-1

2 The person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, establishes written policies and procedures for waived testing that address the following:
- Clinical usage and limitations of the test methodology
- Need for confirmatory testing (for example, recommendations made by the manufacturer for rapid tests) and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)
- Specimen type, collection, and identification, and required labeling
- Specimen preservation, if applicable
- Instrument maintenance and function checks, such as calibration
- Storage conditions for test components
- Reagent use, including not using a reagent after its expiration date
- Quality control (including frequency and type) and corrective action when quality control is unacceptable
- Test performance
- Result reporting, including not reporting individual patient results unless quality control is acceptable
- Equipment performance evaluation

Note 1: Policies and procedures for waived testing are made available to testing personnel.
Note 2: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.

EP Attributes

New	FSA	CMS	DOC	ESP
			D	ESP-1

3 If manufacturers' manuals or package inserts are used as the policies or procedures for each waived test, they are enhanced to include specific operational policies (that is, detailed quality control protocols and any other institution-specific procedures regarding the test or instrument).

EP Attributes

New	FSA	CMS	DOC	ESP
			D	ESP-1

4 The person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, approves in writing policies and procedures for waived testing at the following times:
- Before initial use of the test for patient testing
- Periodically thereafter, as defined by the person whose name appears on the CLIA certificate but at least once every three years
- When changes in procedures occur (for example, when manufacturers' updates to package inserts include procedural changes or when a different manufacturer is used)

EP Attributes

New	FSA	CMS	DOC	ESP
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WT.02.01.01: The person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate identifies the staff responsible for performing and supervising waived testing.
Note 1: Responsible staff may be employees of the hospital, contracted staff, or employees of a contracted service.
Note 2: Responsible staff may be identified within job descriptions or by listing job titles or individual names.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, identifies, in writing, the staff responsible for performing waived testing.

EP Attributes

New	FSA	CMS	DOC	ESP
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2 The person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, identifies, in writing, the staff responsible for supervising waived testing.

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WT.03.01.01: Staff and licensed independent practitioners performing waived tests are competent.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or a qualified designee, provides orientation and training to, and assesses the competency of, staff and licensed independent practitioners who perform waived testing.

EP Attributes

New	FSA	CMS	DOC	ESP

2 Staff and licensed independent practitioners who perform waived testing have received orientation in accordance with the hospital's specific services. The orientation for waived testing is documented.

EP Attributes

New	FSA	CMS	DOC	ESP
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3 Staff and licensed independent practitioners who perform waived testing have been trained for each test that they are authorized to perform. The training for each waived test is documented.

EP Attributes

New	FSA	CMS	DOC	ESP
			D	

4 Staff and licensed independent practitioners who perform waived testing that requires the use of an instrument have been trained on its use and maintenance. The training on the use and maintenance of an instrument for waived testing is documented.

EP Attributes

New	FSA	CMS	DOC	ESP
			D	

5 Competency for waived testing is assessed using at least two of the following methods per person per test:
- Performance of a test on a blind specimen
- Periodic observation of routine work by the supervisor or qualified designee
- Monitoring of each user's quality control performance
- Use of a written test specific to the test assessed

EP Attributes

New	FSA	CMS	DOC	ESP

6 Competence for waived testing is assessed according to hospital policy at defined intervals, but at least at the time of orientation and annually thereafter. This competency is documented.
Note 1: When a licensed independent practitioner performs waived testing that does not involve an instrument and the test falls within their specialty, the hospital may use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual practitioner privileges include the specific waived tests appropriate to the scope of practice that they are authorized to perform. At the discretion of the person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or according to hospital policy, more stringent competency requirements may be implemented.
Note 2: Provider-performed microscopy (PPM) procedures are not waived tests.
EP Attributes

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WT.04.01.01: The hospital performs quality control checks for waived testing on each procedure.
Note: Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The person from the hospital whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate establishes a written quality control plan for waived testing that specifies the method(s) for controlling procedures for quality, establishes timetables, and explains the rationale for choice of procedures and timetables.

EP Attributes

New	FSA	CMS	DOC	ESP
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2 The documented quality control rationale for waived testing is based on the following:
- How the test is used
- Reagent stability
- Manufacturers' recommendations
- The hospital's experience with the test
- Currently accepted guidelines

EP Attributes

New	FSA	CMS	DOC	ESP
				ESP-1

3 For non-instrument-based waived testing, quality control checks are performed at the frequency and number of levels recommended by the manufacturer and as defined by the hospital’s policies.
Note: If these elements are not defined by the manufacturer, the hospital defines the frequency and number of levels for quality control.

EP Attributes

New	FSA	CMS	DOC	ESP

4 For instrument-based waived testing, quality control checks are performed on each instrument used for patient testing per manufacturers' instructions.

EP Attributes

New	FSA	CMS	DOC	ESP

5 For instrument-based waived testing, quality control checks require two levels of control, if commercially available.

EP Attributes

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WT.05.01.01: The hospital maintains records for waived testing.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 Quality control results, including internal and external controls for waived testing, are documented.
Note 1: Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid.
Note 2: Quality control results may be located in the medical record.

EP Attributes

New	FSA	CMS	DOC	ESP
			D	

2 Test results for waived testing are documented in the patient's medical record.

EP Attributes

New	FSA	CMS	DOC	ESP

3 Quantitative test result reports in the medical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served.
Note 1: Semiquantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this element of performance.
Note 2: If the reference intervals (normal values) are not documented on the same page as and adjacent to the waived test result, they must be located elsewhere within the permanent medical record. The result must have a notation directing the reader to the location of the reference intervals (normal values) in the medical record.

EP Attributes

New	FSA	CMS	DOC	ESP

4 Individual test results for waived testing are associated with quality control results and instrument records.
Note: A formal log is not required, but a functional audit trail is maintained that allows retrieval of individual test results and their association with quality control and instrument records.

EP Attributes

New	FSA	CMS	DOC	ESP

5 Quality control result records, test result records, and instrument records for waived testing are retained for at least two years.

EP Attributes

New	FSA	CMS	DOC	ESP