



# The Joint Commission

Accreditation Program: Laboratory

Waived Testing

**Standard WT.01.01.01**

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

**Elements of Performance for WT.01.01.01**

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|-------------|---|-------------------|
| 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 used for diagnosis and treatment and when follow-up testing is required. (See also LD.04.01.01, EP 1)   | <b>A</b>          |
| 2.          | <p><b>D</b> 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:</p> <ul style="list-style-type: none"> <li>- Clinical usage and limitations of the test methodology</li> <li>- 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)</li> <li>- Specimen type, collection, and identification, and required labeling</li> <li>- Specimen preservation, if applicable</li> <li>- Instrument maintenance and function checks, such as calibration</li> <li>- Storage conditions for test components</li> <li>- Reagent use, including not using a reagent after its expiration date</li> <li>- Quality control (including frequency and type) and corrective action when quality control is unacceptable</li> <li>- Test performance</li> <li>- Result reporting, including not reporting individual patient results unless quality control is acceptable</li> <li>- Equipment performance evaluation</li> </ul> <p>Note: The designee should be knowledgeable by virtue of training, experience, and competence about the waived testing performed.</p> | <b>A</b>          |
| 3.          | <p><b>D</b> 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).</p>  | <b>A</b>          |
| 4.          | <p><b>D</b> 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:</p> <ul style="list-style-type: none"> <li>- Before initial use of the test for patient testing</li> <li>- Periodically thereafter, as defined by the person whose name appears on the CLIA certificate but at least once every three years</li> <li>- When changes in procedures occur (for example, when manufacturers' updates to package inserts include procedural changes or when a different manufacturer is used)</li> </ul>  | <b>A</b>          |
| 5.          | Current and complete policies and procedures are available for use during testing to the person performing the waived test.   | <b>A</b>          |
| <b>M</b> 6. | <p>Written policies, procedures, and manufacturers' instructions for waived testing are followed. (See also WT.04.01.01, EPs 3-5)</p> <p>Note: Manufacturers' recommendations and suggestions are surveyed as requirements.</p>   | <b>3</b> <b>C</b> |

**KEY:** **A** indicates scoring category A; **C** indicates scoring category C; **2** indicates situational decision rules apply; **3** indicates direct impact requirements apply; **M** indicates Measure of Success if needed; **D** indicates that documentation is required

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| <b>M</b> | 7. | The criteria for confirmatory testing are followed as specified in the waived testing written procedures.                       | <b>3</b> <b>C</b> |
| <b>M</b> | 8. | Clinical use of results is consistent with the organization's policies and the manufacturers' recommendations for waived tests. | <b>3</b> <b>C</b> |

### Standard WT.02.01.01

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.

#### Elements of Performance for WT.02.01.01

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| 1. | <b>D</b> | 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.  | <b>A</b> |
| 2. | <b>D</b> | 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. | <b>A</b> |

### Standard WT.03.01.01

Staff and licensed independent practitioners performing waived tests are competent.

#### Elements of Performance for WT.03.01.01

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| 1.       |    | 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.   | <b>A</b>          |
| <b>M</b> | 2. | <b>D</b> 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.   | <b>C</b>          |
| <b>M</b> | 3. | <b>D</b> 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.  | <b>C</b>          |
| <b>M</b> | 4. | <b>D</b> 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.  | <b>C</b>          |
| 5.       |    | Competency for waived testing is assessed using at least two of the following methods per person per test:<br>- Performance of a test on a blind specimen<br>- Periodic observation of routine work by the supervisor or qualified designee<br>- Monitoring of each user's quality control performance<br>- Use of a written test specific to the test assessed | <b>3</b> <b>A</b> |

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- M** 6. **D** 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. **C**
- 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)

### Standard 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 liquid.

#### Elements of Performance for WT.04.01.01

1. **D** 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) **A**
2. The documented quality control rationale for waived testing is based on the following: **A**
- How the test is used
  - Reagent stability
  - Manufacturers' recommendations
  - The organization's experience with the test
  - Currently accepted guidelines
- M** 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) **3** **C**
- Note: If these elements are not defined by the manufacturer, the organization defines the frequency and number of levels for quality control.
- M** 4. 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) **3** **C**
- Note: Quality control checks are not required on an individual instrument on days when it is not used for patient 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) **3** **A**

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**Standard WT.05.01.01**

The organization maintains records for waived testing.

**Elements of Performance for WT.05.01.01**

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|-----------------|--------------------|---|-----------------|
| <p><b>M</b></p> | <p>1. <b>D</b></p> | <p>Quality control results, including internal and external controls for waived testing, are documented.<br/>                 Note 1: Internal quality controls may include electronic, liquid, or control zone. External quality controls may include electronic or liquid.<br/>                 Note 2: Quality control results may be located in the clinical record.</p>  | <p><b>C</b></p> |
| <p><b>M</b></p> | <p>2.</p>          | <p>Test results for waived testing are documented in the patient's clinical record.</p>   | <p><b>C</b></p> |
|                 | <p>3.</p>          | <p>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)<br/>                 Note 1: Semiquantitative results, such as urine macroscopic and urine dipsticks, are not required to comply with this element of performance.<br/>                 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.</p> | <p><b>A</b></p> |
|                 | <p>4.</p>          | <p>Individual test results for waived testing are associated with quality control results and instrument records.<br/>                 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.</p>   | <p><b>A</b></p> |
|                 | <p>5.</p>          | <p>Quality control result records, test result records, and instrument records for waived testing are retained for at least two years.</p>  | <p><b>A</b></p> |

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