## CAN A RAPID POINT-OF-CARE ASSAY BE USED TO DIAGNOSE BOTH HIV AND SYPHILIS? EVALUATION OF THE SD BIOLINE HIV/SYPHILIS DUO TEST

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### Background

Accurate diagnosis of syphilis remains a challenge for healthcare providers. Although serological diagnostic tools such as rapid plasma reagin (RPR) and Treponema pallidium particle agglutination (TPPA) have been utilized for decades, both tests require significant time and technician expertise to accurately perform. With many health departments recommending routine syphilis and HIV testing for pregnant mothers and increased-risk populations such as MSM, a rapid, accurate, and easy to use test would substantially benefit clinics and their patients.

### Objective

To evaluate the performance of the SD Bioline HIV/Syphilis Duo Assay (Standard Diagnostics, Inc, South Korea).

### Methods

Blood specimens were collected from Baltimore City Health Department clinic patients between February - September 2009. The specimens were centrifuged to obtain serum aliquots, and the aliquots stored at -80°C. HIV status was ascertained by standard of care testing at the clinic. Syphilis status was ascertained at the clinic by testing with Macro-Vue RPR Card Tests (Becton Dickinson BD Microbiology Systems, Sparks, Maryland, USA), and the stored aliquots were tested in our laboratory by SD Bioline HIV/Syphilis Duo Assay and Serodia TPPA assay (Fujirebio, Tokyo, Japan).

### Results

Of 397 specimens tested for syphilis, 26 specimens were positive by SD Duo (6.5%), 14 specimens were positive by RPR (3.5%); and 34 specimens were positive by TPPA (8.6%). For syphilis, SD Duo sensitivity and specificity, when compared to RPR, were 85.7% (95% CI 57.2 - 97.8%) and 96.4% (95% CI 94.0 - 98.0%), respectively. SD Duo sensitivity and specificity, when compared to TPPA, were 55.9% (95% CI 37.9 - 72.8%) and 98.1% (95% CI 96.1 - 99.2%), respectively. Of 397 specimens tested for HIV, 13 were positive by SD Duo (3.3%) and 11 were positive by the health clinic (2.8%). For HIV, SD Duo sensitivity and specificity, when compared to the health clinic, were 100% (95% CI 71.33 % - 100.00 %) and 99.5% (95% CI 98.1 to 99.9%), respectively.

### Conclusions

The HIV component of the SD Duo performed well. However, our results for the syphilis component, when compared to TPPA and RPR, were less than optimal, and support the need for further testing and assessment.

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<table>
<thead>
<tr>
<th><strong>Syphilis non-treponemal</strong></th>
<th>RPR</th>
<th><strong>SD Duo compared to RPR (n = 397)</strong></th>
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<tbody>
<tr>
<td>Pos</td>
<td>12</td>
<td>Neg 2</td>
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<tr>
<td>Neg</td>
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<table>
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<tr>
<th><strong>Syphilis treponemal</strong></th>
<th><strong>TPPA</strong></th>
<th><strong>SD Duo compared to TPPA (n = 397)</strong></th>
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</thead>
<tbody>
<tr>
<td>Pos</td>
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<td>Neg 15</td>
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<tr>
<td>Neg</td>
<td>7</td>
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<table>
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<tr>
<th><strong>HIV</strong></th>
<th><strong>Health Dept</strong></th>
<th><strong>SD Duo compared to Health Dept (n = 397)</strong></th>
</tr>
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<tr>
<td>Pos</td>
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<td>Neg 1**</td>
</tr>
<tr>
<td>Neg</td>
<td>2</td>
<td>384</td>
</tr>
</tbody>
</table>

**Sensitivity:** 85.7% (57.2 to 97.8%)

**Specificity:** 96.4% (94.0 to 98.0%)

**Prevalence:** 3.5% (1.9 to 5.8%)

**PPV:** 46.2% (26.6 to 66.6%)

**NPV:** 99.5% (98.1 to 99.9%)

**Sensitivity:** 55.9% (37.9 to 72.8%)

**Specificity:** 98.1% (96.1 to 99.2%)

**Prevalence:** 6.0% (6.0 to 11.8%)

**PPV:** 73.1% (52.2 to 88.4%)

**NPV:** 96.0% (93.4 to 97.7%)

**Sensitivity:** 90.9% (58.7 to 98.5%)

**Specificity:** 99.5% (98.1 to 99.9%)

**Prevalence:** 2.8% (1.4 to 4.9%)

**PPV:** 83.3% (51.6 to 97.4%)

**NPV:** 99.7% (98.6 to 100%)

*Confirmed by Bio-Rad MACHTAG HIV-1/2 Rapid Test
**Confirmed by Bio-Rad 4th generation GS-HIV Comb Ag/Ab VIA