

From the Department of Laboratory Medicine - Yale-New Haven Hospital Medical Center

## Clinical Virology Laboratory Newsletter

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### New Diagnostic Algorithm for HIV: Farewell Western Blot

In September, 2013, the Clinical Virology Laboratory at YNHH will adopt the **new HIV diagnostic algorithm recommended by the CDC and approved by the FDA** to provide more rapid, accurate and comprehensive results, and to enhance detection of acute infections (1, 2).

**HIV-1 western blot will no longer be used as the confirmatory test.** For 3 decades, samples positive by an HIV screening test have been “confirmed” by HIV-1 western blot. During this time, HIV screening tests have improved in sensitivity, but the western blot has not.

HIV Screening Test Generation	Antibody detected	HIV-1 p24 Antigen	Original Confirmatory Antibody test	New CDC/FDA Algorithm
First	HIV-1, IgG only	No	HIV-1 IgG western blot	
Second	HIV-1 & 2, IgG only	No	HIV-1 IgG western blot	
Third	HIV-1 & 2, IgG and IgM	No	HIV-1 IgG western blot	HIV-1/HIV-2 Multispot and NAAT
Fourth	HIV-1 & 2, IgG and IgM	Yes		HIV-1/HIV-2 Multispot and NAAT

In acute HIV infections, the HIV-1 western blot becomes positive on average 2-3 weeks after 3<sup>rd</sup> and 4<sup>th</sup> generation screening tests (see **Figure 1**). Thus for acute HIV infections, when patients are most infectious and much transmission occurs, the western blot is falsely negative. In addition, HIV-1 western blot is labor intensive, requires an overnight incubation and is performed only 1-2 times a week. Lastly, HIV-1 western blot can be falsely positive in HIV-2 infection leading to misdiagnoses.

**HIV antibody screen, followed by HIV-1/HIV-2 antibody differentiation instead of w. blot:** The new HIV diagnostic algorithm places a greater emphasis on rapid detection of acute infections to reduce transmission and bring patients into care. The new CDC test algorithm uses either a 3<sup>rd</sup> generation or a 4<sup>th</sup> generation HIV screening test, followed by an HIV-1/HIV-2 differentiation immunoassay (Multispot), which differentiates HIV-1 from HIV-2.

**NAAT:** When clinically indicated, samples that fail to confirm by the Multispot antibody test require an HIV nucleic acid amplification test (NAAT) on a newly collected EDTA plasma sample in order to distinguish a false positive antibody screening test result from an early HIV infection (see **Figure 2**).

The Virology Laboratory currently uses a 3<sup>rd</sup> generation HIV screening test, but will transition to a 4<sup>th</sup> generation antigen/ antibody combo assay when our current test contract can be terminated.

#### Advantages of the new HIV test algorithm include:

1. Multispot results will be available within 2-24 hours of positive HIV screening test results, greatly reducing turnaround time compared to western blots.
2. Multispot detects acute HIV infections one week earlier than western blot
3. Multispot differentiates HIV-1 and HIV-2, whereas HIV-1 western blot commonly misdiagnoses HIV-2 infections.

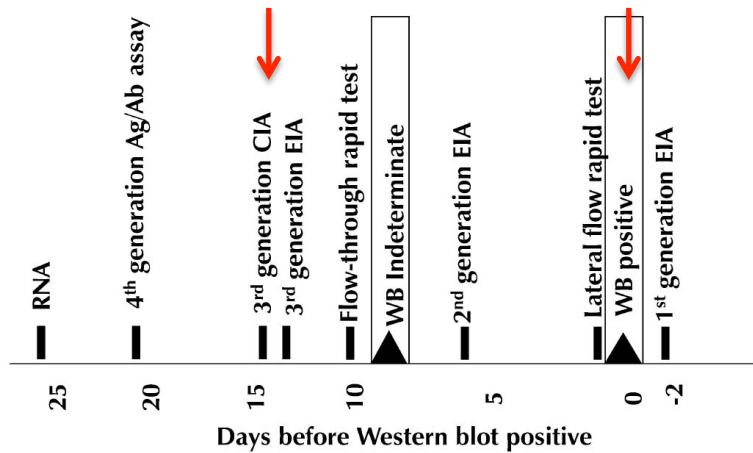
- Multispot indeterminate result report will recommend HIV-1 NAAT on a newly collected EDTA sample to distinguish acute retroviral infection from a false positive screening test result.

The HIV-1 western blot will be available on special request to the Laboratory Director for at least several months. If you have concerns or questions, please contact Marie L. Landry, M.D. Director, Clinical Virology Laboratory, or David Ferguson, Laboratory Manager.

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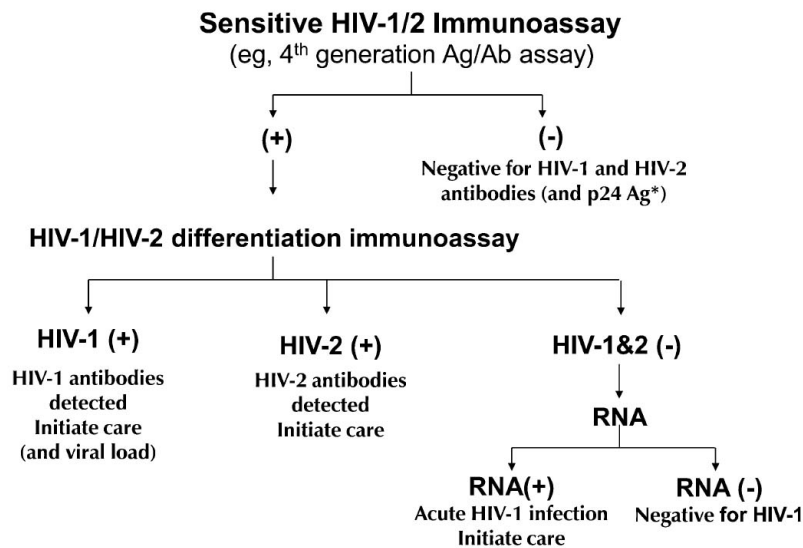
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**Figure 1. Number of days current HIV screening tests become positive BEFORE western blot**



\*CIA= chemiluminescence immunoassay, which is faster and more specific than EIA. CIA is used at YNH. H.

**Figure 2. New HIV diagnostic algorithm recommended by CDC**



Figures are from Reference 2 below

**References:**

- Branson BM. The future of HIV testing. J AIDS, 55 (Suppl 2): S102-S105, 2010.
- Branson BM and Mermin J. Establishing the diagnosis of HIV infection: New tests and a new algorithm for the United States. J Clin Virol, 52S:S3-S4, 2011.