



February 25, 2013

Dear Colleague,

The purpose of this letter is to clarify questions and concerns raised by grantees and sub-grantees of the Health Resources and Services Administration (HRSA) Ryan White HIV/AIDS Program (RWHAP) and Centers for Disease Control and Prevention (CDC) about HIV testing and linkage to care. Pursuant to the legislative intent of the RWHAP and the Administration's National HIV/AIDS Strategy (NHAS), it is imperative that individuals who are potentially eligible for RWHAP-funded services receive an accurate HIV diagnosis and are quickly linked to RWHAP-funded medical care.

In order to be eligible for RWHAP-funded medical care, patients must have a "diagnosis of HIV disease" (Sections 2604(c)(1), 2611, 2651(c)(1) and 2671(a) of the Public Health Service (PHS) Act). There is no legislative requirement for a "confirmed" HIV diagnosis prior to linkage to RWHAP-funded medical care, nor is there any specific statutory or program requirement related to the use of Western blot testing as the only means of confirmatory testing. Confirmatory testing may occur at the RWHAP-funded medical clinic. Tests to confirm the diagnosis of HIV disease could include the following<sup>1</sup>:

- Positive HIV immunoassay and positive HIV Western blot
- Positive HIV immunoassay and detectable HIV RNA
- Two positive HIV immunoassays (should be different assays based on different antigens or different principles)

Having positive results from only one HIV antibody test should not be a barrier to linkage to care to a RWHAP-funded clinic, or other HIV care providers, since the majority of people receiving a positive result from a single test have HIV infection and would benefit from quick linkage to ongoing care and prevention services. For example, an individual with one positive rapid test should be counseled about the likelihood of infection and the real (although small) possibility of a false positive result. He or she should be linked at that time, to an HIV care provider to receive follow-up HIV testing and, if confirmed, medical care.

HIV testing sites that do not obtain confirmatory testing should have a memorandum of understanding with RWHAP-funded programs or other HIV care providers to facilitate the timely linkage of patients to HIV medical care and to accelerate the receipt of an appointment for those who test preliminary positive. The receiving medical clinic must be informed of the individual's unconfirmed preliminary positive HIV test result and the need for confirmation. RWHAP-funded clinics that receive such individuals may choose to arrange an abbreviated first appointment during which the individual receives counseling about HIV testing and a limited evaluation that includes confirmatory HIV testing and potentially other HIV labs.

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<sup>1</sup> These examples are for confirmation of diagnosis of HIV disease for purposes of RWHAP eligibility only. Different standards may be required for purposes of medical care in some medical settings.

HRSA and CDC follow current standards for accurate HIV diagnosis. We recognize that the HIV testing algorithm is changing based on newer lab techniques,<sup>2</sup> and CDC is revising its HIV testing algorithm.<sup>3</sup> Standards of HIV confirmation will continue to evolve with improving technology.

To reiterate, the overarching goal is to diagnose and quickly link persons with HIV into high quality medical care, consistent with the Early Identification of Individuals with HIV/AIDS as required in the RWHAP legislation (Sections 2603(b)(2)(A)(i-iii) and 2617(b)(8)(A-E) of the PHS Act) and the National HIV/AIDS Strategy. CDC-funded HIV testing sites and RWHAP-funded clinical sites that work together will help accomplish a key step outlined in the National HIV/AIDS Strategy: “Establish a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV.”

Sincerely,

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<sup>2</sup> Clinical Laboratory Standards Institute

<sup>3</sup> Branson BM, Mermin J. Establishing the diagnosis of HIV infection: New tests and a new algorithm for the United States. *J Clin Virol* 2011; 52:S3-S4.