Dear CLIAC Committee,

My name is Michele Owen and I am making comments on behalf of the Division of HIV AIDS Prevention, here at CDC. While we understand and support the need for thorough evaluation of tests and maintaining the quality testing practices, we would like to express our concerns over the current process of obtaining CLIA waiver for HIV tests. As we have previously expressed to FDA staff, the two step process of obtaining CLIA waiver for HIV tests (FDA approval by the Center for Biologics Evaluation and Research (CBER) and then assignment of CLIA waiver status by the Center for Devices and Radiological Health CDRH) delays or prevents products from obtaining CLIA waiver status. This has public health implications.

A major goal of our Division is to increase the number of individuals aware of their HIV status. As shown by the HPTN 052 trial, early diagnosis and treatment of HIV can have a significant public health impact. Further, persons early in their infection are highly infectious. Thus, the rapid review of new tests that can detect early infection is of public health importance. We would like to highlight some examples that support our position.

Specifically, there are several recent examples of delays in obtaining CLIA waiver status for HIV tests. One such example is a point of care HIV antigen/antibody combination assay that has the potential for detecting HIV during the early stage. FDA approval for this assay occurred at CBER in August of 2013 and the CLIA waiver determination is still in process with CDRH. A second example is an antibody only rapid HIV test that received FDA approval from CBER in December of 2012 and was just awarded CLIA waiver status in October of 2014. This test allows people who would not otherwise test to be tested with a less invasive sample type. There is a third example in which a manufacturer remains undecided about pursuing a CLIA waiver for a test that has the potential for quicker turn-around time for getting a supplemental (confirmatory test result) to an individual. We have been informed that part of the decision to delay seeking a CLIA waiver is due to the two-step process and the increased clinical trial burden and cost associated with the current CLIA waiver process for HIV tests.

A final point is related to new tests that are likely to enter the FDA approval process in the next few years. These are rapid, low complexity nucleic acid tests (NAT) which are expected to be a major update in HIV testing technology. These tests offer great potential for identifying HIV infected individuals during their most infectious period. In order to help facilitate getting these products approved and waived in a timely manner, we urge streamlining of the CLIA waiver process going forward, so that data can be gathered and evaluated concurrently for FDA approval and CLIA waiver. Thank you for allowing us to present our perspectives on this important issue.

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