

**STATEMENT OF THE
AMERICAN CLINICAL LABORATORY ASSOCIATION
ON APPLICATION CRITERIA FOR WAIVED TESTS**

December 5, 2005

The American Clinical Laboratory Association (ACLA) is pleased to submit comments to the Food and Drug Administration (FDA) on the *Draft Guidance for Industry and Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications*. ACLA is an association representing independent clinical laboratories throughout the United States including local, regional and national laboratories. ACLA members perform a wide variety of laboratory testing and have a strong interest in ensuring that all laboratory testing is as safe and accurate as possible.

ACLA is supportive of the FDA draft document on waiver applications. The document incorporates most of the recommendations made by ACLA in a previous comment period. ACLA particularly appreciates that the guidance incorporates scientifically based flex and validation studies in the application process to demonstrate that the device is simple, accurate and has an insignificant risk of erroneous result when used by a range of personnel and during a range of environmental conditions. ACLA also appreciates that additional emphasis is placed on the use of quality control procedures and that the application criteria will include an evaluation that examines test performance when performed by a control group of untrained or lay users when compared to the same test when performed by certified laboratory personnel. ACLA further agrees with the proposed guidance that test systems be designed for use by those with no more than a seventh grade comprehension level to ensure that the test system instructions will be easily understood.

On the other hand, ACLA continues to be concerned that the current system allows each test that is approved for home use to automatically be approved as a waived test. Determining which tests qualify for waived status, and how those tests are assessed to ensure their safety and accuracy continues to be an issue of concern to the laboratory community. Waived tests should meet the same level of accuracy and predictability as tests performed in moderate and high complexity laboratories. It is not permissible to assume that, because a test is "simple," it will be done correctly and yield an accurate result--regardless of where the test is being performed.

ACLA believes that the *Draft Guidance for Industry and Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications* should at a minimum be applied to all waived tests including those cleared by the FDA for home use. Our fundamental concern is that all testing--regardless of whether it will be performed in a patient's home, a physician office, or a moderate or high complexity laboratory--should be safe, reliable and accurate. Subjecting tests approved for home use to the same

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accuracy and performance standards imposed on other waived laboratory testing is a necessary and proper means of ensuring both test quality and the public health.

ACLA's concerns become especially serious when waived tests are performed in a physician's office or other clinical location, where the patient justifiably expects that the test will have a high degree of accuracy. Because there will be no quality control or other performance testing requirements applied to that test, it must be evident that the test will produce a result that can be relied upon in making clinical decisions, and that the person performing that test will do so correctly. However, if a test was granted waived status based upon its approval for home use, then no such assurances are present, because the criteria applied for home use clearance measure only safety and efficacy, often in comparison to a test that was previously approved. Thus, there is no assessment of criteria such as those now being proposed in the *Draft Guidance for Industry and Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications*.

The following represents ACLA's response to the specific issues raised in the Draft Guidance document.

1. Demonstrating Simple:

ACLA agrees with FDA's proposed criteria including the list of characteristics of a simple test and the characteristics that should not be associated with a simple test.

2. Demonstrating "Insignificant Risk of an Erroneous Result" – Failure Alerts and Fail-Safe Mechanisms.

ACLA agrees with FDA's proposed criteria particularly FDA's note that waived tests should generally be more robust than non-waived tests and as such test manufacturers "should demonstrate that sources of error are controlled or mitigated by fail-safe or failure alert mechanisms". ACLA also agrees that manufacturers should, whenever feasible, include external control materials in the test kit.

3. Demonstrating "Insignificant Risk Of An Erroneous Result" – Accuracy

ACLA agrees with FDA's proposed criteria to demonstrate that the test is accurate in the hands of the intended operator using patient samples collected in the intended testing environment. Further ACLA agrees that test