The Joint Commission E-dition

Effective Date: January 1

Program: Laboratory

Chapter: Waived Testing

Overview:

A laboratory test is an activity that evaluates a substance(s) removed from a human body and translates that 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 fecal occult blood and urine pregnancy screens, are termed "qualitative." A test that is more precise than a qualitative t (pos/neg), but less precise than a quantitative test (numerical), is usua 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 produ a result are instrument-based tests. These can be qualitative, semiquantitative, or quantitative.

Test results that are used to assess a patient's condition or make a clini decision about a patient are governed by the federal regulations known 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, subset of moderate complexity), and waived testing. The high, moderat 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 Joint Commission first developed standards to address waived testi in 1992, and the standards were essentially unchanged until 2005. At th time, The Joint Commission approved revisions to its waived testing standards to address the growing number of waived testing methods, risks to patient safety and quality of care when waived testing is performed improperly, and quality problems revealed by the Centers for Medicare & Medicaid Services (CMS).

The Morbidity and Mortality Weekly Report article, "Good Laboratory Practices for Waived Testing Sites" from November 11, 2005, supports the waived testing requirements. 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 complete error proof, and 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 regulated testing performed by caregivers at the patient bedside or point of care. The current list of methods that are approved as waived is under constant revision, so it is advisable to check the U. S. Food and Drug Administration (FDA), Center for Disease Control and Prevention (CDC), or CMS websites, such as the following, for the most up-to-date information regarding test categorization and complete CLIA '88 requirements:
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http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.c
- http://wwwn.cdc.gov/clia/Resources/WaivedTests/
- http://www.cms.hhs.gov/clia

About This Chapter:

When a patient performs a test on him- or herself (for example, whole blood glucose testing by a patient on his or her own meter cleared by the FDA for home use), the action is not regulated. Only testing performed staff on patients is 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 members 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 but are provided only as examples of how organizations have dealt with these concerns in practice:
- Verification of competency by either confirming that the patient has been previously trained or observing the patient perform his or her 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 Assessme for Nonwaived Testing" (QSA) chapter of the Comprehensive Accreditati Manual for Laboratory and Point-of-Care Testing.

Chapter Outline:

I. Policies and Procedures (WT.01.01.01)

II. Identification of Staff Performing and Supervising Waived Testing (WT.02.01.01)

III. Competency of Staff Performing Waived Testing (WT.03.01.01)

IV. Performance of Quality Control Checks (WT.04.01.01)

V. Recordkeeping (WT.05.01.01)

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.

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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 person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate approves a consistent approach for when waived test results can be use for diagnosis and treatment and when follow-up testing is required. (See also LD.04.01.01, EP 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

2 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or qualified designee, establishes written policies and procedures for waive testing that address the following:
- Clinical usage and limitations of the test methodology
- Need for confirmatory testing (for example, recommendations made b 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 wh quality control is unacceptable
- Test performance
- Result reporting, including not reporting individual patient results unles 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	CLIA	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	CLIA	DOC	ESP
			D	ESP-1

4 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate, or qualified designee, approves in writing policies and procedures for waive testing at the following times:
- Before initial use of the test for patient testing
- Periodically thereafter, as defined by the person whose name appears 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 differe manufacturer is used)

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

5 Current and complete policies and procedures are available for use durir testing to the person performing the waived test.

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

6 Written policies, procedures, and manufacturers' instructions for waived testing are followed. (See also WT.04.01.01, EPs 3–5)
Note: Manufacturers' recommendations and suggestions are surveyed a requirements.

EP Attributes

New	FSA	CLIA	DOC	ESP
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WT.02.01.01: The person from the organization whose name appear 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 organization, contracted staff, or employees of a contracted service.
Note 2: Responsible staff may be identified within job descriptions o by listing job titles or individual names.

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Human Resources			ESP-1

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

EP Attributes

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

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	CLIA	DOC	ESP
	- Human Resources		D	ESP-1

4

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

EP Attributes

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

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	CLIA	DOC	ESP
	- Human Resources			ESP-1

6 Competence for waived testing is assessed according to organization pol 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 testi that does not involve an instrument and the test falls within his or her specialty, the organization 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 th scope of practice that he or she is authorized to perform. At the discretio of the person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate or according to organization policy, more stringent competency requiremer may be implemented.
Note 2: Provider-performed microscopy (PPM) procedures are not waive tests. (See also HR.01.06.01, EP 18 for PPM Competency Requirements)

EP Attributes

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

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WT.04.01.01: The organization 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 liqu

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

1 The person from the organization whose name appears on the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate approves a written quality control plan for waived testing that specifies t method(s) for controlling procedures for quality, establishes timetables, and explains the rationale for choice of procedures and timetables. (See also LD.04.01.01, EP 1)

EP Attributes

New	FSA	CLIA	DOC	ESP
			D	ESP-1

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

EP Attributes

New	FSA	CLIA	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 organization’s policies. (See also WT.01.01.01, EP 6)
Note: If these elements are not defined by the manufacturer, the

organization defines the frequency and number of levels for quality control.

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Waived Testing			ESP-1

4 For instrument-based waived testing, quality control checks are perform on each instrument used for patient testing per manufacturers' instructions. (See also WT.01.01.01, EP 6)

EP Attributes

New	FSA	CLIA	DOC	ESP
	- Waived Testing			

5 For instrument-based waived testing, quality control checks require two levels of control, if commercially available. (See also WT.01.01.01, EP 6

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

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WT.05.01.01: The organization maintains records for waived testing

Rationale: Not applicable.

Introduction: Not applicable

Elements of Performance

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

EP Attributes

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

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

EP Attributes

New	FSA	CLIA	DOC	ESP

3 Quantitative test result reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values) specific the test method used and the population served. (See also DC.02.03.01 EP 2)
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 o the same page as and adjacent to the waived test result, they must be located elsewhere within the patient's permanent clinical record. The res must have a notation directing the reader to the location of the referenc intervals (normal values) in the patient's clinical record.

EP Attributes

New	FSA	CLIA	DOC	ESP

	§493.1291 (d)	ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1

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

EP Attributes

New	FSA	CLIA	DOC	ESP
				ESP-1