Dual Point-of-Care Tests for Syphilis and HIV

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The burden of mother-to-child transmission of syphilis

**Syphilis (2012):**

930,000 pregnant women with syphilis resulted in **350,000** adverse pregnancy outcomes

50% occur as stillbirths or neonatal deaths
Prevention of Congenital Syphilis

SYPHILIS  →  Test  ←  PENICILLIN

STILLBIRTH  →  Prevention  ←  PREVENTION
Syphilis testing

- Is recommended during antenatal care but testing is limited in many resource poor settings
- Relies on serology for presence of antibodies to the causative agent *Treponema pallidum*
- Until recently required laboratory testing of serum specimens with screening and confirmatory components
- Single rapid syphilis tests have been available since 2005 at a cost of 1 USD per test but have seen limited uptake
Dual Point-of-Care tests for HIV and Syphilis

- Three test kits available for use, one is currently WHO pre-qualified
- Systematic review of field performance for both HIV and syphilis good as currently available tests
- WHO pre-qualification performance
  - Sensitivity and specificity for HIV, 100% and 99.5%
  - Sensitivity and specificity for syphilis, 87% and 99.5%
<table>
<thead>
<tr>
<th>Test name</th>
<th>Time to result</th>
<th>Specimen type</th>
<th>Description</th>
<th>WHO Prequalification status</th>
<th>Shelf life</th>
<th>Volume of sample required</th>
</tr>
</thead>
<tbody>
<tr>
<td>SD BIOLINE HIV/Syphilis Duo</td>
<td>Interpret test results within 15-20 minutes after adding assay diluent. (timer required)</td>
<td>Whole blood, serum or plasma</td>
<td>Solid phase immunochromatographic assay</td>
<td>Accepted to list of prequalified in vitro diagnostics as of October 2015</td>
<td>1-30 °C for 24 months</td>
<td>10 µL</td>
</tr>
<tr>
<td>Chembio DPP HIV-Syphilis Assay</td>
<td>Total test time of 15 to 30 minutes</td>
<td>Whole blood, serum or plasma</td>
<td>Immunochromatographic rapid test</td>
<td>Not listed as of March 2017</td>
<td>15-30 °C for 24 months</td>
<td>10 µL</td>
</tr>
<tr>
<td>MedMira Multiplo TP/HIV</td>
<td>Results read immediately</td>
<td>Whole blood, serum or plasma</td>
<td>Rapid vertical flow immunoassay</td>
<td>Not listed as of March 2017</td>
<td>2-30 °C for 24 months</td>
<td>35-40 µl</td>
</tr>
</tbody>
</table>
Advantages of Dual Point-of-Care tests for HIV and Syphilis

- Rapid dual tests:
  - Cost-effective and
  - Effective at preventing adverse pregnancy outcomes as compared to using separate rapid tests for HIV and syphilis

- Test kits can be purchased using Global Fund resources

- Accelerate progress towards targets for validation of Elimination of Mother to Child Transmission of HIV and syphilis (EMTCT)
Interim Guidance on Rapid Dual HIV/Syphilis Tests

WHO Information Note on the Use of Dual HIV/Syphilis Rapid Diagnostic Tests (RDT)

Information Note

Advice for countries using or planning to introduce dual HIV/syphilis RDT in antenatal services and other testing sites.