DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

6th December 2005

Docket No. 2001D-0044

Re: Draft Guidance for CLIA Waiver Applications

Dear Sir or Madam:

The Division of Sexually Transmitted Disease Prevention (DSTDP), National Center for HIV, STD, and TB Prevention provides national leadership to prevent STDs. These efforts are accomplished as a result of our close collaboration with health departments, health-care providers and non-governmental organizations. The use of diagnostic tests to detect STDs is crucial for the development and implementation of appropriate management and preventative strategies. We believe that rapid diagnostic tests [ie. point of care (POC) tests] are beneficial in settings where patients may not return for test results and thus fail to be adequately treated. DSTDP welcomes the opportunity to comment on the Food and Drug Administration's (FDA's) draft guidance CLIA waiver applications.

General Comments

Clinical laboratory science has advanced in the past 20 years as a result of the development of better diagnostic tests that provide results faster and more accurately. One measurement of these technological advancements is the increase of CLIA waived tests from 8 in 1992 to approximately 70 in 2004. Test sites that may be waived from CLIA requirements include adult day care centers, ambulances, correctional institutions, health fairs, mobile clinics, pharmacies, outreach vans, and schools. Test sites exempt from CLIA must still be certified and are subject to periodic inspection by CLIA surveyors. This is distinct from home test options where a waived test may be self-administered. The draft guidance does not provide justification for blanket exclusion of tests for reportable diseases from CLIA waivers. Regulatory restriction in this area may limit test development and access to care for STDs particularly in clinical situations with no laboratory facilities, and other sites such as correctional institutions and some schools which have high rates of infection.

Clinical utility of any test is a function of its accuracy and application. The draft recommendations correctly place a reliance of analytical approaches for test evaluation but should also take into account the impact that POC tests can have on public health practice. However since many of the most useful screening applications using these tests would be in relatively low prevalence settings, it may not be feasible to achieve the level of evaluation suggested in the draft document.

DSTDP is deeply committed to supporting STD case surveillance and case reporting; maintaining and supporting such surveillance is a critical part of our mission. However, the issue of surveillance should not affect how a laboratory test is categorized; for example, with regard to syphilis, STD case reporting for surveillance purposes is not based solely on the results of laboratory testing but requires contact with the provider and review of health department records. Such activities are not precluded by the location of the testing site. Furthermore, while taking responsibility for national disease surveillance, CDC recognizes the importance of early detection of infection among those who would have been missed if POC tests were not available for CLIA waived laboratories. Therefore, DSTDP agrees with our DHAP colleagues in endorsing activities that enhance detection, even if there is the possibility of some compromise of reporting.

Specific Comments

Section II. Demonstrating "Simple"

1. Page 7/8; bulleted section "*Under the approach recommended in this guidance, FDA considers that a simple test should have characteristics such as the following*"; Bullet 9: "*Provides instructions and materials for obtaining and shipping specimens for confirmation testing, in cases where such testing is clinically advisable*". Delete "*and materials*" since this would increase test cost. Clarify if the intent is to ship the collected and processed specimen or a new specimen for confirmatory testing.

2. Page 8; bulleted section "*We believe that a test that is simple should not have the following characteristics*"; Bullet 3 "*Results need to be reported to a public health department at the state or local level e.g., tests for sexually transmitted diseases, since this is not a requirement that would be explained in the device labeling*". Justification for excluding reportable diseases as simple by virtue or labeling language and not test complexity is questionable. DSTDP supports the use of these tests in settings that are properly certified as CLIA waived sites and where results are used by a health care provider for management. Health care provider and, in some states, laboratories are responsible for notifying local, state and/or federal health officials of a reportable disease. The value of local/state/national disease notification is well recognized and would not be hampered by waived POC tests. We are concerned that this restriction will impede future CDC recommendations for the use of POC tests in settings that provide services to individuals that would otherwise not return for their results and subsequent treatment. We believe, therefore that the statement should be deleted.

Section IV. Demonstrating insignificant risk of an erroneous result – "Accuracy"

1. Page 26; first paragraph; "*The goal should be to have a minimum of 120 samples positive by CM and a minimum of 120 samples negative by CM*". The need to

evaluate 120 positive samples seems to be better suited for tests that have not received any prior evaluations. Consideration for decreasing this number should be given since these tests have been FDA cleared and are being re-evaluated for a CLIA waiver. The performance would have been documented in the original 510(k) and a similar sample size may not be required. We believe that archival samples or high quality spiked samples could be of greater value in operator evaluation than indicated in the draft recommendations.

If you have any questions, please call me at (404) 639-8260, Dr. Stuart Berman, Branch Chief, Epidemiology and Surveillance Branch at (404) 639-8846 or Dr. Ron Ballard, Branch Chief, Laboratory Reference and Research Branch at (404) 639-2143.

Sincerely,

Dr. John Douglas,
Director, Division of STD Prevention,
NCHSTP,
Centers for Disease Control and Prevention.