2007 Waived Testing

Overview

The federal regulation governing laboratory testing, known as the Clinical Laboratories Improvement Amendments of 1988 (CLIA '88), classifies testing into four complexity levels: high complexity, moderate complexity, Provider Performed Microscopy (PPM, a sub-set of moderate complexity), and waived testing. The high, moderate, and PPM levels, otherwise called non-waived testing, have specific and detailed requirements regarding personnel qualifications, quality assurance, quality control, and other systems. Joint Commission requirements and laboratories or sites that perform non-waived testing are located in the Quality Control chapter. Waived testing, on the other hand, has few requirements and are less stringent then the requirements for non-waived testing.

The same laboratory test can be available by more than one method within an laboratory, and those methods can be of different complexity levels. Waived testing is the most common complexity level performed by caregivers at the patient bedside or point of care (POC). The list of methods that are approved as waived is under constant revision, so it is advisable to check the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), or Centers for Medicare and Medicaid Services (CMS) Web sites for the most up-to-date information regarding test categorization and complete CLIA requirements. Those Web sites are as follows:

- www.fda.gov/cdrh/clia/index.html
- www.phppo.cdc.gov/clia
- www.cms.hhs.gov/clia

A laboratory test is an activity that evaluates substances 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, such as what occurs when recording a urine color. Test results that are used to assess a patient condition or make a clinical decision about a patient are governed by CLIA '88.

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), usually scored on a graded scale (1+, 2+, 3+) is termed "semi-quantitative". Tests with analysis steps that rely on the use of an instrument to produce a result are instrument-based tests. These can be qualitative, semi-quantitative, or quantitative.

When a patient performs a test on himself 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. Testing performed by one individual on another individual while carrying out professional responsibilities is an activity regulated by CLIA ’88. This distinction is important when caring for patients who monitor their own health care (e.g. testing of glucose or prothrombin times with home devices).

Standards, Rationales, Elements of Performance, and Scoring

Standard WT.1.10

The director named on the CLIA certificate establishes policies and procedures that define the context in which waived test results are used in patient care, treatment, and services.

Elements of Performance for WT.1.10

B 1. The director named on the CLIA certificate determines the context in which waived tests are used.

(M)C 2. Clinical use of results is consistent with the laboratory’s policies and the manufacturer’s recommendations for waived tests.

B 3. Quantitative test result reports in the clinical record are accompanied by reference intervals specific to the test method used and population served.
Note: *Semi-quantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this EP.*

A 4. For qualitative and quantitative tests, criteria for confirmatory testing is specified in the written procedures.

B 5. These written procedures are based on clinical usage and limitations of the test methodology.

(M) C 6. The criteria for confirmatory testing is followed as specified in the written procedures.

Standard WT.1.20

The director named on the CLIA certificate identifies the staff responsible for performing and supervising waived testing.

Elements of Performance for WT.1.20

B 1. The identity of staff members who perform testing is documented.

B 2. The identity of staff members who direct or supervise testing is documented.

Note: These individuals may be employees of the organization, contracted staff, or employees of a contracted service.

Standard WT.1.30
Staff receive, specific training and orientation for the tests they perform, and demonstrate satisfactory levels of competence.

Rationale for WT.1.30
For waived tests to be performed properly, the staff performing them must be qualified to do so. Staff members who perform waived testing have specific training for each test performed. This training can be acquired through organization or other training programs, such as those provided by another health care organizations or manufacturers.

Elements of Performance for WT.1.30
B 1. Staff members who perform testing have been oriented according to the laboratory's specific services.

B 2. Staff members who performs testing have been trained for each test he or she is authorized to perform.

B 3. Staff members who perform testing that requires the use of an instrument have been trained on the use and maintenance of that instrument.

B4. Competence is assessed according to laboratory policy at defined intervals, but at least at the time of orientation and annually thereafter.

B5. Current competency is assessed using at least two of the following methods per person per test:

- Performing a test on a blind specimen[1]
- Having the supervisor or qualified delegate periodically observe routine work
- Monitoring each user's quality control performance
- Written testing specific to the method assessed

B 6. The director named on the CLIA certificate or qualified designee evaluates and documents evidence of orientation, training, and competency.
Note: *Staff who perform instrument-based testing, including but not limited to physicians, licensed independent practitioners, contracted staff, and RNs, participate in training and competence demonstrations.*

Standard WT.1.40

[1] **Blind specimen –** a sample with known value tested by personnel who do not know the expected result.

Policies and procedures governing specific testing-related processes are current, approved, and readily available.

Rationale for WT.1.40

Current and up-to-date policies and procedures are an important reference tool in managing laboratory testing activities. Testing policies and procedures include requirements that are in compliance with the manufacturer's recommendations regarding all of the following, as applicable:

- Specimen type (e.g. a method for whole blood is not used for spinal fluid)
- Storage conditions for test components (e.g. compliance with directions such as stored away from direct light, temperature requirements, open container expiration dates, and so forth)
- Instrument maintenance and function checks, such as calibration
- Quality control frequency and type
- Result follow-up recommendations (e.g. a recommendation to repeat the test when results are higher or lower than the reportable range of the test[2])
- Tests approved by the FDA for home use only are not used for professional purposes (e.g. glucose meters cleared for home use only are not used in a hospital setting by nursing staff except as patient education)

Elements of Performance for WT.1.40

A 1. The director named on the CLIA certificate or a qualified designee approves policies and procedures at the following times:

- Before initial use of the test for patient testing
- Periodically thereafter, defined by the director but at least once every three years
- When there are changes in procedures[3]

B 2. Written policies and procedures address the following items:

- Specimen type, collection, identification, and required labeling
- Specimen preservation, as appropriate
- Instrument maintenance and function checks, such as calibration
- Storage conditions for test components
  Note: *No reagent is used after its expiration date*
- Quality control (including frequency and type) and remedial action
- Result reporting
  Note: *Individual patient results are not reported unless the quality control is acceptable*
- Equipment performance evaluation
- Test performance

[2] **Reportable range –** the span of test result values over which the laboratory can verify the accuracy of the instrument or test system measurement response.

[3] **Changes in procedures –** manufacturer updates to package inserts can include procedural changes or a different manufacturer is used.

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

B 4. Current and complete policies and procedures are readily available to the person performing the test.

B 5. Written policies, procedures, and manufacturer's instructions are followed.

Standard WT.1.50
Quality control checks are conducted on each procedure.

Elements of Performance for WT.1.50
B 1. The director named on the CLIA certificate establishes a written quality control plan that specifies how procedures will be controlled for quality, establishes timetables, and explains the rationale for choice of procedures and timetables.

B 2. The documented quality control rationale is based on the following:

- How the test is used
- Reagent stability
- Manufacturers' recommendations
- The organization's experience with the test
- Currently accepted guidelines

B 3. Quality control procedures are performed at least as frequently as recommended by the manufacturer or defined by the laboratory's policies.
Note: *If frequency of quality control is not defined by the manufacturer, the organization defines frequency of quality control.*

(M)C 4. For instrument-based waived testing, quality control requirements include two levels of control, if commercially available.

(M) C 5. For instrument-based waived testing, quality control procedures are performed at least once each day on each instrument used that day for patient testing.

Standard WT.1.60
Quality control and test result records are maintained.

Elements of Performance for WT.1.60

(M) C 1. Quality control results are documented, including internal and external (liquid and electronic).
Note: *Quality control results may be located in the clinical record.*

(M) C 2. Test results are documented in the clinical record.

B 3. Individual test results are associated with quality control 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.*

A 4. Quality control and test result records are retained for at least two years.