NEW YORK
state department of
HEALTH

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Commissioner

Sue Kelly
Executive Deputy Commissioner

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Dear Colleague:

The purpose of this letter is to update clinicians, laboratory directors, and others interested in HIV diagnosis about a new HIV testing algorithm that may soon be introduced by clinical laboratories for diagnosis of HIV infection. Developments in HIV testing technologies over the past few years have allowed assessment of testing algorithms that do not rely on traditional confirmatory tests such as Western blot or IFA (immunofluorescent antibody) assays.[1] Although further guidance on use of such algorithms - including a recommendation for a specific test sequence - is expected from CDC later in 2012, laboratory guidelines[2] and evaluation data[3] have been made available that allow laboratories to consider making a change in their HIV diagnostic practices now that would eliminate use of Western blot in the vast majority of new diagnoses of HIV.

New Laboratory Algorithm

The new laboratory algorithm for HIV diagnosis relies on use of a sensitive first test that detects HIV-1 and HIV-2 antibodies or combines antibody/antigen detection.[1] If this test is reactive, a supplemental test is used to differentiate between HIV-1 and HIV-2 antibodies. If the second test is reactive for HIV-1 antibodies, the individual is considered to have a confirmed HIV-1 infection, and clinicians may proceed with tests appropriate for initial evaluation of an infected individual. Likewise, if the second test is reactive for HIV-2 antibodies, the individual is considered to have a confirmed HIV-2 infection, and clinicians may proceed accordingly. If the result of the first supplemental test is discrepant with the initial preliminary positive result, a nucleic acid test (NAT) is recommended to distinguish between a false positive result and an acute/early HIV infection.

Implications for Rapid Point-of-Care Testing

The change in the HIV testing algorithm applies to clinical laboratories only, as confirmation of HIV infection cannot be made at the point-of-care using CLIA-waived tests at this time. Health care providers and community based organizations that hold a New York State Department of Health (NYSDOH) Limited Service Laboratory Registration to perform rapid HIV testing will not be directly affected; however, testing providers should become aware of the new laboratory algorithm and become familiar with the types of supplemental HIV tests that may be used by clinical laboratories to confirm preliminary positive results.

HIV Reporting

In a communication dated November 18, 2011, CDC advised surveillance programs that diagnoses of HIV confirmed by the new algorithm will meet the surveillance case definition for HIV infection. The NYSDOH Bureau of HIV/AIDS Epidemiology will be issuing specific guidance to laboratories with NYSDOH permits to conduct diagnostic HIV testing regarding their obligations to report results of the new testing algorithm as more information becomes

available. The NYSDOH Bureau of HIV/AIDS Epidemiology and the New York City Department of Health and Mental Hygiene HIV Surveillance and Field Services Program will also work with clinicians to understand the documentation needed for reporting of HIV and AIDS diagnoses as required by Public Health Law 2130.

Laboratory Standards

The NYSDOH Wadsworth Center's Clinical Laboratory Evaluation Program (CLEP) is evaluating changes that may be required in laboratory standards and permits to accommodate the new testing algorithm. Further information to this regard will be sent under separate cover to laboratory directors and administrators.

As it becomes available, additional information and guidance will be posted on the NYSDOH website at www.health.ny.gov/diseases/aids/testing/. Questions may be directed to hivtesting@health.state.ny.us. The new HIV testing algorithm offers the opportunity to provide infected persons and their clinicians more accurate and timely information on HIV-1 and HIV-2 infection as well as the opportunity to improve capacity to detect acute HIV infection. We look forward to collaborating with you in continuing the important work of prevention, diagnosis and treatment of HIV infection by incorporating the HIV testing algorithm into routine diagnostic testing and HIV surveillance.

Sincerely,

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References:

[1] Branson, BM. The Future of HIV Testing. J Acquir Immune Defic Syndr 2010;55:S102-S105.

[2] CLSI M-53A Criteria for Laboratory Testing and Diagnosis of HIV, 2011.

[3] Update on HIV Diagnostic Testing Algorithms. Journal of Clinical Virology Vol 52, Supplement 1, pp. S1-S90 (December 2011) accessed at www.journalofclinicalvirology.com.