# Peer Review Plan for "Recommendations for Tests for the Laboratory Diagnosis of HIV Infection in the United States"

**Title:** Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations

**Subject of Report:** This report outlines recommended combinations of initial and supplemental diagnostic tests for use with serum or plasma specimens in the laboratory diagnosis of HIV infection, and provides examples for the interpretation and reporting of test results. This report does not address testing methods or strategies for screening blood, organ, or tissue donations.

**Purpose of Report:** The purpose of the report is to recommend a framework for the stepwise application of HIV diagnostic tests to establish an accurate laboratory diagnosis of HIV infection based on the performance characteristics of antibody, combination antigen-antibody, and nucleic acid tests for HIV that have been approved by the Food and Drug Administration. The report updates the 1989 CDC recommendation for Interpretation and Use of the Western Blot Assay for Serodiagnosis of HIV-1 Infections, the 1992 CDC recommendation for Testing for Antibodies to HIV-2 in the United States, and the 2004 recommendation for Protocols for Confirmation of Reactive Rapid HIV Tests.

**Type of Dissemination:** ISI
**Timing of Review (including deferrals):** February – May 2014
**Type of Review (panel, individual or alternative procedure):** individual
**Opportunities for the Public to Comment (how and when):** Subject-matter experts participated in a 2009-2010 review of available testing technologies and identified proposed HIV testing algorithms, their advantages and disadvantages, and additional data needed for validation. As these data accumulated, the algorithm for HIV testing was formulated and included in the HIV testing algorithms approved by the consensus process of the Clinical Laboratory Standards Institute (CLSI) in June 2011 (CLSI Approved Guideline M-53A). The draft HIV testing recommendations and supporting data were again reviewed and comments solicited from subject matter experts from public health laboratories, clinical laboratories, commercial laboratories, HIV testing programs, and diagnostics industry representatives at the December 2012 HIV Diagnostics Conference. Additional public engagement and verbal comment was solicited from the CDC-HRSA Advisory Committee, the Association of Laboratory Immunologists, and College of American Pathologists during March through September 2013.
**Peer Reviewers Provided with Public Comments before the Review:** No; comments were provided at time of the review.
**Anticipated Number of Reviewers:** 5
**Primary Disciplines or Expertise:** HIV laboratory testing (including antibody tests and nucleic acid tests); clinical immunology of HV infection; clinical management of HIV infection; infectious disease diagnostics
**Reviewers Selected by (agency or designated outside organization):** CDC, American Society for Microbiology
**Public Nominations Requested for Reviewers:** No

**Peer Reviewers:**

Beavis, Kathleen R., MD, F(CAP), F(ASCP)
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Areas of expertise: virology, pathology, laboratory medicine

Rosenberg, Eric S., MD
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Areas of expertise: Infectious disease, immunology and pathogenesis of HIV infection, clinical management of HIV infection

Swenson, Paul D., PhD
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Areas of expertise: Laboratory testing for HIV including HIV-1/HIV-2 immunoassays, Western blot, pooled HIV-1 RNA testing; syphilis and hepatitis serology, nucleic acid testing for hepatitis C, chlamydia trachomatis and Neisseria gonorrhea

Schmitz, John, PhD
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Areas of Expertise: Diagnostic immunology

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Areas of Expertise: Microbiology, Infectious Disease Diagnostics

**Charge to Peer Reviewers of "Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations"**
February 20, 2014

CDC has determined that the updated recommendations for laboratory testing for HIV infection constitute scientific information that will have a clear and substantial impact on important public policies and private sector decisions. The Information Quality Act requires peer review of these draft recommendations by specialists in the field who were not involved in their development to ensure the quality, objectivity, utility and integrity of information disseminated by Federal agencies. Thank you for agreeing to serve as a peer reviewer.

These recommendations describe the types and sequence of assays that should be used to establish the laboratory diagnosis of HIV infection. They are intended for use by laboratories authorized to conduct testing on serum or plasma specimens with assays categorized as moderate or high complexity under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). In your review of the recommendations, we ask that you:

1. Provide an evaluation of the updated recommendations overall and their applicability for HIV diagnosis;
2. Evaluate the appropriateness of the methods used to develop these recommendations and the strength of the authors' inferences;
3. Point out any omissions or oversights in the literature cited as the evidence base for these recommendations;
4. Identify any biases, oversights, omissions, or inconsistencies in the interpretations, findings, and conclusions;
5. Provide advice on the reasonableness of judgments made from the scientific evidence;
6. Ensure that scientific uncertainties are clearly identified and characterized, that the potential implications of any uncertainties for the proposed recommendations are clear, and
7. Assess whether the authors sufficiently acknowledge limitations in the evidence used to develop the recommendations and any limitations of the recommendations themselves for the intended purpose of the accurate laboratory diagnosis of HIV infection.

We would also welcome other comments, for example, on improving their usability or other suggestions about the use of terminology, etc.

Thank you once again for your assistance with the review of these updated recommendations. We recognize and appreciate the commitment of time and energy this this will involve. After receiving your comments, we will forward to all reviewers a copy of CDC's responses to all the comments received.

We look forward to hearing from you.

With best regards,

Bernard M. Branson, M.D.
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National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Peer Reviewers' Comments and CDC/ATSDR's Response to Reviewers' Comments
http://www.cdc.gov/hiv/pdf/Peer_Review_Comments.pdf

Link to Guidelines published June 26th 2014

http://www.cdc.gov/hiv/pdf/HIVtestingAlgorithmRecommendation-Final.pdf
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