

History Tracking Report: 2009 to 2010 Requirements

Accreditation Program: Laboratory

2009 Chapter: Waived Testing

Standard WT.1.10

2009 Standard Text:

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.

2009 Standard: WT.1.10

2009 EP: 1

2009 EP Text:

Revision Type: Retain

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

2009 Standard: WT.1.10

2009 EP: 2

2009 EP Text:

Revision Type: Retain

Clinical use of results is consistent with the organization's policies and the manufacturer's recommendations for waived tests.

2009 Standard: WT.1.10

2009 EP: 3

2009 EP Text:

Revision Type: Retain

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.

Standard WT.01.01.01

2010 Standard Text:

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

2010 Standard: WT.01.01.01

2010 EP: 1

2010 EP Text:

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 used for diagnosis and treatment and when follow-up testing is required. (See also LD.04.01.01, EP 1)

2010 Standard: WT.01.01.01

2010 EP: 8

2010 EP Text:

Clinical use of results is consistent with the organization's policies and the manufacturers' recommendations for waived tests.

2010 Standard: WT.05.01.01

2010 EP: 3

2010 EP Text:

Quantitative test result reports in the patient's clinical record for waived testing are accompanied by reference intervals (normal values) specific to the test method used and the population served. (See also DC.02.03.01, EP 12)
 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 patient's permanent clinical record. The result must have a notation directing the reader to the location of the reference intervals (normal values) in the patient's clinical record.

2009 Standard: WT.1.10**2009 EP:** 4**2010 Standard:** WT.01.01.01**2010 EP:** 2**2009 EP Text:**

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

Revision Type: Consolidate**2010 EP Text:**

The person from the organization 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: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.

2009 Standard: WT.1.10**2009 EP:** 5**2009 EP Text:**

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

Revision Type: Consolidate**2010 Standard:** WT.01.01.01**2010 EP:** 2**2010 EP Text:**

The person from the organization 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: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.

2009 Standard: WT.1.10**2009 EP:** 6**2009 EP Text:**

The criteria for confirmatory testing is followed as specified in the written procedures.

Revision Type: Retain**2010 Standard:** WT.01.01.01**2010 EP:** 7**2010 EP Text:**

The criteria for confirmatory testing are followed as specified in the waived testing written procedures.

Standard WT.1.20

2009 Standard Text:

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

Standard WT.02.01.01

2010 Standard Text:

The person from the organization 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 organization, 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.

2009 Standard: WT.1.20

2009 EP: 1

2009 EP Text:

The identity of staff members who perform testing is documented.

Revision Type: Retain

2010 Standard: WT.02.01.01

2010 EP: 1

2010 EP Text:

The person from the organization 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.

2009 Standard: WT.1.20

2009 EP: 2

2009 EP Text:

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.

Revision Type: Retain

2010 Standard: WT.02.01.01

2010 EP: 2

2010 EP Text:

The person from the organization 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.

Standard WT.1.30

2009 Standard Text:

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

2009 Standard: WT.1.30

2009 EP: 1

2009 EP Text:

Staff members who perform testing have been oriented according to the organization's specific services.

Revision Type: Retain

2009 Standard: WT.1.30

2009 EP: 2

2009 EP Text:

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

Revision Type: Retain

2009 Standard: WT.1.30

2009 EP: 3

2009 EP Text:

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

Revision Type: Retain

Standard WT.03.01.01

2010 Standard Text:

Staff and licensed independent practitioners performing waived tests are competent.

2010 Standard: WT.03.01.01

2010 EP: 2

2010 EP Text:

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.

2010 Standard: WT.03.01.01

2010 EP: 3

2010 EP Text:

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.

2010 Standard: WT.03.01.01

2010 EP: 4

2010 EP Text:

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.

2009 Standard: WT.1.30

2009 EP: 4

2010 Standard: WT.03.01.01

2010 EP: 6

2009 EP Text:

Revision Type: Retain

2010 EP Text:

Competence is assessed according to {jc}organization{/2} policy at defined intervals, but at least at the time of orientation and annually thereafter.

Competence for waived testing is assessed according to organization 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 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 the scope of practice that he or she is authorized to perform. At the discretion 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 requirements may be implemented.

Note 2: Provider-performed microscopy (PPM) procedures are not waived tests. (See also HR.01.06.01, EP 18 for PPM Competency Requirements)

2009 Standard: WT.1.30

2009 EP: 5

2010 Standard: WT.03.01.01

2010 EP: 5

2009 EP Text:

Revision Type: Retain

2010 EP Text:

Current competency is assessed using at least two of the following methods per person per test: Performing a test on a blind specimen*Having the supervisor or qualified delegate periodically observe routine workMonitoring each user's quality control performanceWritten testing specific to the method assessed*Blind specimen – a sample with known value tested by personnel who do not know the expected result.

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

2009 Standard: WT.1.30

2009 EP: 6

2010 Standard: WT.03.01.01

2010 EP: 1

2009 EP Text:

Revision Type: Retain

2010 EP Text:

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.

The person from the organization 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.

Standard WT.1.40

2009 Standard Text:

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

2009 Standard: WT.1.40

2009 EP Text:

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

2009 EP: 1

Revision Type: Retain

Standard WT.01.01.01

2010 Standard Text:

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

2010 Standard: WT.01.01.01

2010 EP: 4

2010 EP Text:

The person from the organization 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)

2009 Standard: WT.1.40

2009 EP: 2

2010 Standard: WT.01.01.01

2010 EP: 2

2009 EP Text:

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

Revision Type: Consolidate

2010 EP Text:

The person from the organization 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: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.

2009 Standard: WT.1.40

2009 EP: 3

2010 Standard: WT.01.01.01

2010 EP: 3

2009 EP Text:

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).

Revision Type: Retain

2010 EP Text:

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).

2009 Standard: WT.1.40

2009 EP: 4

2010 Standard: WT.01.01.01

2010 EP: 5

2009 EP Text:

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

Revision Type: Retain

2010 EP Text:

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

2009 Standard: WT.1.40

2009 EP: 5

2010 Standard: WT.01.01.01

2010 EP: 6

2009 EP Text:

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

Revision Type: Retain

2010 EP Text:

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 as requirements.

Standard WT.1.50

2009 Standard Text:

Quality control checks are conducted on each procedure.

Standard WT.04.01.01

2010 Standard Text:

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 liquid.

2009 Standard: WT.1.50

2009 EP: 1

2009 EP Text:

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.

Revision Type: Retain

2010 Standard: WT.04.01.01

2010 EP: 1

2010 EP Text:

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 the 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)

2009 Standard: WT.1.50

2009 EP: 2

2009 EP Text:

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

Revision Type: Retain

2010 Standard: WT.04.01.01

2010 EP: 2

2010 EP Text:

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

2009 Standard: WT.1.50

2009 EP: 3

2009 EP Text:

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

Revision Type: Retain

2010 Standard: WT.04.01.01

2010 EP: 3

2010 EP Text:

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.

2009 Standard: WT.1.50**2009 EP:** 4**2010 Standard:** WT.04.01.01**2010 EP:** 5**2009 EP Text:****Revision Type:** Retain**2010 EP Text:**

For instrument-based waived testing, quality control requirements include two levels of control, if commercially available.

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

2009 Standard: WT.1.50**2009 EP:** 5**2010 Standard:** WT.04.01.01**2010 EP:** 4**2009 EP Text:****Revision Type:** Retain**2010 EP Text:**

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

For instrument-based waived testing, quality control checks are performed each day on each instrument used for patient testing or per manufacturers' instructions, if more stringent. (See also WT.01.01.01, EP 6)

Note: Quality control checks are not required on an individual instrument on days when it is not used for patient testing.

Standard WT.1.60

2009 Standard Text:

Quality control and test result records are maintained.

2009 Standard: WT.1.60

2009 EP: 1

2009 EP Text:

Revision Type: Retain

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

2009 Standard: WT.1.60

2009 EP: 2

2009 EP Text:

Revision Type: Retain

Test results are documented in the clinical record.

2009 Standard: WT.1.60

2009 EP: 3

2009 EP Text:

Revision Type: Retain

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.

2009 Standard: WT.1.60

2009 EP: 4

2009 EP Text:

Revision Type: Retain

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

Standard WT.05.01.01

2010 Standard Text:

The organization maintains records for waived testing.

2010 Standard: WT.05.01.01

2010 EP: 1

2010 EP Text:

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 clinical record.

2010 Standard: WT.05.01.01

2010 EP: 2

2010 EP Text:

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

2010 Standard: WT.05.01.01

2010 EP: 4

2010 EP Text:

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.

2010 Standard: WT.05.01.01

2010 EP: 5

2010 EP Text:

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