## Supplement 6. Diagnostic Accuracy of Nucleic Acid Amplification Tests for Gonorrhea Screening

<table>
<thead>
<tr>
<th>Test (Reference)</th>
<th>Definition of a positive screening test</th>
<th>Reference standard</th>
<th>Prevalence (%)</th>
<th>TP (n)</th>
<th>FP (n)</th>
<th>FN (n)</th>
<th>TN (n)</th>
<th>Sens (%)</th>
<th>Spec (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>PLR</th>
<th>NLR</th>
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<tbody>
<tr>
<td><strong>Site: Endocervix</strong></td>
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<tr>
<td>TMA (24)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs</td>
<td>TMA</td>
<td>1.5</td>
<td>23</td>
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<td>SDA</td>
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<tr>
<td>TMA (25)</td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>TMA</td>
<td>6.5</td>
<td>27</td>
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<td>418</td>
<td>96.4</td>
<td>99.5</td>
<td>93.1*</td>
<td>99.8*</td>
<td>202.5*</td>
<td>0.04*</td>
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<tr>
<td>PCR (24)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs</td>
<td>TMA</td>
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<td>22</td>
<td>0</td>
<td>1</td>
<td>2246</td>
<td>95.7</td>
<td>100.0</td>
<td>100.0*†</td>
<td>100.0*</td>
<td>Unable to calculate</td>
<td>0.04*</td>
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<tr>
<td>SDA (24)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs</td>
<td>TMA</td>
<td>1.5</td>
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<td>2</td>
<td>2241</td>
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<td>99.8</td>
<td>84.0*</td>
<td>99.9*</td>
<td>512.5*</td>
<td>0.09*</td>
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<tr>
<td>SDA (25)</td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>TMA</td>
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<td>1</td>
<td>421</td>
<td>96.3</td>
<td>99.5</td>
<td>92.9*</td>
<td>99.8*</td>
<td>203.7*</td>
<td>0.04*</td>
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<tr>
<td>SDA (25)</td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
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<td>2</td>
<td>407</td>
<td>92.9</td>
<td>99.3</td>
<td>89.7*</td>
<td>99.5*</td>
<td>126.9*</td>
<td>0.07*</td>
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<td>TMA (26)</td>
<td>Positive culture with biochemical confirmation or positive result from one NAAT confirmed by second NAAT</td>
<td>Culture TMA</td>
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<td>0</td>
<td>4</td>
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<td>90.0</td>
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<td>98.8*</td>
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<td>0.10*</td>
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<td>PCR (27)</td>
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<td>TMA</td>
<td>1.1</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>1116</td>
<td>100.0</td>
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<td>Unable to calculate</td>
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<tr>
<td><strong>Site: Vagina, Self- Collected</strong></td>
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<tr>
<td>TMA (26)</td>
<td>Positive culture with biochemical confirmation or positive result from one NAAT confirmed by second NAAT</td>
<td>Culture TMA</td>
<td>2.5</td>
<td>39</td>
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<td>2194</td>
<td>98.0</td>
<td>100.0</td>
<td>100.0*</td>
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<td>PCR (27)</td>
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<td>TMA</td>
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<td>1</td>
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<td>100.0</td>
<td>99.9</td>
<td>92.3</td>
<td>100.0</td>
<td>1120.0*</td>
<td>0.00*</td>
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</tbody>
</table>
### Site: First Catch Urine, Female

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Criteria</th>
<th>TMA</th>
<th>SDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>TMA (25)</td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>6.5</td>
<td>22 0 6 422 78.6 100.0 100.0* 98.6* Unable to calculate 0.21*</td>
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<tr>
<td>TMA (24)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs</td>
<td>1.5 22 1 1 2268 95.7 100.0 95.7* 100.0* 2170.4* 0.04*</td>
<td></td>
</tr>
<tr>
<td>PCR (24)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs</td>
<td>1.5 23 1 0 2255 100.0 100.0 95.8* 100.0* 2256.0* 0.00*</td>
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<tr>
<td>SDA (24)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in endocervical swab and/or FCU; each NAAT was evaluated based on results of other 2 NAATs</td>
<td>1.5 23 0 2246 100.0 99.9 88.5* 100.0* 749.7* 0.00*</td>
<td></td>
</tr>
<tr>
<td>SDA (25)</td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>6.5 27 2 0 421 100.0 99.5 93.1* 100.0* 211.5* 0.00*</td>
<td></td>
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<tr>
<td>SDA (25)</td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>6.5 23 2 5 414 82.1 99.5 92.0* 98.8* 170.9* 0.18*</td>
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<tr>
<td>PCR (27)</td>
<td>≥ 1 positive result from each reference NAAT</td>
<td>1.1 11 1 1 1123 91.7 99.9 91.7 99.9 1030.3* 0.08*</td>
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</table>

### Site: First Catch Urine, Male

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Criteria</th>
<th>TMA</th>
<th>SDA</th>
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</thead>
<tbody>
<tr>
<td>TMA (22)</td>
<td>Both urethral swab and FCU positive on ≥ 1 of 2 NAATs; or positive on both tests for ≥ 1 specimen type</td>
<td>13.8 100 4 10 730 90.9 99.5 96.2* 98.7* 166.8* 0.09*</td>
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</tr>
<tr>
<td>TMA (25)</td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>14.5 12 3 0 502 100.0 99.4 80.0* 100.0* 168.3* 0.00*</td>
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</tr>
<tr>
<td>TMA (23)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in urethral swab and/or FCU</td>
<td>9.2 7 0 0 465 100.0 100.0 100.0* 100.0* Unable to calculate 0.00*</td>
<td></td>
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<tr>
<td>PCR (23)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in urethral swab and/or FCU</td>
<td>9.2 7 0 0 465 100.0 100.0 100.0* 100.0* Unable to calculate 0.00*</td>
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<tr>
<td>SDA (38)</td>
<td>Positive result from ≥ 2 NAATs with different target regions in urethral swab and/or FCU</td>
<td>9.2 7 1 0 464 100.0 99.8 87.5* 100.0* 465.0* 0.00*</td>
<td></td>
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</table>
### Site: Male Urethra

<table>
<thead>
<tr>
<th>Reference Assay</th>
<th>Assay Comparison</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>PLR</th>
<th>NLR</th>
<th># Samples</th>
</tr>
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<tbody>
<tr>
<td><strong>SDA (25)</strong></td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>TMA SDA</td>
<td>14.5</td>
<td>12</td>
<td>4</td>
<td>0</td>
<td>501</td>
<td>100.0</td>
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<tr>
<td><strong>SDA (25)</strong></td>
<td>≥ 1 positive result from each reference NAAT; for assay comparison, positive result required from each of other 2 assays</td>
<td>TMA SDA</td>
<td>14.5</td>
<td>12</td>
<td>1</td>
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<td>92.3</td>
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<tr>
<td><strong>PCR (27)</strong></td>
<td>≥ 1 positive result from each reference NAAT</td>
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<td>5</td>
<td>1</td>
<td>0</td>
<td>1126</td>
<td>100</td>
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</table>

* Calculated.
† Estimated PPV 93.8 to 99.9% (based on hypothetical prevalence range of 1 to 50%).

**Abbreviations:** FCU = first catch urine; FN = false negative; FP = false positive; n = number; NAAT = nucleic acid amplification test; NG = Neisseria gonorrhoea; NLR = negative likelihood ratio; NPV = negative predictive value; PCR = polymerase chain reaction; PLR = positive likelihood ratio; PPV = positive predictive value; ref = reference; SDA = strand displacement assay; Sens = sensitivity; Spec = specificity; TMA = transcription-mediated assay; TN = true negative; TP = true positive.