Performance of the Abbott ARCHITECT HIV Ag/Ab Combo Assay in a Low Incidence Population


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Abstract

Background: In March 2015, the Massachusetts State Public Health Laboratory (MA-SPHL) implemented the automated Abbott ARCHITECT system for HIV Ag/Ab combo (CMIA) to handle increasing HIV testing volume and test all submissions for HCV antibody. The performance characteristics for 12,998 specimens, through August 2015, are reported.

Methods: Serum specimens were collected and shipped to the laboratory within 72 hours for testing using the CDC-recommended algorithm of screening with a 4th generation antigen/antibody combination immunoassay and testing repeatedly reactive specimens with the BioRad MultiSpot HIV-1/HIV-2 antibody differentiation immunoassay (ADI). If results were discordant, an HIV RNA NAT was performed.

Results: Of the 12,998 specimens, 4,150 (32.0%) were reactive by both CMIA and ADI. Two-hundred (1.6%) were reactive by CMIA only and 79 (0.6%) were reactive by ADI only. The signal-to-cut off value (S/CO) of the true positives ranged from 5.45 to 977.13 with a mean of 500.24. The S/CO of the combo immunoassay false positives ranged from 1.01 to 42.15 with a mean of 5.08. The S/CO of true positives varied on repeat testing by 10%, while S/CO varied by 22% at the low end of the spectrum than the high end.

Conclusions: By changing to the Abbott Architecture automated platform, the laboratory gained increased testing volume and decreasing TAT, while achieving simultaneous testing for HCV antibody; however, the increased percentage of false positives required additional testing. With the CMIA, significant variance at low S/CO values was observed, supporting the need for supplemental testing.

Methods:

• All testing was performed according to the package insert. Specimens with a signal-to-cut off (S/CO) ratio of 1.0 or greater are considered reactive.

• All reactive specimens were repeated in duplicate and the average of the three S/CO calculated.

• The results of the Architect were compared to the results of the BioRad during the same time period of the previous year, i.e., March 13, 2014 to July 24, 2015 (Architect) compared to March 13, 2014 to July 24, 2014 (BioRad).

Data:

<table>
<thead>
<tr>
<th>System</th>
<th>Performance Summary</th>
<th>S/C Range</th>
<th>S/C Mean</th>
<th>S/C Variability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Architect</td>
<td>Tested = 12998</td>
<td>True Positive = 111</td>
<td>S/C = 5.45-977.13</td>
<td>500.24</td>
</tr>
<tr>
<td></td>
<td>Reactive = 126</td>
<td>False positive = 29</td>
<td>S/C = 1.0-42.15</td>
<td>5.08</td>
</tr>
<tr>
<td></td>
<td>Non-Reactive = 12,841</td>
<td>True Negative = 12,841</td>
<td>S/C &lt; 1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Acute Phase = 2</td>
<td>PVP = 81.5%</td>
<td></td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>Non-Reactive = 7,129</td>
<td>True Negative = 7,129</td>
<td>S/C = &lt;1.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reactive 103 (1.4%)</td>
<td>PVP = 93.64%</td>
<td></td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>False Positive 7</td>
<td>Acute Phase = 0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>True Positive 7</td>
<td>Non-Reactive = 7,137</td>
<td>PVP = 93.64%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Discussion

• Massachusetts is considered a low incidence state with only 629 new cases reported in 2014. Cases have continued to decline since 2005 when 887 cases were diagnosed.

• The automation allowed the lab to increase from 7,240 specimens between March 13, 2014 to July 24, 2015, an 80% increase in test volume, with the same number of FTE’s in the lab section.

• The S/C variability compared to the mean was much greater at the low end of the spectrum than the high end.

• PVN was determined to be 100%, since surveillance indicates no patient was reported to be positive for HIV to DPH post test performance and report.

Conclusions

• The Architect offers significant value in that it is a throughput random access instrument.

• There is additional supplemental testing needed because of an increase false positives.

• At the low end of the S/C there is greater variation upon repeat testing.

Further Information

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