

## CLIA Waived Drug Testing

The Clinical Laboratory Improvement Amendment Program not only sets standards for clinical laboratory testing but is also the governing body that issues certificates to laboratories across the United States. It is CLIA's purpose to make sure that all laboratory test results are accurate, reliable and relevant no matter where the test was conducted.

Every laboratory system, examination and assay is categorized for its level of complexity. The assigned scores are 1, 2 and 3, with 1 as the lowest level of complexity, and 3 as the highest level of complexity. A score of 2 is given for test that falls in between the characteristics listed for 1st and 3rd levels of complexity.

Based on **42 CFR 493.17** the criteria for the level of complexity categorization are:

- Training and experience
- Knowledge
- Interpretation and judgment
- Characteristics of steps of operation
- Reagents and material preparation
- Test system troubleshooting and equipment maintenance and
- Quality control, calibration, proficiency of testing materials

## CLIA Waived Drug Tests

CLIA Waived drug tests are those test systems that have been approved for a waiver based on the CLIA 7-point criteria and those cleared by the Federal Food and Drug Administration for home use, and those listed in the CLIA regulations. These are simple tests with a low risk for erroneous results. Drug test dip cards and drug test cups are considered CLIA Waived tests. Sites that only perform waived testing require a CLIA certification. CLIA has granted waived status to over 200,000 laboratories across the United States. Fees collected from applicants are used as funding for the agency.

## Importance of CLIA Waived Drug Testing Kits

One of the requirements of CLIA for waived tests is that they must be simple and have low potential risk for errors. However, this does not mean those waived tests are 100% error proof. Mistakes can happen anywhere in the testing process. It is possible that the specimen is tainted, or the manufacturer's instructions were not faithfully followed when the person in charge of the testing is not very familiar with the testing system.

There are some CLIA waived tests that have the potential to impact patients negatively if done incorrectly. The result of a CLIA waived test may be used for adjusting the dosage of a particular medication. For example, a person on blood-thinning medication needs prothrombin time (PT) testing to determine the INR of his blood. An incorrect reading of his PT could lead his doctor to either increase or decrease his medication which could either lead to bleeding or clotting. An erroneous reading on glucose monitoring in diabetics and human immunodeficiency virus (HIV) antibody, can lead to unintentional consequences. In connection, Centers for Medicare and Medicaid Services (CMS) has started on-site visits to laboratories with certificate of waiver under CLIA, to promote quality laboratory testing.

Since 2002, CMS has committed to visit 2% of these laboratories across the United States to further sound laboratory practices. The agency will make sure that laboratory personnel handle quality testing in ways that:

- Protect the safety of patient
- Meet the laboratory's regulatory compliance
- The laboratory conducts tests fitting for a certificate of waiver facility

It is the duty of CMS to ensure that all laboratories receive the instruction needed to improve health care quality through accurate and reliable test results.

## CLIA Waived Test Requirements

Under the CLIA, a laboratory must conduct only tests which the CDC and FDA have determined to be simple and that the risk of erroneous results are greatly reduced. Such tests are relieved from most CLIA requirements and the laboratories that conduct such tests are not lined up for routine inspections.

The requirements for waived laboratories are:

- Enrollment in the CLIA program
- Payment of applicable fees biennially
- Adherence to manufacturer's test instructions