Xpert® *C. difficile/Epi*

45-minutes Detection & Differentiation of Clostridium difficile & the Epidemic 027 Strain

Identify. Differentiate. Prevent.

US-IVD. For *In Vitro* Diagnostic Use.

Cepheid®
A better way.

The epidemic strain of *Clostridium difficile* (027/NAP1/BI) is known to produce a significantly higher number of *C. difficile* spores[1,2] and toxins[2,3]. The epidemic strain has also been identified as a cause of hospital outbreaks worldwide.[4,5,6,7,8] Healthcare professionals can now be informed on the epidemic *C. difficile* strain and make appropriate infection control decisions.

The Need

Numerous 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[1,2,3]
- 027/NAP1/BI strain has been identified as a cause of outbreaks around the world[4,5,6,7,8]
- Incremental costs due to *C. difficile* infection can be as high as $7,179[9] per patient

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[10]

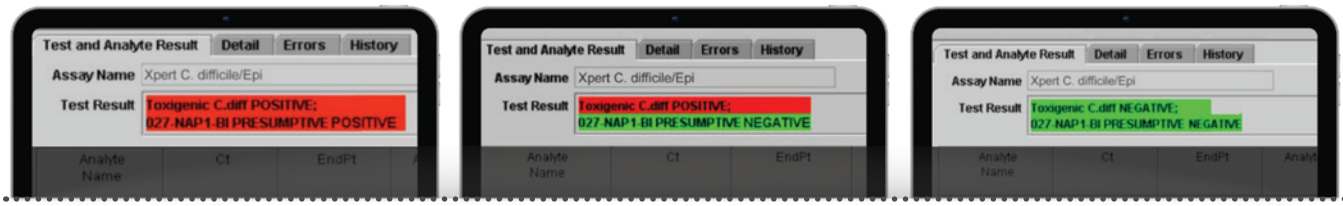
		Reference Culture & PCR-Ribotyping			
		Toxin B + 027+	Toxin B + 027 –	Negative	Total^
Xpert *C. difficile/Epi**	Toxin B+ 027/NAP1/BI +	89	5	31	125
	Toxin B+ 027/NAP1/BI -	0	217	86	303
	Negative	1	21	1841	1863
	Total	90	243	1958	2291

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

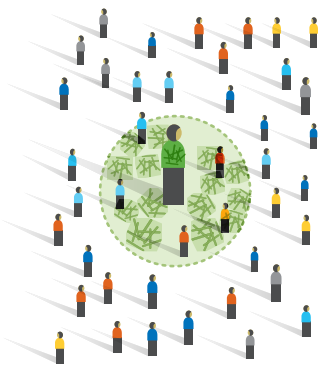
Toxigenic *C. difficile*		Toxigenic *C. difficile* / 027/NAP1/BI	
Sensitivity	93.39% (311/333)	POS Agreement	98.89% (89/90)
Specificity	94.02% (1841/1958)	NEG Agreement	98.36% (2165/2201)

Simple Results

Delivers a Simple Result That is Easy to Understand

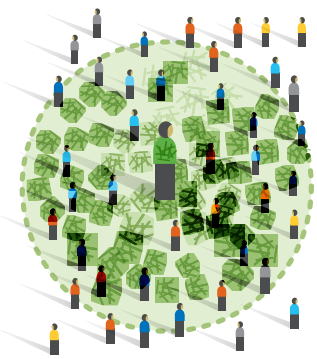


Stop the Spread



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

1

Insert swab into Elution reagent vial and break at score

2

Vortex and dispense sample into Port S

3

Insert cartridge and start test

CATALOG INFORMATION

Xpert® *C. difficile/Epi*	10 tests	GXCDIFF/EPI-10
	120 tests	GXCDIFF/EPI-120

References:

1 Åkerlund T, et al. Increased Sporulation Rate of Epidemic *Clostridium difficile* Type 027/NAP1. J Clin Microbiol. Apr 2008, 46 (4) 1530-1533.

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4 Kallen AJ, et al. Complete restriction of fluoroquinolone use to control an outbreak of *Clostridium difficile* infection at a community hospital. Infect Control Hosp Epidemiol. 2009 Mar;30(3):264-72.

5 Kuijper EJ, et al. Update of *Clostridium difficile*-associated Disease due to PCR Ribotype 027 in Europe. Eurosurveillance. Apr–Jun 2007. 12(3-6):163-166.

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7 McDonald LC, et al. An Epidemic, Toxin Gene-variant Strain of *Clostridium difficile*. N Engl J Med. 2005 Dec 8;353(23):2433-41.

8 Loo VG, et al. A predominantly clonal multi-institutional outbreak of *Clostridium difficile*-associated diarrhea with high morbidity and mortality. N Engl J Med. 2005 Dec 8;353(23):2442

9 Jarvis WR, et al. National Point Prevalence of *Clostridium difficile* in US Health Care Facility Inpatients, 2008. Am J Infect Control. 2009 May;37(4):263-70.

10 Xpert® *C. difficile/Epi* Package Insert. 300-9680, Rev J. Apr 2020.

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CORPORATE HEADQUARTERS

904 Caribbean Drive
Sunnyvale, CA 94089 USA

TOLL FREE **+1.888.336.2743**
PHONE **+1.408.541.4191**
FAX **+1.408.541.4192**

EUROPEAN HEADQUARTERS

Vira Solelh
81470 Maurens-Scopont France

PHONE **+33.563.82.53.00**
FAX **+33.563.82.53.01**
EMAIL **cepheid@cepheideurope.fr**

www.**Cepheid**.com