Waived Testing Key Terms

CLIA (Clinical Laboratory Improvement Amendments)	Federal regulations established to ensure accuracy, reliability, and timeliness of laboratory test results regardless of where the test is performed.
Waived Test	A simple laboratory test with a low risk for error or harm if performed incorrectly; approved by the FDA for home or office use.
CMS (Centers for Medicare & Medicaid Services)	The government agency responsible for administering the CLIA program and issuing laboratory certificates.
FDA (Food and Drug Administration)	The agency that determines which laboratory tests can be categorized as "waived."
CDC (Centers for Disease Control and Prevention)	Provides technical assistance, training, and guidelines for quality laboratory practices.
Certificate of Waiver	A document issued by CMS that allows a facility to perform only CLIA-waived tests.
Quality Control (QC)	Routine testing of known materials (controls) to verify that the test system and reagents are performing correctly.
Quality Assurance (QA)	A comprehensive program that monitors the entire testing process—pre-analytical, analytical, and post-analytical—to ensure accurate results.
Competency	The demonstrated ability of personnel to correctly perform testing procedures and produce reliable results.
Calibration	The process of adjusting an instrument or test system to ensure accuracy in measurement.
Reagent	A chemical or substance used in a test that reacts with the patient specimen to produce a measurable result.
Specimen	A sample of blood, urine, or other body fluid collected for laboratory testing.
Control Sample	A known specimen used to check the accuracy of a test system; should produce a predictable result.
Lot Number	A unique identification code assigned to a batch of test kits or reagents for traceability and quality purposes.

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Expiration Date	The date after which a reagent, test strip, or control may no longer produce accurate results.
Documentation	Recording all test results, QC checks, maintenance, and any problems to ensure traceability and compliance.
Pre-analytical Phase	The part of testing that includes specimen collection, labeling, storage, and preparation before testing.
Analytical Phase	The actual testing process when the specimen is analyzed.
Post-analytical Phase	The stage after testing where results are recorded, verified, and reported.
Proficiency Testing	External testing used by non-waived labs to check accuracy; not required for waived labs, but good practice for quality improvement.
CLIA ID Number	A unique identification number assigned by CMS to each laboratory or waived testing site.
Package Insert	The manufacturer's written instructions that explain how to properly perform the test, handle specimens, interpret results, and perform QC.
Deviation	Any variation or departure from standard procedure that may affect test results or quality.
Preventive Maintenance	Regular care and servicing of instruments to prevent problems and ensure reliable performance.
Accuracy	How close a test result is to the true or accepted value.
Precision	The ability of a test to produce the same result consistently when repeated under the same conditions.