Performance evaluation of a dual HIV/Syphilis rapid test in a community-based clinic, Los Angeles

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Overview

• Dual rapid assays detect antibodies for both HIV and Syphilis.
• Performance of the Multiplex for detecting antibodies:
  • HIV: Sensitivity=98.2%(90.3%,99.9%); specificity=100%(96.4%,100%).
  • Syphilis: Sensitivity= 45.1%(31.1,59.7); Specificity=97.1%(91.8% - 99.4%)
  • Sensitivity increases with RPR titer; ranging from 8.3%(0.2%,38.5%) when RPR is Non-Reactive (↓antibodies) to 100%(66.4%,100%), when RPR≥1:8 (↑antibodies).
• The differentiation between active/recent syphilis infection (↑antibodies) and past infection(↓antibodies) could be an important tool when screening populations with high prevalence of syphilis.

Methods


Reference assays:
Fingerstick whole blood compared to serum tested in the laboratory for HIV and TP antibodies.
  • HIV: Abbott Architect HIV Ag/Ab Combo
  • Syphilis: Serodia TP-Particle Agglutination with reflex to RPR/titer

Data Analysis: We calculated sensitivity and specificity with respective 95% confidence intervals (CI).

Background

• Currently, there is no dual HIV/Syphilis FDA-approved device.
• The INI Multiplex HIV-1/HIV-2/Syphilis Antibody Test (BioLytical, Richmond, BC, Canada) is a rapid in vitro qualitative immunoassay detecting IgG antibodies to HIV-1(gp41), HIV-2(gp36) and Treponema pallidum(p17, p47) in whole/fingerstick blood, serum or plasma.
• Test yields results in 60 seconds

Results

In total, 156 patients participated in the evaluation
• 55 had detectable HIV antibodies,
• 51 had antibodies for TP and 39 had reactive RPR. No invalid results

Table 1: Performance of the Multiplex for detection of HIV antibodies.

<table>
<thead>
<tr>
<th>Multiplex</th>
<th>HIV reference</th>
<th>Total</th>
<th>Sensitivity (95%CI)</th>
<th>Specificity (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>54 (TP)</td>
<td>54</td>
<td>98.2% (90.3,99.9)</td>
<td>100% (96.4, 100)</td>
</tr>
<tr>
<td>-</td>
<td>1 (FN)</td>
<td>102</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>55</td>
<td>101</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 2: Performance of the Multiplex for detection of antibodies for syphilis.

<table>
<thead>
<tr>
<th>Multiplex</th>
<th>TP</th>
<th>TPPA</th>
<th>Total</th>
<th>Sensitivity (95%CI)</th>
<th>Specificity (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>23</td>
<td>3</td>
<td>26</td>
<td>45.1% (31.1,59.7)</td>
<td>97.1% (92,99.4)</td>
</tr>
<tr>
<td>-</td>
<td>28</td>
<td>102</td>
<td>130</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>51</td>
<td>105</td>
<td>156</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 1: Sample collection and testing

Figure 2: Sensitivity of the Multiplex for detection of TP antibodies, stratified by RPR titer.

Conclusions

• The Multiplex showed excellent performance for detection of HIV antibodies
• Sensitivity for syphilis detection increased in higher RPR titers.
• Further research should evaluate its role for screening.
• Limitations: small sample size reduces the accuracy of our results

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