GeneXpert NG/CT Test: Interpreting Results

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No analytical instrument is 100% accurate

• The limit of detection (LOD) is the lowest # of either CT or NG that can be distinguished from negative samples with 95% confidence.
  – C. trachomatis: ~75-134 Ebs/mL
  – N. gonorrhoeae: ~2-3 CFU/mL

• The RT-PCR cycle threshold is based on how many cycles it take to get the LOD.

• Specimens with quantities near the LOD may give inconsistent results.
Amplification Curve and Cycle Threshold (Ct)

CYCLE THRESHOLD

30.0
For In Vitro Diagnostic Use Only.

Assay Name: Xpert CT-NG

Test Result: CT DETECTED; NG DETECTED

Cycles threshold numbers

Legend:
- CT1; Primary
- NG2; Primary
- NG4; Primary
- SAC; Primary
- SPC; Primary
## Cepheid package insert: Reproducibility by Study Site

<table>
<thead>
<tr>
<th>Urine, N=10</th>
<th>Site 1</th>
<th>Site 2</th>
<th>Site 3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exp&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Inexp&lt;sub&gt;2&lt;/sub&gt;</td>
<td>Exp</td>
</tr>
<tr>
<td>CT &amp; NG high pos</td>
<td>CT</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>NG</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>CT &amp; NG low pos</td>
<td>CT</td>
<td>50%</td>
<td>60%</td>
</tr>
<tr>
<td></td>
<td>NG</td>
<td>40%</td>
<td>70%</td>
</tr>
</tbody>
</table>

1. Exp=Experienced operator
2. Inexp=Inexperienced operator
Factors affecting the cycle threshold

- Mix the urine sample immediately before transferring into transport tube.
- Filling the transport tube to the line on the tube.
- Mix the transport tube vigorously (not gently) immediately before transferring sample into cassette.
Suggestions for Competency Assessment

• Using known positive samples, compare the cycle threshold (ct) for CT, NG, and SAC over multiple days and/or technologists.

• Duplicate samples with inconsistent ct suggest poor mixing or delay of pipetting after mixing for those with high ct.

• Compare the ct among technologists.
Controls: internal

• System control
• Reagent and Probe Check Control
• Sample Processing Control (SPC)
• Sample Adequacy Control (SAC)
Controls: External

• After showing reproducibility, month testing only.

• Commercially made
  – ZeptoMetrix: cost about $172.00 to test 3 controls.

• Previously tested samples
  – CAP panels (only if using swab transporter)
  – Freeze left over samples at -80°C (can be thawed and re-frozen)
  – Do not used left over ProbeTec samples
Questions