

Standards BoosterPak™ for Waived Testing



The Joint Commission

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Director, Standards Interpretation Group
The Joint Commission
1 Renaissance Boulevard
Oakbrook Terrace, Illinois 60181

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Preface

A laboratory test is an activity that evaluates a substance(s) removed from a human body and translates that evaluation into a result. Test results that are used to assess a patient's 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).

The US Food and Drug Administration (FDA) is responsible for the complexity categorization of commercially marketed laboratory tests as defined by CLIA '88, while the US Centers for Medicare & Medicaid Services (CMS) is responsible for the implementation of CLIA itself. The FDA classifies testing into complexity levels based on CLIA '88 criteria: high complexity, moderate complexity, provider-performed microscopy procedures (PPMP), and waived testing. The nonwaived categories (moderate and high complexity) and PPMP have specific and detailed requirements regarding personnel qualifications, quality assurance, quality control, and other systems. Waived testing has fewer requirements, and regulations are less stringent than the requirements for nonwaived testing.

Waived Testing as a Patient Safety Issue

Waived testing is the most common regulated testing performed by caregivers at the patient bedside or point of care.^{1,2} Although waived testing is less complex, that does not mean that it lacks importance or that errors do not pose a risk to patients. Although by law waived tests should have insignificant risk of erroneous results, these tests are not completely error proof, and some have potential for serious negative impacts on patient health if performed incorrectly. The most current list of methods that are approved as waived can be found on the websites of the FDA, CMS, or the US Centers for Disease Control and Prevention (CDC):

- <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm>
- <http://www.cms.hhs.gov/clia>
- <http://wwwn.cdc.gov/clia/resources/waivedtests/>

Regulatory Oversight

CLIA '88 federal oversight includes all testing on human specimens for the purposes of health assessment or for the diagnosis, prevention, or treatment of disease.³ Laboratories performing such tests are required to have an appropriate CLIA certificate from the US Department of Health and Human Services, with the certificate specific to the nature of the testing performed. This CLIA certificate is necessary for the laboratory to legally test human specimens, as well as to be eligible for payment through the Medicare/Medicaid programs. Facilities performing only waived testing can apply for a Certificate of Waiver. Facilities holding Certificates of Accreditation or Compliance can perform moderate- or high-complexity testing, as well as waived testing. Some organizations have multiple CLIA certificates; some choose to license their waived testing program under a Certificate of Waiver, separate from their main laboratory CLIA certificate. Organizations should determine the most appropriate certification(s) for their waived and nonwaived testing, based on their specific laboratory testing governance, various departments involved in laboratory testing, current laboratory accreditations, and so forth. A more detailed description of the various CLIA certificates, the CLIA certificate application process, inspection information, guidelines, and FAQs can be found at <http://www.cms.hhs.gov/CLIA>.

1. US Centers for Medicare & Medicaid Services. CLIA Labs by Certificate Type (Non-Exempt Only). Jun 2014. Accessed Jul 21, 2014. <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/statcer.pdf>.
2. Rauch CA, Nichols JH. Laboratory accreditation and inspection. *Clin Lab Med*. 2007;27(4):845–858.
3. US Centers for Disease Control and Prevention. Regulations for implementing the Clinical Laboratory Improvement Amendments of 1988: A summary. *MMWR Recomm Rep*. 1992 Feb 28;41(RR-2):1–17. Accessed Jul 21, 2014. <http://www.cdc.gov/mmwr/preview/mmwrhtml/00016177.htm>.

- Compliance with CLIA is assessed either through a CMS certification process utilizing the CLIA requirements, or through one of the private, nonprofit organizations whose requirements are equal to, or more stringent than, the CLIA regulations. The Joint Commission is one of these organizations. A complete list of these alternate accreditation organizations can be found at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf>. In addition, some states have more rigorous regulations for laboratory testing, such as the licensing of any personnel performing laboratory testing or procedures, which may include waived testing. In such situations, the more stringent requirements and regulations must be followed.
- When performing waived testing, all manufacturers' instructions must be followed, including using the test within the specified limitations. Deviation from the manufacturers' instructions and/or performing testing outside of specified intended use and limitations is considered "off label" and changes the testing to high complexity. When this happens, the testing location is required to meet all the CLIA regulations that apply to high complexity testing.

About This BoosterPak

This BoosterPak™ discusses standards and criteria from multiple accreditation programs related to the performance of waived testing. It is designed to assist you with the following three activities:

1. Identifying regulatory requirements that impact clinical areas related to waived testing
2. Understanding practices that will meet the regulatory requirements and provide a reliable level of practice related to waived testing procedures
3. Finding other resources that can assist you with additional regulatory information, process improvement activities, and leading practices related to your waived testing program

The Joint Commission's Waived Testing (WT) standards, in many instances, contain similar standard and element of performance (EP) language for all accreditation programs. An exception to this is the noun describing the care setting. For example, when referring to the accredited organization, in some instances the word *laboratory* is used rather than *hospital* or *organization*. Likewise, some accreditation programs use the term, *patient*, while others use *patient or resident* or *individual served*. For the purposes of this document, the general terms *organization* and *patient* will be used. In addition to the waived testing standards, this BoosterPak discusses two other relevant standards:

1. Infection Prevention and Control (IC) Standard **IC.02.02.01**, which addresses the cleaning, disinfection, and sanitization of medical equipment, devices, and supplies.
2. Leadership (LD) Standard **LD.04.01.01**, which addresses the organization's compliance with law and regulation.

Some requirements may not be applicable to every accreditation program. Please refer to the applicability grids that accompany each standard discussed in Section A. Description of Standard and Implementation Expectations.

The language in this BoosterPak is designed to help the reader differentiate actions that are recommended from actions that are required. If the term *must* is used, then the item in question is a requirement. Other points should be considered recommendations only.

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A. Description of Standard and Implementation Expectations

Standard WT.01.01.01

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

Applicability

Ambulatory/Office-Based Surgery	Behavioral Health	Home Care	Hospital/Critical Access Hospital*	Laboratory	Nursing Care Center
EPs 1–8	EPs 1–8	EPs 1–7, 9	EPs 1–8	EPs 1–8	EP 8 only

* The "Waived Testing" standards are applicable to Critical Access Hospitals effective January 1, 2015.

Elements of Performance for WT.01.01.01

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 tests results can be used for diagnosis and treatment and when follow-up testing is required. (*See also* LD.04.01.01, EP 1)
2. 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.*
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).
4. 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)
5. Current and complete policies and procedures are available for use during testing to the person performing the waived test.
 6. Written policies, procedures, and manufacturers' instructions for waived testing are followed. (*See also* WT.04.01.01, EPs 3–5)
 7. The criteria for confirmatory testing are followed as specified in the waived testing written procedures.
 8. Clinical use of results is consistent with the organization's policies and the manufacturers' recommendations for waived tests.
 9. **For home health agencies and hospices that elect to use The Joint Commission deemed status option:**
If the organization engages in laboratory testing, it maintains compliance with the Clinical Laboratory Improvements of 1988 (CLIA '88).

Implementation Expectations

- Waived testing procedures are complete and include the key components as listed in the standard.
- Waived testing procedures have been approved and undergo periodic review as defined by the organization.
- Waived testing procedures are readily available to testing personnel.
- Manufacturers' recommendations and instructions are incorporated into facility procedures and are followed by testing personnel.
- Confirmatory testing policies are followed by testing personnel where applicable.
- Waived testing is used as per manufacturers' recommendations and organization-specific policies.
- **For home health agencies and hospices that elect to use The Joint Commission deemed status option:**
Ensure compliance with CLIA '88 regulations.
Note: *The organization is exempt from CLIA '88 requirements when it only assists an individual in self-administering a waived test using an appliance that has been cleared by the FDA for waived testing.*
- One of the keys to compliance with this standard is ensuring that the organization is documenting information appropriately. EP 2 of this standard requires that written policies and procedures for waived testing be established, and it lists the information that must be included in those policies and procedures. EP 3 requires that if manufacturers' manuals or inserts are used as the policies or procedures for each waived test, they are enhanced to include specific operational policies (for example, detailed quality control protocols). EP 4 requires that the person from the organization whose name appears on the CLIA certificate, or a qualified designee, approves in writing the policies and procedures for waived testing. Failure to ensure that actions are documented as required can result in a Requirement for Improvement.

Strategies for Compliance

- Routinely review manufacturer package inserts to ensure that the information included in procedures is up-to-date.
- Ensure that staff can readily locate procedures associated with waived testing. These procedures can be hard copy or electronic. If both formats are in use, ensure that the documents match with regard to revision date, document number, and so forth. Perform mock surveys asking staff to retrieve procedures and locate specific information within the procedure to demonstrate familiarity with documents and use.
- Ensure that staff can speak to the use of confirmatory testing, where applicable, through the performance of mock tracers or surveys.
- Perform audits to ensure that confirmatory testing is being performed according to policy, where applicable.
- Review the manufacturer's recommendations for the clinical use of the waived test in question and ensure that your use of the test is appropriate according to the manufacturer's clinical statements. Use of a waived test in a manner that is not consistent with the manufacturer's statements can be considered "off label" use. If the waived device or product is used for any purpose not specified in the package insert, or for a population not specified by the manufacturer, their use is classified as a high-complexity test, and would therefore require the additional validations specified by CLIA '88 for high-complexity testing. FDA guidelines on appropriate clinical use, as well as off-label criteria, are available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380325.pdf> and <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380327.pdf>.
- Organizations must use waived testing instrumentation that has been FDA approved for professional use. The use of devices purchased at retail stores is unacceptable.

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.*

Applicability

Ambulatory/Office-Based Surgery	Behavioral Health	Home Care	Hospital/Critical Access Hospital	Laboratory	Nursing Care Center
EPs 1–2	EPs 1–2	EPs 1–2	EPs 1–2	EPs 1–2	NA

Elements of Performance for WT.02.01.01

1. 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.
2. 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.

Implementation Expectations

- The organization can provide documentation of the staff **performing** waived testing. The person from the organization whose name appears on the CLIA certificate, or a qualified designee, must identify, in writing, the staff responsible for performing waived testing. A designee should be knowledgeable by virtue of training, experience, and competence about the waived testing being performed.
- The organization can provide documentation of the staff **supervising** waived testing. The person from the organization whose name appears on the CLIA certificate, or a qualified designee, must identify, in writing, the staff responsible for supervising waived testing.
- Examples of such documentation can include written job descriptions and/or standard operating procedures.

Strategies for Compliance

- Define the operators performing waived testing in writing by name, or as part of their job description.
- Define the designees providing waived testing supervisory oversight in writing by name or as part of their job description.
- Keep operator lists up-to-date and inactivate access for terminated employees in a timely manner.
- If policy states operators perform waived testing based on their job description, periodically review the job description(s) to ensure that the waived testing duties are listed appropriately and are not in need of revision.

Standard WT.03.01.01

Staff and licensed independent practitioners performing waived tests are competent.

Applicability

Ambulatory/Office-Based Surgery	Behavioral Health	Home Care	Hospital/Critical Access Hospital	Laboratory	Nursing Care Center
EPs 1–6	EPs 1–6	EPs 1–6	EPs 1–6	EPs 1–6	EPs 1–6

Elements of Performance for WT.03.01.01

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.
2. Staff and licensed independent practitioners who perform waived testing have received orientation in accordance with the organization's specific services. The orientation for each waived test is documented.
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.
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.
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
6. 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. [Applicable to AHC, CAH, HAP, LAB, OBS]*

Note 2: *Provider-performed microscopy (PPM) procedures are not waived tests. (See also HR.01.06.01, EP 18 for PPM Competency Requirements) [Applicable to AHC, CAH, OME, HAP, LAB]*

Implementation Expectations

- A policy should be in place that describes in detail the orientation process and the competency assessment process. Training should be specific to the device or product being used. Studies of hospital-based blood glucose programs identify the most significant levels of sustained improvement occurred when programs placed a primary focus on staff training, both initial and ongoing.⁴
- A policy should be in place to address situations in which an employee does not meet the minimum requirements of the competency assessment. The action taken and the final results should be documented in the employee's personnel file.
- Staff should have written job descriptions. These job descriptions should be retained in the employee's personnel file.
- Ensure that employee competency for waived testing is assessed using at least two of the following four methods and that documentation of such is clear and concise:
 1. Performance of a test on a blind specimen
 2. Periodic observation of routine work by the supervisor or qualified designee
 3. Monitoring of each user's quality control performance
 4. Use of a written test specific to the test assessed
- Ensure that competency is assessed at the intervals defined by the organization.
- Documentation requirements for this standard include the following:
 - o Documentation that staff and licensed independent practitioners who perform waived testing have received orientation in accordance with the organization's specific services
 - o Documentation that staff and licensed independent practitioners who perform waived testing have received training for each test they are authorized to perform
 - o Documentation that staff and licensed independent practitioners who perform waived testing have received training on how to use and maintain instruments used for waived testing
 - o Documentation that the competency of staff and licensed independent practitioners who perform waived testing has been assessed according to organization policy at defined intervals.
- For LAB only, the orientation paperwork should include a statement that the newly hired employee is able to perform the waived testing duties listed in the paperwork, and the statement should be signed by the employee after successfully completing the waived testing orientation
- For LAB only, newly hired employees are oriented and assessed for competency by a qualified individual. The qualified individual is the laboratory director, supervisor, or designee. This assessment is documented prior to any unsupervised patient contact.

Strategies for Compliance

- Develop a standardized approach to orientation of new employees to waived testing duties. If possible, designate a staff member to oversee new employee orientation, training, and competency assessment; to standardize training materials and processes; and to ensure that training documentation is complete for any/all waived testing personnel.
- Develop a competency assessment schedule and ensure that everyone is on the same schedule to more efficiently manage the competency process. This may require having a reassessment done early to get the employee into the established annual cycle. Large organizations may choose to split competencies into two time periods during the year to facilitate the large number of operators.

4. Jones BA, Howanitz PJ. Bedside glucose monitoring quality control practices. A College of American Pathologists Q-Probes study of program quality control documentation, program characteristics, and accuracy performance in 544 institutions. *Arch Pathol Lab Med.* 1996;120(4):339–345.

- Consider adding waived testing competency (or one of the two assessment methods) to an established employee “Skills Day” or annual skills fair to facilitate completing the annual competency process.
- If using a written test, define the threshold for a “passing” grade and document the follow-up and corrective action for operators without an initial passing score. (See Figure 1, below.)
- Utilize the annual competencies to reinforce and reeducate on those items and concepts identified as potential recurrent issues, even if already addressed during the preceding year. Studies demonstrate that the added benefits of a well-managed competency include performance consistency among staff, proactive identification of performance issues, and timely performance feedback to staff.⁵
- Some instruments have lockout capabilities for operators beyond their recertification time frame. Consider utilizing the function to ensure operator compliance with competency policies, with laboratory director guidance, and with feedback.
- Perform mock tracers periodically to ensure orientation and competency documentation on operators is complete and available.
- Identify a readily available resource person in the organization for staff in waived testing locations to contact with questions.

Figure 1. Sample Competencies Grid

Waived Test	Blind Test	Observation	User QC	Written Test

Organizations can use the above grid to indicate which competencies for waived testing they have identified by each test. QC, quality control.

5. Gerbasi S. Competency assessment in a team-based laboratory. *MLO Med Lab Obs.* 2000;32(9):46–52, 54.

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.*

Applicability

Ambulatory/Office-Based Surgery	Behavioral Health	Home Care	Hospital/Critical Access Hospital	Laboratory	Nursing Care Center
EPs 1–5	EPs 1–5	EPs 1–6	EPs 1–5	EPs 1–5	EPs 3–5

Elements of Performance for WT.04.01.01

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 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)
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
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.*
4. For instrument-based waived testing, quality control checks are performed on each instrument used for patient testing per manufacturer's instructions. (*See also* WT.01.01.01, EP 6)
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)
6. For instrument-based waived testing performed by a staff member in home health or residential hospice settings, quality control checks are performed per manufacturers' instructions. (*See also* WT.01.01.01, EP 6)

Implementation Expectations

- A policy should be in place that describes the quality control process for any non–instrument-based waived testing procedures. At minimum, these checks are performed at the frequency and number recommended by the manufacturer and as defined by the organization’s policies.
- A policy should be in place that describes the quality control process for any instrument-based waived testing procedures. At minimum, the checks are performed at the frequency and number recommended by the manufacturer.
- A policy should be in place to address the need for corrective action when quality control is not acceptable, including not reporting individual patient results until quality control is acceptable.
- A quality review process should be in place to provide oversight for any/all waived testing performed, and the reviews should be conducted routinely by a qualified staff member. Reviews should be documented and corrective action noted, when applicable. This process should be part of the overall quality management program for the laboratory, or for the waived testing program itself, as applicable.
- Documentation requirements for this standard includes the following:
 - Written quality control plan for waived testing that specifies the method for controlling procedures for quality, establishes timetables, and explains the rationale for choice of procedures and timetables

Strategies for Compliance

- Perform mock tracers periodically to ensure that quality control data are readily available for the specific patient who is audited.
- Follow your policies and procedures for performing and documenting quality control testing for internal quality control (if applicable) as well as external.
- Use two levels of quality control for instrument-based tests if the controls are commercially available.
- Some instruments may be interfaced so the documentation occurs automatically, while others (kit testing) may have to be entered manually.
- Address compliance failures. Depending on the significance of the noncompliance and potential impact on patients and the organization, the organization’s response could be one-on-one retraining for a few staff members, or, for persistent problems, the organization could ban an individual from performing a particular test. If a department is experiencing widespread noncompliance, neglect of instruments, and/or proficiency testing failures, the decision could be made to pull the test from the entire department.
- Perform mock surveys with waived testing personnel on a periodic basis to ensure that staff are knowledgeable and can speak to corrective actions for unacceptable quality control results and are aware that patient results for the affected test cannot be released until the unacceptable quality control event has been resolved.
- Routinely perform rounding on patient care areas to assess waived testing reagents and supplies for appropriate expiration dating and so forth.
- Assign quality control checks for staff on a rotating basis, rather than assigning a single individual, to ensure ongoing competency with this process for all staff.

Standard WT.05.01.01

The organization maintains records for waived testing.

Applicability

Ambulatory/Office-Based Surgery	Behavioral Health	Home Care	Hospital/Critical Access Hospital	Laboratory	Nursing Care Center
EPs 1–5	EPs 1–5	EPs 1–5	EPs 1–5	EPs 1–5	EPs 1–4

Elements of Performance for WT.05.01.01

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 clinical record.*

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

3. 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* [Document and Process Control (DC) Standard] DC.02.03.01, EP 14)

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.*

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.*

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

Implementation Expectations

- A procedure should be in place that describes the quality control reporting process for each waived test. This procedure should address how to record and report internal and/or external quality control results, as appropriate for the specific waived test involved.
- The organization should ensure that quality control results are documented. This must include both internal and external controls. Internal controls could be electronic, liquid, or control zone, whereas external quality controls may be electronic or liquid. These quality control results can be documented within the medical record.
- The patient's medical record must include all test results for waived testing for that patient.

- A procedure should be in place that describes the patient reporting process for each waived test. The procedure should address how to record and report the patient result, as appropriate for the specific waived test involved.
- Record retention policies should state that waived testing patient results, quality control results and instrument records are to be retained for a minimum of two years. Ensure that a process is in place to store documents appropriately for the retention period and that the documents are able to be retrieved in a timely manner.

Strategies for Compliance

- Ensure that the organization's policies and procedures for waived testing quality control clearly describe how quality control should be documented. For example, if an organization uses a check mark to indicate that a positive result was positive or a negative result was negative, then its policies should define what the check mark represents.
- Document reference intervals along with patient results. Normal values need to be recorded with the patient results.
- Ensure that documentation of tests can be linked to documentation of quality control. The organization should be able to link the patient's results to the reagent or the instrument. Ensure that lot numbers are recorded.
- Build hard stops into electronic documentation systems so that the person entering information cannot move to the next screen unless all necessary information has been entered. For example, an individual cannot move past a certain screen unless lot numbers or reference intervals have been entered.
- If using a paper system for documentation, keep logbooks in the testing areas. Periodically review the logs to identify errors or information gaps.
- Perform mock tracers and/or chart audits periodically to ensure that quality control data and maintenance records are readily available for the specific patient data/date that are audited.
- Perform mock tracers and/or chart audits periodically to ensure that patient results are documented appropriately in the medical record for the patient audited. This is of particular importance for waived testing results that are reported in the medical record in a manual (non–electronic-interfaced) manner.
- Perform mock surveys with waived testing personnel on a periodic basis to ensure that staff are knowledgeable and can speak to corrective actions for unacceptable quality control results and are aware that patient results for the affected test cannot be released until the unacceptable quality control event has been resolved.
- Kit tests must have positive and negative internal quality control results documented with each test result. Some examples of commonly used kit tests are urine pregnancy, rapid strep test, and influenza tests.
- Instrument-based testing (glucometers, prothrombin time/International Normalized Ratio [PT/INR]) has external quality control results, and these do not have to be documented with each patient test result, though they do need to be documented so they can be reviewed.
- Quality control policies must, at a minimum, meet manufacturers' requirements, but an organization may decide that its policies should require more quality control testing.
- When introducing new waived quantitative testing methods, ensure that a normal or reference range is reported appropriately with the patient test result. Include a printout/copy as part of your method validation documentation. The requirements for validation of a waived test are set by the CLIA '88 laboratory director and usually based on manufacturer's performance information.

Standard IC.02.02.01

The organization reduces the risk of infections associated with medical equipment, devices, and supplies.

Applicability

Ambulatory/Office-Based Surgery	Behavioral Health	Home Care	Hospital/Critical Access Hospital	Laboratory	Nursing Care Center
EPs 1–5	EPs 1, 3, 4	EPs 1, 3, 4, 6, 7	EPs 1–5	EPs 1–4	EPs 1–5

Rationale for IC.02.02.01

The CDC estimates that 46.5 million surgical procedures are performed in hospitals and ambulatory settings each year; this includes approximately 5 million gastrointestinal endoscopies. Each of these procedures involves contact with a medical device or surgical instrument. A major risk of all such procedures is the introduction of pathogens that can lead to infection. Additionally, many more people are at risk of developing an infection from contact with medical equipment, devices, or supplies while seeking other health services. Failure to properly clean, disinfect, or sterilize, and use or store medical equipment, devices, and supplies, not only poses risks for the person seeking health services, but also carries the risk for person-to-person transmission of infections.

There are numerous steps involved in the cleaning, disinfecting, and sterilizing of medical equipment, devices, and supplies. It is critical that health care workers follow standardized practices to minimize infection risks related to medical equipment, devices, and supplies. In order to maintain a reliable system for controlling this process, organizations pay attention to the following:

- Orientation, training, and competency of health care workers who are processing medical equipment, devices, and supplies
- Levels of staffing and supervision of the health care workers who are processing medical equipment, devices, and supplies
- Standardization of process regardless of whether it is centralized or decentralized
- Reinforcing the process (for example, the use of placards which list the steps to be followed, according to manufacturer's guidelines)
- Ongoing quality monitoring

Elements of Performance for IC.02.02.01*

The organization implements infection prevention and control activities when doing the following (EPs 1–4):

1. Cleaning and performing low-level disinfection of medical equipment, devices, and supplies.

Note: *Low-level disinfection is used for items such as blood glucose meters. Additional cleaning and disinfecting is required for laboratory equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions.*

Note: *Intermediate-level disinfection may be used in the clean-up of blood and/or body fluid spills. When decontaminating the autopsy room and handling tissues where prion disease is suspected or confirmed, high-level disinfection is often used in combination with sterilization.*

* Only the EPs that are relevant to waived testing have been included here. Please see the "Infection Prevention and Control" chapter of your *Comprehensive Accreditation Manual* to read the complete standard.

3. Disposing of medical equipment, devices, and supplies.
4. Storing medical equipment, devices, and supplies.
5. When reprocessing single-use devices, the organization implements infection prevention and control activities that are consistent with regulatory and professional standards.

Implementation Expectations

- This standard covers all waived testing equipment.
- The organization must comply with US Occupational Safety & Health Administration (OSHA) requirements for handling hazardous chemicals and blood-borne pathogens. Refer to http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10051.
- Manufacturers' guidelines for disinfection are to be followed. Ensure that staff are performing the disinfections as a standardized practice to minimize the infection risks associated.
- A policy should be in place that addresses specific or standard precautions to use when performing disinfection duties associated with waived testing and that addresses how staff is notified of any additional requirements, such as when a patient is in isolation.
- The personal protective equipment (PPE) selected should be appropriate for the task and the risk of exposure.
- The organization must comply with state and local requirements for the disposal of hazardous waste.

Strategies for Compliance

- Have PPE and disinfecting supplies readily available
- Ensure that staff can readily locate policies associated with the disinfection of equipment, devices, and supplies. These policies can be hard copy or electronic. If both formats are in use, ensure that the documents match with regard to revision date, document number, and so forth.
- Placards with disinfection directions may prove useful, particularly for isolation patients. Locate them where they are readily available for easy reference.
- Perform ongoing mock surveys with staff members to ensure that they are using the correct process for disinfection.
- If special disinfection procedures are used for isolation patients, ensure that the operators are knowledgeable about the specific differences and/or additional steps taken. For example, if possible dedicate a single PT/INR meter for use with that patient. Also ensure cleaning of glucometers and PT/INR meters after every use with an isolated patient.
- Reinforce the steps of the disinfection procedures as part of the annual competency process.
- Do a direct observation of staff during cleaning, disinfection, and sterilization processes.

Standard LD.04.01.01

The organization complies with law and regulation.

Applicability

Ambulatory/Office-Based Surgery	Behavioral Health	Home Care	Hospital/Critical Access Hospital	Laboratory	Nursing Care Center
EPs 1–2	EPs 1–3	EPs 1–3, 10, 13	EPs 1–3, 16–18	EPs 1–4	EPs 1–3

Elements of Performance for LD.04.01.01*

1. The organization is licensed, is certified, or has a permit, in accordance with law and regulation, to provide the care, treatment, or services for which the organization is seeking accreditation from The Joint Commission.

Note 1: For home health agencies that elect to use The Joint Commission deemed status option: *If state or local law requires licensure of home health agencies, a home health agency that is not normally subject to licensure must be approved by the licensing authority as meeting the standards established for licensure.*

Note 2: *Applicable law and regulation include, but are not limited to, individual and facility licensure, certification, U.S. Food and Drug Administration regulations, Drug Enforcement Agency regulations, Centers for Medicare & Medicaid Services regulations, Occupational Safety and Health Administration regulations, Department of Transportation regulations, Health Insurance Portability and Accountability Act, and other local, state, and federal laws and regulations.*

Note 3: *Each service location that performs laboratory testing (waived or nonwaived) must have a Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificate as specified by the federal CLIA regulations (42 CFR 493.55 and 493.3) and applicable state laws. (See also WT.01.01.01, EP 1; WT.04.01.01, EP 1)*

2. The organization provides care, treatment, and services in accordance with licensure requirements, laws, and rules and regulations.
3. Leaders act on or comply with reports or recommendations from external authorized agencies, such as accreditation, certification, or regulatory bodies.
4. Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) certificates for nonwaived laboratory testing list all specialties and subspecialties for which the laboratory reports patient results.
15. **For ambulatory surgical centers that elect to use The Joint Commission deemed status option:** The organization complies with part 493 of the Code of Federal Regulations.
Note: *Part 493 of the Code of Federal Regulations requires organizations who perform laboratory testing to maintain compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).*

* Only the EPs that are relevant to waived testing have been included here. Please see the “Leadership” chapter of your *Comprehensive Accreditation Manual* to read the complete standard.

Implementation Expectations

- Organizations should be aware of the federal, state, and local laws and regulations that apply to them and ensure that they are in compliance—including, but not limited to, the FDA, CMS, the US Drug Enforcement Agency, Department of Transportation regulations, OSHA regulations, the Health Insurance Portability and Accountability Act, and local, state, and federal laws and regulations.
- Organizations should stay abreast of developments, reports, changing requirements, and other communication from regulatory agencies, industry organizations, and accreditation bodies such as The Joint Commission.
- Ensure that the organization is in compliance with CLIA '88 regulations, and that its CLIA certificate is kept up-to-date.

Strategies for Compliance

- Be aware of CLIA certification expiration dates and facilitate renewals in a timely fashion, allowing for potentially lengthy processing times for the renewal.
- When the CLIA certificate is about to expire and renewal paperwork is submitted, it is important for the organization to keep copies in case there is a delay or the submission is lost.
- Organization changes can affect the CLIA certificate. For example, the location of the organization may no longer be accurate, or the director named on the certificate may have changed. Periodically review the CLIA certificate to ensure that it is current and accurate.
- If an organization is cited for not having an up-to-date CLIA certificate, the organization has 10 days in which to provide additional information to clarify the situation.
- Failure to maintain a valid CLIA certificate could result in the organization receiving an accreditation decision of Preliminary Denial of Accreditation. The surveyor would be obligated to notify The Joint Commission's Central Office.

B. Frequently Asked Questions, and Definitions of Key Terms

Frequently Asked Questions

This section discusses frequently asked questions that were submitted by accredited organizations and answered by The Joint Commission's Standards Interpretation Group. Visit http://www.jointcommission.org/standards_information/jcfaq.aspx for more information.

Color-Blind Testing

Q. Is employee color-blind testing required?

- A. The Joint Commission standards do not specifically require either visual acuity or color-blind testing for employees. The Human Resources (HR) standards require assessment of the employees' abilities to fulfill the expectations of their job descriptions. Color-blind testing may be used as part of an organization's initial or ongoing competency assessment program, but other mechanisms that evaluate an individual's ability to interpret colorimetric determinations would also be acceptable.

Laboratory Director for Waived Testing

Q. What are the suggested minimum qualifications for the laboratory director on a CLIA Certificate of Waiver?

- A. For waived testing, there are no federally defined qualifications for the laboratory director in the CLIA '88. The individual should have the technical knowledge and experience required to oversee the specific laboratory testing performed. The Joint Commission further recommends that the individual at least meet the minimum qualification route otherwise defined in the CLIA '88 regulations for moderate-complexity testing personnel (42 CFR 493, Subpart M). Individual states may also have applicable regulations and licensure requirements for the laboratory director.

Note that the laboratory director is legally responsible for all testing performed under the CLIA certificate. Nonphysicians serving as laboratory director should seek professional advice regarding the necessity of additional professional liability insurance.

Laboratory Director of Record

Q. Please explain the title of "Laboratory Director."

- A. *Laboratory director* is the title afforded by regulation to the individual whose name appears on the laboratory service's CLIA certificate. This individual is the laboratory director of record for CMS and Joint Commission purposes. The laboratory director is responsible for all testing performed by the laboratory service. For nonwaived testing, this individual is typically a pathologist. Other physicians or laboratory professionals may qualify if they have the prerequisite education and years of experience required by the federal regulations. For waived testing, there are no federally defined qualifications for the laboratory director. In all cases, individual states may also have applicable regulations and licensure requirements for the laboratory director.

For the purposes of accreditation and CLIA '88 records, the title of laboratory director should not be confused with the job description title of "laboratory director," sometimes given to an individual who provides administrative oversight of the laboratory. This is often an experienced laboratory professional with a bachelor's or master's degree. The laboratory director of record may delegate in writing a variety of oversight activities to the administrative director, including technical responsibilities, in accordance with their qualifications and as permitted by regulation.

Qualifications for the laboratory director of record for nonwaived testing are described in the CLIA '88 regulations under Subpart M: "Personnel for Nonwaived Testing," 493.1351 – 493.1495. The entire text of the requirement is located at <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/apcsubm.pdf>.

Patient/Client Self Glucose Testing

Q: If a patient performs a glucose test on his or her own personal glucose meter, can the results be used for treatment decisions?

A: Yes, if the medical staff/leaders are informed of such a process, the patient understands the risks, and the process is approved in written policy by the organization's leadership.

Such a practice bears similarities to use of a reference laboratory. When using a reference laboratory, organizations must verify that the laboratory is compliant with applicable law and regulation. This is evidenced by having a current CLIA certificate and a successful biennial inspection. When using a patient's result from self-testing, the health care provider does not have the same types of assurance provided by compliant reference laboratories, such as adequate competency, successful quality control or proper equipment maintenance.

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:

1. Verify competency by either confirming the patient/resident/client has been previously trained or observing the patient perform his or her first test.
2. Require the patient to perform quality control, if available for the meter, each day results are used.
3. Correlate the patient's first glucose result with testing by a main laboratory.
4. Confirm all critical and nonlinear instrument values with testing by the main laboratory.

Professional vs. Home Use Tests

Q: How do we know if a particular waived test or instrument, such as a glucose meter, is approved for professional use?

A: Laboratory tests classified as waived may be approved for professional use, home use (sold over-the-counter), or both. Tests approved for "home use only" are not appropriate for use by health care professionals in a Joint Commission–accredited organization.

To determine if a test is approved for professional use, you can sometimes find the information in the manufacturer's package insert or by calling the manufacturer directly. You may also check the 510(k) summary that was submitted to the FDA by the manufacturer for approval. Many of these are available electronically through the following website: <http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/>.

To find this information organizations should perform the following four steps:

1. Enter the name of the device in the search field.
2. Locate the device in the list produced by the search.
3. Click on the "Summary" for the device to open the 510(k) document.
[Located on the sixth line from the bottom of the box that appears.]
4. Read the 510(k) summary, particularly the section titled "Intended Use."

If the language indicates that the instrument may be used in professional settings or by health care professionals, then it meets the standards requirement.

Provider-Performed Microscopy Procedures (PPMP)

Q: Where can I find further information on PPMP testing?

- A: Joint Commission requirements for provider-performed microscopy procedures (PPMP) are located in the *Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing*. Additional information may also be found on the Laboratory Services FAQ page: http://www.jointcommission.org/standards_information/jcfaq.aspx?ProgramId=42.

PPMP is specified in federal regulations as a subset of moderately complex tests. On-site review by an accreditation body is not federally required; however, Joint Commission laboratory surveyors will review a sampling of these services. Federal requirements for PPMP testing may be found in CLIA '88, located at 42.CFR.493: <http://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part493/content-detail.html>.

Rapid Group A Strep Testing and Culture Follow-Up

Q: Is it required to perform culture follow-up on all negative rapid group A strep screens?

- A: The manufacturer's package insert recommends that all negative rapid group A strep screens be followed up with a culture. The Joint Commission surveys compliance with following these manufacturer instructions. Thus, culture follow-up should be performed unless the laboratory has performed a study that justifies discontinuing such testing.

An acceptable study consists of age-specific (adults versus children) parallel testing that demonstrates acceptable correlation of results from rapid testing against cultures for the laboratory's setting. The study may be simple (20–100 samples) and rely on existing data. Correlations tend to be better for the adult population as compared to children, as specimens are easier to collect and they have a higher colonization rate. Specimens from children have a higher potential for a false negative rapid test (low colonization, difficult collection) and a higher risk of further disease (such as rheumatic or scarlet fever), thus culture follow-up is recommended for this population.

This approach is consistent with the American Academy of Pediatrics guidelines (*Red Book*, 2012), Infectious Diseases Society of America Guidelines for Diagnosis and Management of Group A Streptococcal Pharyngitis, and current recommendations for acute pharyngitis from the CDC. See the following links for more information:

- Adults: <http://www.cdc.gov/getsmart/campaign-materials/info-sheets/adult-acute-pharyngitis.html>
- Pediatrics: <http://www.cdc.gov/getsmart/campaign-materials/info-sheets/child-pharyngitis.html>

A laboratory will be considered compliant if an age-based study was performed and the laboratory director and physicians have considered these guidelines in developing the approved laboratory policy.

Reagents Stored with Medications or Specimens

Q: Can laboratory reagents be stored in a refrigerator that also contains medications or laboratory specimens?

- A: Yes, laboratory reagents may be stored in the same refrigerator as medications or laboratory specimens. In both cases, there should be distinctly marked and separated areas in the refrigerator to minimize any risk of contamination from spills. Sealed containers may be used as a further measure to prevent contamination. Preferably, medications should be stored on upper shelves and laboratory reagents on lower shelves.

Conversely, laboratory reagents should be stored on upper shelves, with laboratory specimens on lower shelves.

Temperature monitoring and security requirements may be different for medications and laboratory reagents. The organization should follow the more stringent policy when these are stored together.

Screening vs. Definitive

Q: How is it determined if a waived test is screening or definitive?

A: Within an organization, waived testing must be defined as either screening or definitive. The intention of the requirement is for the organization to promote a uniform standard of care and set expectations as to when confirmatory testing should be performed.

A test is considered definitive when the organization determines that a clinical treatment decision or diagnosis may be made based on the result. For example, bedside glucose checks performed in order to adjust sliding scale insulin would be considered definitive. Although a test may be considered definitive, it does not preclude performance of additional testing to support medical diagnosis or treatment. Confirmatory testing may still be ordered. This is often done for critical glucose levels, even when the result may be within the linear (for example, reportable) range of the glucose analyzer.

A test is considered screening when an organization determines that additional information from testing or other procedures would be required to make a treatment decision or diagnosis. An example of this would be a physician office that performs rapid group A strep testing, but follows up with cultures prior to determining whether or not to administer antibiotics.

When a test is considered screening, the organization's policies should state that additional information must be obtained through further testing or other procedures before any treatment or diagnostic decisions are made. For the purpose of promoting a uniform standard of care, confirmatory testing must be specified in the written procedure, if it is required.

Survey of Urine Drug Testing in a Behavioral Health Care Facility

Q: What does The Joint Commission require if urine drug screens are performed in a behavioral health care facility?

A: All organizations that perform urine drug testing must obtain the federally required CLIA '88 license and abide by applicable Joint Commission standards. This is required even if the organization uses the test as a screen and then refers the sample to another laboratory for confirmatory testing. To determine which CLIA license is appropriate, it is first necessary to know the test complexity assigned by the FDA for the test system being used, which may be waived, moderate, or high, based on several factors. The test complexity may be obtained by contacting the manufacturer or locating the information in the package insert.

The level of complexity then determines which CLIA license is required and the subsequent criteria that apply for various aspects of testing, such as inspection, personnel qualifications, and quality control. These requirements apply both to organizations that choose to provide the testing and to those organizations that are required to provide the testing by law and regulation. For clarity, Joint Commission standards do not require organizations to perform urine drug testing.

For a urine drug test classified as waived, the following applies:

- The organization must have a current Certificate of Waiver obtained from their state CLIA office.
- The testing is reviewed during the organization's routine triennial survey.

For moderately complex urine drug testing, the requirements are as follows:

- The organization must have a current certificate for moderate-complexity testing obtained from their state CLIA office.
- The CLIA certificate must have the following specialty/subspecialty listing: Chemistry/Toxicology.
- The testing is surveyed under the standards in the *Comprehensive Accreditation Manual for Laboratories and Point-of-Care Testing (CAMLAB)*, which are more stringent than the waived testing standards.
- The testing is reviewed during a biennial survey, which is separate from the organizational triennial survey.

For moderately complex testing, organizations must fill out a separate application to request a biennial laboratory survey. An organization may formally request an exemption from the Joint Commission laboratory survey if it is performing only one moderately complex laboratory test and the organization can provide evidence of a state CLIA inspection every two years.

Test Complexity—Waived, Moderate, and High

Q. How can I verify the test complexity designation for a particular laboratory test?

- A. Commercial test systems are evaluated by the FDA and assigned one of the following three complexity designations:
1. Waived
 2. Moderate
 3. High

Moderate and high complexity are often referred to as “nonwaived” testing.

The complexity designation may be printed in the manufacturer's package insert. It can also be searched online in the FDA's database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm>.

Waived Testing and Proficiency Testing

Q. Is proficiency testing required for waived tests?

- A. The Joint Commission standards do not require participation in proficiency testing for those test systems classified by the FDA as waived complexity. Some organizations may voluntarily participate in proficiency testing as good practice or use proficiency testing as part of their competency assessment program. The Joint Commission will survey each organization according to its own policies relative to proficiency testing for waived testing.

Physician Competency for Waived and PPMP Testing

Q: Are competency assessments required for physicians performing waived or PPMP testing?

- A: For PPMP, annual competency assessment is required for all testing personnel, including physicians. When a physician performs waived testing that does not involve an instrument, there is no Joint Commission requirement for documentation of competency when the test is a logical part of his or her specialty and the organization has specifically privileged the physician for that test. Through the medical

staff credentialing process, individual physicians may be privileged for those specific waived tests appropriate to their scope of practice, and no further assessment of skills or documentation of competence would be required. At the discretion of the medical director of Laboratory Services designated on the CLIA certificate or organizational policy, more stringent competency requirements may be implemented.

Q: Is it required or recommended to notify The Joint Commission of unsatisfactory performance or unsuccessful status in proficiency testing?

- A. There are three different proficiency testing statuses for nonwaived regulated analytes in which different actions are required. Proactively initiating contact with the Joint Commission proficiency testing monitoring staff is specifically recommended in the most severe circumstance of Subsequent Unsuccessful status (described below).

The three proficiency testing status designations are as follows:

1. Unsatisfactory status

Definition: A single proficiency testing event with a score of less than 100% for ABO, Rh, and compatibility testing, or less than 80% for all other testing.

Action: Document investigation and remedial action sufficient to prevent recurrence. There is no requirement to contact or submit a Plan of Action to The Joint Commission. The records will be reviewed during the laboratory's next on-site survey.

2. Unsuccessful status

Definition: A cumulative event in which the laboratory has had an Unsatisfactory score on two out of three consecutive proficiency testing events.

Action: Document investigation and remedial action sufficient to prevent recurrence. The Joint Commission will identify the Unsuccessful status through its routine proficiency testing monitoring activities and contact the laboratory to request a Plan of Action. The Plan of Action will be reviewed by staff in The Joint Commission's Central Office. You are not required to contact The Joint Commission prior to receiving this request.

3. Subsequent Unsuccessful status

Definition: A cumulative event in which the laboratory has had Unsuccessful proficiency testing status two times in the past five years.

Action: Document investigation and remedial action sufficient to prevent recurrence. Consider voluntarily ceasing testing for the involved analyte(s) and proactively contacting The Joint Commission in writing to formally report this action. The Joint Commission will identify the Subsequent Unsuccessful status through its routine proficiency testing monitoring activities and contact the laboratory to request a Plan of Action. If the laboratory has not already ceased testing, a formal notification to cease testing may be issued by The Joint Commission and be in effect for a minimum of six months. The Plan of Action will be reviewed by staff in The Joint Commission's Central Office. When a laboratory chooses to voluntarily cease testing before being formally notified to do so, The Joint Commission has additional discretion to work with the laboratory and permit reinstatement in a shorter time frame when the Plan of Action has been determined acceptable.

Note that the recommendations stated above apply to the regulated analytes for nonwaived testing. Regulated analytes are those specified in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Subpart I. For waived testing and other non-waived unregulated analytes, participation in proficiency testing is a voluntary best practice.

For more information on these issues, visit the following websites:

- Frequently asked questions about proficiency testing, including the list of regulated analytes for non-waived testing, can be found in CLIA brochure No. 8: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIAbrochure8.pdf>.
- Information about The Joint Commission's proficiency testing monitoring, including contact information, can be found at the following website: http://www.jointcommission.org/accreditation/lab_proficiency_testing.aspx.

Reference Ranges in Medical/Clinical Record

Q: Do reference ranges have to be on the same page (printed or electronic) as the laboratory result?

A: No. Although it is preferred to have the reference range documented on the same page and adjacent to the laboratory result, the requirement is flexible enough to accommodate different information management systems when it is impractical to do so. For both waived and nonwaived testing, the following two criteria must be met when reference ranges are not supplied on the same page along with the laboratory result:

1. The reference range must be located elsewhere within the permanent medical/clinical record.
2. The result must have a notation directing the reader to the location of the reference range(s) in the medical/clinical record.

Waived Testing Logs

Q: Is it required to maintain logs for waived testing?

A: The standards do not require a log sheet to be maintained for waived tests. The organization is required to be able to correlate the quality control results with the individual test results. Examples of typical correlated information would include the following: a client identifier, date of testing, test kit lot number, test result, quality control lot numbers, quality control results, and a testing personnel identifier. Logs are useful for compiling this information in one comprehensive document. Alternatively, the organization may choose to document this information in the client chart or utilize a combination of document sources to correlate the information. For example, an organization performing occult blood testing elects to document the date of testing, client result, quality control result, and testing personnel initials in the client chart. A separate inventory log is maintained to track the lot of reagents and test cards in use at the time of testing. Performance of initial quality control for the lot, when required by the organization's policy, could also be documented on the inventory log prior to releasing the kit for general use.

Definitions of Key Terms

Clinical and Laboratory Standards Institute (CLSI): A global, nonprofit, standards-developing organization for clinical and laboratory services that promotes the development and use of voluntary consensus standards and guidelines within the health care community. Until 2005 CLSI was known by the name National Committee on Clinical Laboratory Standards (NCCLS).

Clinical Laboratory Improvement Amendments of 1988 (CLIA '88): Federal legislation that created uniform federal standards for regulating laboratory testing. CLIA '88 unified the disparate federal and state standards regulating clinical laboratories and extended government oversight to all testing facilities, including physician offices.

Competency: The ability of an individual to perform a job properly. A competency is a set of defined behaviors that provide a structured guide enabling the identification, evaluation, and development of the behaviors in individual employees.

Complexity: Test categorization by the FDA, using seven criteria to designate a laboratory test procedure or evaluation into one of three categories: waived, moderate, or high. The complexity category determines what specific standards and regulations apply to the test.

Element of Performance (EP): Specific action(s), process(es), or structure(s) that must be implemented to achieve the goal of a standard. The scoring of EP compliance determines an organization's overall compliance with a standard.

Expiration date: The date after which the product, when stored under recommended conditions, should no longer be used.

Hazardous materials and waste: Materials whose handling, use, and storage are guided or defined by local, state, or federal regulation, such as OSHA's Regulations for Bloodborne Pathogens regarding the disposal of blood and blood-soaked items and the Nuclear Regulatory Commission's regulations for the handling and disposal of radioactive waste. This also includes hazardous vapors (for example, gluteraldehyde, ethylene oxide, nitrous oxide) and hazardous energy sources (for example, ionizing or nonionizing radiation, lasers, microwave, ultrasound). Although The Joint Commission considers infectious waste as falling into this category of materials, federal regulations do not define infectious or medical waste as hazardous waste.

Laboratory director: An individual who is usually employed to serve in a medical and administrative capacity as head of the laboratory. He or she also may serve as liaison for the laboratory with the hospital's administration and governing board.

Laboratory test order: A request for laboratory testing sent to the laboratory in writing, electronically, or verbally with follow-up written authorization.

Orientation: A process used to provide initial training and information while assessing the competency of clinical staff relative to job responsibilities and the organization's mission and goals.

OSHA: Occupational Safety and Health Administration, an agency of the US government under the Department of Labor with the responsibility of ensuring safety at work and a healthful work environment.

Performance improvement: Data collection and analysis for the purpose of providing an indication of the organization's performance on a specified process or outcome.

Point-of-Care Testing: Laboratory testing performed at or near the site where clinical patient care is provided. Point-of-care testing can be of waived or nonwaived complexity.

Quality control: Refers to those processes and procedures designed to ensure that the results of laboratory analysis are consistent, comparable, accurate, and within specified limits of precision.

Safety: The degree to which the risk of an intervention (for example, use of a drug, or a procedure) and risk in the care environment are reduced for a patient and other persons, including health care practitioners. Safety risks may arise from the performance of tasks, from the structure of the physical environment, or from situations beyond the organization's control (such as weather).

Staff: As appropriate to their roles and responsibilities, all people who provide care, treatment, or services in the organization, including those receiving pay (for example, permanent, temporary, part-time personnel, as well as contract employees), volunteers, and health profession students. The definition of *staff* does not include licensed independent practitioners who are not paid staff or who are not contract employees.

Standard precautions: Infection prevention and control measures for reducing the risk of transmission of blood-borne and other pathogens from both recognized and unrecognized sources of infection. They are applied to all patients regardless of their diagnosis or presumed infection status.

Transmission-based precautions: Infection prevention and control measures to protect against exposure to a suspected or identified pathogen. These precautions are specific and based on the way the pathogen is transmitted. Categories include contact, droplet, airborne, and a combination of these.

US Food and Drug Administration (FDA): A federal agency responsible for monitoring trading and safety standards in the food and drug industries

Waived testing: Examinations or procedures that are cleared by the FDA and employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; pose no reasonable risk of harm to the patient if the test is performed incorrectly; or have been cleared by the FDA for home use.

C. Resources for Additional Information

This section contains additional information and links that can be helpful to organizations seeking to comply with Joint Commission Waived Testing standards.

Assessing Compliance During the On-Site Survey

During an on-site survey, Joint Commission surveyors will directly observe the following (includes, but is not limited to) related to waived testing:

- Patient identification process
- Compliance with the organization's infection control policies, including the following:
 - Personal protective equipment
 - Expiration dates of antimicrobial gels/foams in use
 - Disposal of hazardous and nonhazardous waste
 - Disinfection of equipment
- Process for waived testing for patients in isolation
- Expiration dating and proper storage of reagents, supplies, and so forth
- Quality control, maintenance, and testing performance, as applicable
- Confidentiality and privacy for patients
- Compliance with the organization's policies and procedures relating to the performance of waived testing
- Waived testing is performed based on written orders, protocols, and so forth.

When assessing compliance with waived testing requirements, surveyors will interview employees who perform waived testing regarding the following issues:

- Knowledge of and access to procedures on waived testing
- Knowledge of handling of abnormal, critical, or unexpected results related to waived testing
- Confirmatory testing of waived testing results, where applicable

Surveyors will also review the following:

- Orientation, training, and competency documents
- Job descriptions for staff who perform and/or oversee waived testing
- Human Resources records: Per CLIA '88, waived testing requires only on-the-job training, but organizations can define additional education or experience requirements; such documents are to be available for review.
- Policies and procedures related to waived testing
- Policies and procedures related to patient identification
- Policies and procedures related to infection control
- Quality control records
- New equipment performance evaluations
- Equipment records (refrigerators, freezers, room temperature, and so forth)
- Proficiency testing, where applicable (not required for waived testing, but organizations can choose to participate as part of their quality assurance programs, with appropriate corrective actions when results are unacceptable)

Figure 2. Commonly Confused Tests

The following table lists tests that many health care providers mistakenly believe to be waived, though they are not, as well as their corresponding complexity levels according to CLIA '88.

AmniSure	Moderately complex
Activated clotting time (ACT)	Moderately complex
Serum pregnancy tests	Moderately complex
AmnioTest	Highly complex
iSTAT (when the blood sample is collected in a syringe)	Moderately complex
Provider-performed microscopy tests	Moderately complex

Clinical and Laboratory Standards Institute Standards and Guidelines

The Joint Commission Laboratory Accreditation Standards at times reference documents created by the Clinical and Laboratory Standards Institute (CLSI). CLSI promotes the development and use of voluntary laboratory consensus standards and guidelines within the health care community. Documents are available (for purchase) that address waived testing; point-of-care testing; specimen collection, including patient identification; quality management systems; and process improvement.

The documents in the table below are available from the Clinical and Laboratory Standards Institute and are referenced to the Joint Commission Laboratory Accreditation Standards chapters.

Figure 3. CLSI Documents

C40-A	Measurement Procedures for the Determination of Lead Concentrations in Blood and Urine: Approved Guideline
C49-A	Analysis of Body Fluids in Clinical Chemistry: Approved Guideline
GP16-A3	Urinalysis; Approved Guideline—Third Edition
GP31-A	Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline
GP34-A	Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline
GP39-A6	Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition
GP41-A6	Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Sixth Edition
GP42-A6	Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition
GP43-A4	Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Fourth Edition
GP44-A4	Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition
<i>(continued on page 30)</i>	

Figure 3. CLSI Documents (continued)

H02-A5	Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard—Fifth Edition
H07-A3	Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard—Third Edition
H15-A3	Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition
H21-A5	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition
NBS03-A	Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns; Approved Guideline
NBS04-A	Newborn Screening by Tandem Mass Spectrometry; Approved Guideline
POCT01-A2	Point-of-Care Connectivity; Approved Standard—Second Edition
POCT02-A	Implementation Guide of POCT01 for Health Care Providers; Approved Guideline
POCT04-A2	Point-of-Care In Vitro Diagnostic (IVD) Testing; Approved Guideline—Second Edition
POCT05-A	Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline
POCT07-A	Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline
POCT08-A	Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline
POCT09-A	Selection Criteria for Point-of-Care Testing Devices; Approved Guideline
POCT12-A3	Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition
POCT13-A2	Glucose Monitoring in Settings Without Laboratory Support; Approved Guideline—Second Edition
POCT14-A	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline
QMS01-A4	Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition
QMS03-A3	Training and Competence Assessment; Approved Guideline—Third Edition
QMS06-A3	Quality Management System: Continual Improvement; Approved Guideline—Third Edition
QMS07-A2	Application of a Quality Management System Model for Respiratory Services; Approved Guideline—Second Edition
QMS10-A	A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline

Source: Clinical and Laboratory Standards Institute. CLSI Documents Referenced to The Joint Commission Laboratory Accreditation Standards Chapters. (Updated Jul 2013.) Accessed Jul 22, 2014. <http://www.clsi.org/wp-content/uploads/2013/07/CLSIJoint-Commission-Crosswalk-2013-SM.pdf>.

Additional Resources and Links

For additional information on waived testing, related standards, laws and regulations, and laboratory safety, visit the following links:

- For notification of revisions of Joint Commission standards and policies: See *The Joint Commission Perspectives*® newsletter, available through your organization's *Joint Commission Connect*™ extranet site.
- For tips and strategies for complying with Joint Commission standards (including waived testing), CMS rules, mock tracer scenarios, and performance measurement information: See *The Joint Commission: The Source*™ newsletter, published by Joint Commission Resources: <http://www.jcrinc.com/the-source/>.
- For FDA list of current waived analytes: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm>
- For links of interest to CLIA regulated laboratories, complied by the CDC: <http://wwwn.cdc.gov/clia/resources>
- For further information regarding cleaning and performing low-level disinfection of medical equipment, devices, and supplies: http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html
- For further information regarding cleaning and performing intermediate and high-level disinfection of laboratory equipment, devices, and supplies: http://www.cdc.gov/hicpac/Disinfection_Sterilization/acknowledg.html
- For CLIA resources from CMS: <http://www.cms.hhs.gov/clia>
- For a CDC *Morbidity and Mortality Weekly Report (MMWR)* on good laboratory practices for waived testing sites: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>
- For the CDC's CLIA information home page: <http://wwwn.cdc.gov/CLIA/default.aspx>
- For CDC's *To Test or Not to Test* booklet on waived testing: <http://wwwn.cdc.gov/clia/resources/waivedtests/pdf/wavedtestingbookletweb.pdf>
- For CDC's *Ready? Set? Test!* Booklet on waived testing: <http://wwwn.cdc.gov/CLIA/Resources/WaivedTests/pdf/ReadySetTestBooklet.pdf>
- For CDC's *Ready? Set? Test!* Online Course: <https://cdc.train.org/DesktopModules/eLearning/CourseDetails/CourseDetailsForm.aspx?tabid=96&courseid=1033476>
- For information on the CMS CLIA Certificate of Waiver Laboratory Project: http://www.cms.gov/regulations-and-guidance/legislation/clia/certificate_of_-waiver_laboratory_project.html
- For the US Agency for Healthcare Research and Quality's Clinical Practice Guideline Clearinghouse: <http://www.guideline.gov>
- For a list of tests considered waived by the FDA from January 2000 to the present: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/testswaived.cfm>
- For FDA advice on CLIA waivers: <http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm393233.htm>
- For American Association for Clinical Chemistry Laboratory Medicine Practice Guidelines: <http://www.aacc.org/members/nacb/lmpg/pages/default.aspx#>