Determine Combo was successfully implemented. HIV-1 antibody specificity was comparable to package insert specifications for high risk population, but more data is needed to verify Ag sensitivity and specificity. The clinic linkage-to-care process was modified due to the Determine Combo HIV-1 Ab false positive frequency. Testing algorithm was modified to test Determine nonreactive specimens for acute infections by the Abbott Combo IA. Alere Determine is a higher cost to the clinic due to PT enrollment and additional license fee. Use of Determine with serum/plasma requires more specimen preparation and licensed technical staff to perform the test.

Lessons Learned

- Determine Combo was successfully implemented.
- HIV-1 antibody specificity was comparable to package insert specifications for high risk population, but more data is needed to verify Ag sensitivity and specificity.
- The clinic linkage-to-care process was modified due to the Determine Combo HIV-1 Ab false positive frequency.
- Testing algorithm was modified to test Determine nonreactive specimens for acute infections by the Abbott Combo IA.
- Alere Determine is a higher cost to the clinic due to PT enrollment and additional license fee.
- Use of Determine with serum/plasma requires more specimen preparation and licensed technical staff to perform the test.

Results (see tables)

A total of 3,272 Determine Combo tests were performed from 12/2/2014 to 8/31/2015. 2.8% (91/3272) were preliminary HIV-1 Ab positive, 75.8% (69/91) were confirmed by the laboratory-based algorithm (table 1). The observed specificity of 99.32% (3203/3225) is within the Determine 95% CI (97.7-99.5%). In addition, 50 Determine Combo reactive specimens were also tested by Clearview Complete (table 2). More false-positive HIV-1 Ab results were observed with Determine Combo and there was an absence of p24 Ag detection in the first nine months of use.

<table>
<thead>
<tr>
<th>Test</th>
<th>Total #</th>
<th>Ab +</th>
<th>P24+</th>
<th>Negative</th>
<th>False-positives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Determine Combo Reactive</td>
<td>50</td>
<td>47</td>
<td>3</td>
<td>N/A</td>
<td>13</td>
</tr>
<tr>
<td>Clearview Complete</td>
<td>50</td>
<td>38</td>
<td>N/A</td>
<td>12</td>
<td>1</td>
</tr>
<tr>
<td>Abbott Combo IA</td>
<td>50</td>
<td>37</td>
<td>13</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Orgenics, Alere manufacturing partner, opened investigation on test performance on false negative and false positive cases.

References

3. Alere Determine™ HIV-1/2 Ag/Ab Combo package insert.

Acknowledgements

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