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Waived Testing

Waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."[i] Common examples include blood glucose tests, fecal occult blood tests, and rapid strep tests. While risk is minimal, Joint Commission standards ensure quality and safety while performing waived tests in hospital settings.

Background and Rationale

All facilities in the United States performing laboratory testing on human specimens for purposes of health assessment are regulated under the Clinical Laboratory Improvement Amendment (CLIA) requirements.[ii] However, certain tests are "waived" from the CLIA requirements due to their simplicity and minimal risk. The Food and Drug Administration (FDA) maintains a list of the tests which it has determined meet the waived criteria after reviewing a manufacturer's application for a test system waiver.[iii]

While waived tests are typically simple, they are not completely error proof. It is important that healthcare personnel perform these tests correctly and according to manufacturers' instructions to avoid errors or serious health impacts. Errors can lead to patient harm, including misdiagnosis, delayed or inappropriate treatment, and medication errors,[iv] as well as legal or regulatory risks. Joint Commission standards align with CLIA and go beyond regulatory requirements to ensure safety and quality while performing waived tests in hospital settings.

Standards

The 2025 waived testing *National Performance Goal*™ requires:

- Policies and procedures for waived tests are established, current, approved and readily available. Hospitals ensure:
  - The person from the hospital whose name appears on the CLIA certificate, or a qualified designee, establishes written policies and procedures for waived tests that include specific criteria.
  - Policies or procedures for each waived test are consistent with manufacturer's instructions for use and include specific operational policies (that is, detailed quality control protocols and any other institution-specific procedures regarding the test or instrument).

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- Staff performing waived tests are competent:
  - Staff who perform waived testing have been trained for each test that they are authorized to perform, and this training is documented.
  - Competence for waived testing is assessed and documented according to hospital policy at defined intervals, but at least at the time of orientation and annually thereafter. Competency is assessed using more than one method (e.g., performance of a test on a blind specimen, periodic observation of routine work, monitoring of quality control performance, written testing).

i Clinical Laboratory Improvement Amendments (CLIA) of 1988 provide the authority for certification and oversight. https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia **ii** Centers for Disease Control and Prevention (CDC). Clinical Laboratory Improvement Amendments (CLIA). https://www.cdc.gov/clia/php/about/index.html **iii** US Food and Drug Administration Public Databases. Clinical Laboratory Improvement Amendments Current Waived Analytes. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm **iv** CDC Laboratory Quality. Waived Tests. https://www.cdc.gov/lab-quality/php/waived-tests/index.html. September 11, 2024.

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**National Patient Safety Goals are now a part of the National Performance Goals.*