Xpert® C. difficile/Epi


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45-minute Detection & Differentiation of Clostridium difficile & the Epidemic 027 Strain
The epidemic strain of Clostridium difficile (027/NAP1/BI) is known to produce a significantly higher number of C. difficile spores\textsuperscript{1,2} and toxins\textsuperscript{2,3}. The epidemic strain has also been identified as a cause of hospital outbreaks worldwide\textsuperscript{4,5,6,7,8}. Healthcare professionals can now be informed on the epidemic C. difficile strain and make appropriate infection control decisions.

\section*{THE NEED}
Numerus outbreaks caused by the epidemic strain of C. difficile (027/NAP1/BI strain) highlight the need for rapid and accurate differentiation of C. difficile 027/NAP1/BI strains in order to stay ahead of an outbreak:

- Higher risk of cross contamination with 027/NAP1/BI strain due to more efficient sporulation\textsuperscript{1,2,3}
- 027/NAP1/BI strain has been identified as a cause of outbreaks around the world\textsuperscript{4,5,6,7,8}
- Incremental costs due to C. difficile infection can be as high as $7,179\textsuperscript{9} per patient

\section*{THE SOLUTION}
Xpert C. difficile/Epi is the first commercially available test in the world to detect and differentiate the epidemic strain of C. difficile (027/NAP1/BI). With rapid and accurate identification of the epidemic strain, Infection Control professional can stay ahead of potential outbreak:

- Innovative multiplex design enables detection of C. difficile Infection (CDI) and 027/NAP1/BI strain call-out in a single cartridge
- On-demand testing of samples from suspected CDI patients provides on-demand epidemiological surveillance data clinicians can act on
- Monitoring and reporting of the epidemic strain enables clinicians to improve infection control efforts

Cepheid’s Xpert C. difficile/Epi test provides on-demand results you can trust and empowers your clinical team to better manage patients.
PERFORMANCE
Performance characteristics of Xpert® C. difficile/Epi were determined against broth enriched toxigenic culture and strain typing methods.

Performance Characteristics of Xpert C. difficile/Epi vs. Enriched Toxigenic Culture and PCR-Ribotyping

<table>
<thead>
<tr>
<th>REFERENCE CULTURE &amp; PCR-RIBOTYPING</th>
<th>Toxin B + 027+</th>
<th>Toxin B + 027 –</th>
<th>NEGATIVE</th>
<th>TOTAL a</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xpert C. difficile/Epi A</td>
<td>89</td>
<td>5</td>
<td>31</td>
<td>125</td>
</tr>
<tr>
<td>Toxin B+ 027/NAP1/BI +</td>
<td>0</td>
<td>217</td>
<td>86</td>
<td>303</td>
</tr>
<tr>
<td>NEGATIVE</td>
<td>1</td>
<td>21</td>
<td>1841</td>
<td>1863</td>
</tr>
<tr>
<td>TOTAL b</td>
<td>90</td>
<td>243</td>
<td>1958</td>
<td>2291</td>
</tr>
</tbody>
</table>

a. Xpert results shown are for first or second attempt. Approximately 3.2% of the specimens were indeterminate on the first attempt.
b. 2 specimens were culture positive but were not strain typeable due to contamination and are not included in the performance characteristics above.

TOXIGENIC C. DIFFICILE
Sensitivity: 93.39% (311/333)
Specificity: 94.02% (1841/1958)

TOXIGENIC C. DIFFICILE / 027/NAP1/BI
POS Agreement: 98.89% (89/90)
NEG Agreement: 98.36% (2165/2201)

SIMPLE RESULTS
Delivers a simple result that is easy to understand.

STOP THE SPREAD
TOXIGENIC C. DIFFICILE NON-027 STRAINS PRODUCE TOXIN AND C. DIFFICILE SPORES
INFECTION CONTROL RISK

TOXIGENIC C. DIFFICILE 027 STRAIN PRODUCES HIGHER VOLUME OF TOXIN AND SPORES COMPARED TO A WILD-TYPE
HIGHER OUTBREAK RISK
WORKFLOW:
3 EASY STEPS
Total hands-on time: <1 Minute

1. Insert swab into Elution reagent vial and break at score
2. Vortex and dispense Sample into Port S
3. Insert Cartridge and start assay

Ordering Information

Xpert C. difficile/Epi (10 test) ......................................................... Catalog No. GXCDIFF/EPI-10

References:
2. Warny et al., Lancet 2005; 366: 1079–84
5. Kuijer et al., Eurosurveillance Vol 12, Issues 9-6, Apr-Jun 2007
6. Muto et al., Clinical Infectious Diseases 2007; 45:1966-73

For In Vitro Diagnostic Use.

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