

The Xpert™ C. difficile advantage: **Rapid and Easy-to-use**

- Fully automated process reduces handling time to just minutes
- Random access for flexibility and workflow optimization
- Rapid results to improve patient management
- Fully integrated reagent and instrument system for accuracy and reproducibility

1. Insert swab into Elution reagent vial and break at score
2. Vortex and dispense Sample into port S
3. Dispense Reagent 1 into port 1
4. Dispense Reagent 2 into port 2
5. Insert cartridge and start assay

Total hands-on time = 2 minutes

Xpert™ C. difficile

Accurate detection of C. difficile – in less than one hour.



Ordering Information

Xpert™ C. difficile Catalog No. GXCDIFFICILE-10
(10 Cartridges with reagents)

References:

1. Zilberberg et al. Emerging Infectious Diseases, Vol 14, No 6, 2008
2. Kuijper et al. European Society of Clinical Microbiology & Infectious Diseases, CMI, 12 (Suppl 6), 2-18
3. Mundy et al. Infection 2007; 35: 300-307
4. UK Office for National Statistics
5. National Prevalence Study of Clostridium Difficile in U.S. Healthcare Facilities. www.apic.org

THE PURCHASE OF THIS PRODUCT ALLOWS THE PURCHASER TO USE IT FOR THE PERFORMANCE OF DIAGNOSTIC SERVICES FOR HUMAN IN VITRO DIAGNOSTICS. NO GENERAL PATENT OR OTHER LICENSE OF ANY KIND OTHER THAN THIS SPECIFIC RIGHT OF USE FROM PURCHASE IS GRANTED HEREBY. NO OTHER RIGHTS ARE CONVEYED EXPRESSLY, BY IMPLICATION OR ESTOPPEL TO ANY OTHER PATENTS. FURTHERMORE, NO RIGHTS FOR RESALE ARE CONFERRED WITH THE PURCHASE OF THIS PRODUCT.

CORPORATE HEADQUARTERS

904 CARIBBEAN DRIVE
SUNNYVALE, CA 94089
USA
TOLL FREE: 1.888.336.2743
PHONE: 1.408.541.4191
FAX: 1.408.734.1346

EUROPEAN HEADQUARTERS

VIRA SOLELH
81470 MAURENS-SCOPONT
FRANCE
PHONE: 33.563.82.53.00
FAX: 33.563.82.53.01

Xpert™ *C. difficile*: Accurate detection of *C. difficile* – in less than one hour.

Clostridium difficile infection (CDI) is a serious healthcare-associated infection that results in severe diarrhea and, in serious cases, death.¹ Current screening tests lack sensitivity and take up to 72 hours. Cepheid's on-demand Xpert *C. difficile* test eliminates the need for additional or repeat testing and identifies *C. difficile* toxin producing strains in less than one hour.

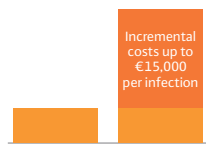
Xpert: in action

Problem:

C. difficile infections (CDI) have been increasing in incidence and severity, and are associated with an increase in length of hospital stays, costs, morbidity and mortality.¹ CDI is also reported to be the most common cause of hospital acquired diarrhea and necessitates rapid and accurate diagnosis.

- In major EU countries CDI incidence is reported at 11 per 10,000 admissions²
- Highly virulent (027-NAP1-BI) strains have caused outbreaks of severe disease in Europe and North America — with mortality rates above 50%³
- The number of reported deaths are rising and, in the case of England and Wales, increasing by 72% between 2005 and 2006⁴

Incremental costs associated with *C. difficile* infection²



Contributing Cost Factors:

- incremental LOS
- isolation costs
- environmental cleanup
- additional therapies

Lack of reliable and timely diagnosis, treatment, and infection control can dramatically increase costs.

Solution:

Xpert *C. difficile* detects the presence of toxin-producing *Clostridium difficile* in less than one hour. Detection of three targets: Toxin B, Binary Toxin, and *tcdC* deletion provides superior coverage and offers presumptive identification of the 027/NAP1/B1 epidemic strains.

- Clinicians can promptly administer therapy for improved patient outcomes
- Timely implementation of infection control initiatives to reduce spread of infection within institution⁵
- Superior test sensitivity eliminates the need for additional or repeat testing

CDI has become a substantive and growing burden in hospitalized patients prompting the need for earlier and accurate detection. The impact of Cepheid's Xpert *C. difficile* test can be significant: With one-hour detection, clinicians can now initiate therapy and appropriate infection prevention and control measures sooner, leading to better patient management.

Sensitive and Specific:

Accurate detection for prompt identification of *C. difficile* infection.

Sensitivity: 100%
Specificity: 93%

Performance characteristics of the Xpert™ *C. difficile* Assay as compared to Toxinogenic Culture

		Toxinogenic Culture		
		<i>C. difficile</i> pos	027/NAP1/B1 pos	Negative
Xpert <i>C. difficile</i>	Toxin B+	34	0	16
	027/NAP1/B1	0	0	1
	Negative	0	0	234
		34	0	251

Identification of 027/NAP1/B1 Strain:

The only rapid test which identifies epidemic strains.

Sensitivity: 100%
Specificity: 91%

Performance characteristics of the Xpert *C. difficile* Assay as compared to PCR Ribotyping

		Toxinogenic Culture and PCR-ribotyping	
		027/NAP1/B1 pos	027/NAP1/B1 neg
Xpert <i>C. difficile</i>	027/NAP1/B1 pos	14	1*
	027/NAP1/B1 neg	0	10

* Discrepant Analysis on-going

Broad Coverage:

The only rapid test which identifies three targets: Toxin B, Binary Toxin, and *tcdC* deletion.

Xpert *C. difficile* result algorithm

		Individual Targets and combination			
		Toxin B+	<i>tcdC</i> deletion	Binary Toxin	Internal Control
Xpert <i>C. difficile</i> result	Negative	–	–	–/+	+
	<i>C. difficile</i> Positive	+	–	+	N/A
	<i>C. difficile</i> Positive	+	+	–	N/A
	Epidemic <i>C. difficile</i> Positive	+	+	+	N/A