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.

<table>
<thead>
<tr>
<th>HIV Screening Test Generation</th>
<th>Antibody detected</th>
<th>HIV-1 p24 Antigen</th>
<th>Original Confirmatory Antibody test</th>
<th>New CDC/FDA Algorithm</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>HIV-1, IgG only</td>
<td>No</td>
<td>HIV-1 IgG western blot</td>
<td></td>
</tr>
<tr>
<td>Second</td>
<td>HIV-1 &amp; 2, IgG only</td>
<td>No</td>
<td>HIV-1 IgG western blot</td>
<td></td>
</tr>
<tr>
<td>Third</td>
<td>HIV-1 &amp; 2, IgG and IgM</td>
<td>No</td>
<td>HIV-1 IgG western blot, HIV-1/HIV-2 Multispot and NAAT</td>
<td></td>
</tr>
<tr>
<td>Fourth</td>
<td>HIV-1 &amp; 2, IgG and IgM</td>
<td>Yes</td>
<td>HIV-1/HIV-2 Multispot and NAAT</td>
<td></td>
</tr>
</tbody>
</table>

In acute HIV infections, the HIV-1 western blot becomes positive on average 2-3 weeks after 3rd and 4th 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 3rd generation or a 4th 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 3rd generation HIV screening test, but will transition to a 4th 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
4. 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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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 YNHH.

Figure 2. New HIV diagnostic algorithm recommended by CDC

References: