DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention
Atlanta GA 30329

June 26th, 2014

Dear Colleague:

The Centers for Disease Control and Prevention (CDC) has issued updated recommendations for HIV testing by laboratories in the United States. The new recommended algorithm has several advantages over the previous testing algorithm: more accurate laboratory diagnosis of acute and established HIV-1 infection, more accurate laboratory diagnosis of HIV-2 infection, fewer indeterminate test results, and faster turnaround times for most test results. The complete recommendations titled ***Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations*** and a quick reference guide can be downloaded from the Division of HIV/AIDS Prevention's website at http://www.cdc.gov/hiv/testing/lab/guidelines.

Key changes recommended for laboratories performing diagnostic HIV testing on serum or plasma specimens are:

1. Initiate testing for HIV with a 4th generation antigen/antibody combination immunoassay.
2. Test specimens with a repeatedly reactive antigen/antibody immunoassay results with an antibody immunoassay that differentiates HIV-1 antibodies from HIV-2 antibodies. As of June 27, 2014, the Multispot HIV-1/2 Rapid Test is the only assay approved by the Food and Drug Administration (FDA) for this indication. Note that the criteria for interpretation of Multispot test results, when it is used as a differentiation assay in the diagnostic algorithm, require the presence of both HIV-1 indicators for a positive interpretation.
3. Specimens that are reactive on the initial 4th generation immunoassay and nonreactive or indeterminate on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested with an HIV-1 nucleic acid test (NAT).
4. Laboratories should use this same testing algorithm, beginning with a 4th generation immunoassay, with serum or plasma specimens submitted for testing after a reactive (preliminary positive) result from any rapid HIV test (including the HIV-1/HIV-2 antibody differentiation assay, when it is used as an initial rapid test, and the HIV-1/HIV-2 antigen/antibody combination rapid test). No further testing is required if the result of the laboratory's initial 4th generation immunoassay is nonreactive.
5. The HIV-1 Western blot is no longer part of the recommended algorithm for HIV testing.

Results of all laboratory tests performed as part of the testing algorithm, as well as the overall interpretation, should be reported to the provider. All states, the District of Columbia, and United States territories and dependent areas require that laboratories report test results indicative of HIV infection to public health authorities in the patient's jurisdiction of residence. Results from the testing algorithm with a negative overall interpretation should not be reported to the health department. If the interpretation of the testing algorithm is positive, indicating the presence of HIV infection, or if all tests in the algorithm are not completed and the interpretation is inconclusive, laboratories should report the results of all laboratory tests that were performed and the overall interpretation to the health department.

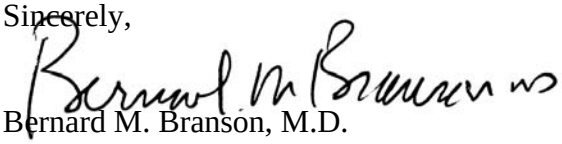
CDC recommends use of Logical Observation Identifiers Names and Codes (LOINC) when laboratories report HIV test results to health departments. Using a single LOINC (69668-2) for the HIV-1/HIV-2 antibody differentiation assay (Multispot) is preferable to reporting a separate LOINC for HIV-1 and for HIV-2, because the latter may be misinterpreted as referring to separate HIV-1 and HIV-2 immunoassays and not the FDA-approved differentiation assay. Below is a listing of the FDA-approved tests that can be used in the recommended HIV testing algorithm and their associated LOINC, available at http://loinc.org/.

Test	LOINC
HIV-1/HIV-2 Ag/Ab combo immunoassay (4th generation) Abbott Architect HIV Ag/Ab Combo Assay (Abbott Laboratories) GS HIV Combo Ag/Ab EIA (Bio-Rad Laboratories)	**56888-1**
HIV-1/HIV-2 antibody differentiation immunoassay Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad Laboratories)	**69668-2**
HIV-1 RNA assay Aptima HIV-1 RNA Qualitative Assay (Hologic Gen-Probe)	**5018-7, 5017-9, 25835-0**

The updated testing recommendations represent a significant advance for the laboratory diagnosis of HIV infection. However, no diagnostic test or algorithm can be completely accurate in all cases. Biologic causes for both false-positive and false-negative HIV test results have been reported, but specimen mix-up or mislabeling are the most frequent reasons for incorrect HIV test results. Inconsistent or conflicting test results should always be investigated with follow-up testing on a newly collected specimen.

Thank you for your commitment to accurate HIV testing.

Sincerely,



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