The Geenius test demonstrated 99.7% (656/658) agreement with HIV. Excluding specimens that were initially reactive for both HIV and Multispot, 9 of 14 (64%) specimens with HIV-indeterminate Geenius results were resolved as HIV negative. Two specimens classified as HIV positive (untypable) by the Geenius assay were initially reactive for both HIV and Multispot.

**Results**

<table>
<thead>
<tr>
<th>Geenius classification vs CDC Algorithm</th>
<th>HIV Positive</th>
<th>HIV Positive</th>
<th>HIV Indeterminate</th>
<th>HIV Negative</th>
<th>Row Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDC algorithm interpretation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV-Negative</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>HIV-Indeterminate</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>HIV-Positive</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Row Total</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>14</td>
</tr>
</tbody>
</table>

**Geenius results compared with MultiSpot**

- **HIV-1**: 100% agreement with 100% positive for both Geenius and MultiSpot.
- **HIV-2**: 100% agreement with 100% positive for both Geenius and MultiSpot.
- **HIV-1/2**: 100% agreement with 100% positive for both Geenius and MultiSpot.

**Geenius results compared with CDC algorithm**

- Geenius classified 656 of 658 (99.7%) specimens as HIV positive.
- Of 1 specimen, 654 (99.4%) were classified as HIV positive.
- Two specimens classified as HIV positive (untypable) by the Geenius assay were initially reactive for both HIV and Multispot.
- Previous, 1 specimen gave a false negative result on negative 4th generation screening, and 1 was HIV-2 negative and 1 was HIV-1-Indeterminate by Geenius.

**Discussion**

The Geenius test demonstrated 99.7% (656/658) agreement with HIV-1 samples identified by the CDC algorithm.

- **Discordant**: In a total of 17 specimens, 6 specimens were reactive for HIV-1 and HIV-2 by Multispot.
- **Geenius**: 9 of these classified HIV-1 only by Geenius.
- 8 were classified HIV-1 by Multispot after the package insert dilution protocol but were HIV-1 positive by Geenius.

**Conclusion**

- Overall, 9 of 14 (64%) specimens with HIV-indeterminate Geenius results were resolved as HIV negative.
- Two specimens classified as HIV positive (untypable) by the Geenius assay were initially reactive for both HIV and Multispot.

**Aknowledgement**

Bio-Rad Laboratories donated the Geenius kits used for this study.

**Questions? Contact:**

Kevin P. Delaney, MPH  
Division of HIV/AIDS Prevention  
National Center for HIV/AIDS, Viral Hepatitis, and STD and TB Prevention  
US Centers for Disease Control and Prevention  
kdelaney@cdc.gov