

Xpert[®]
C.difficile

Rapid and Accurate. *It's About Time.*

Xpert[®] C. difficile

Detection of *Clostridium difficile* in 45 minutes.

“Patients infected with *C. difficile* are a source of transmission to other patients, therefore it is important that infected patients are detected as early as possible. Rapid molecular testing, providing wholly accurate results in 45 minutes, when combined with isolation of infected patients, provides an important new weapon in our battle against healthcare associated infections.”

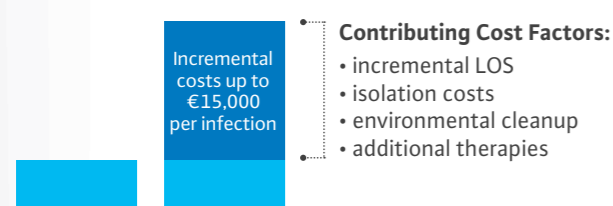
Professor Richard James
Director of the Center for Healthcare Associated Infections
University of Nottingham

The Need

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

Incremental costs associated with *C. difficile* infection²



LACK OF RELIABLE AND TIMELY DIAGNOSIS, TREATMENT, AND INFECTION CONTROL CAN DRAMATICALLY INCREASE COSTS.

Currently screening tests lack sensitivity and it can take up to 72 hours before a result becomes available to the physicians. This has forced clinicians to choose between speed or accuracy.

The Solution

Xpert® *C. difficile* detects the presence of toxin-producing *Clostridium difficile* in 45 minutes. Detection of three targets: Toxin B, Binary Toxin (cdtA), and *tcdC* deletion provides superior coverage and offers presumptive identification of the 027/NAP1/B1 epidemic strains. This new solution delivers both speed and accuracy and eliminates the need for additional or repeat testing.

- Clinicians can promptly administer therapy for improved patient outcomes
- Timely implementation of infection control initiatives to reduce spread of infection within institution⁴
- 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 45-minute detection, clinicians can now initiate therapy and appropriate infection prevention and control measures sooner, leading to better patient management.

Performance

Performance characteristics of Xpert® *C. difficile* were determined in a prospective investigation study by comparing Xpert *C. difficile* on the GeneXpert® System with broth enriched toxigenic culture.

PERFORMANCE CHARACTERISTICS OF XPRT® *C. DIFFICILE* AS COMPARED TO TOXIGENIC CULTURE

		Toxigenic Culture	
		<i>C. difficile</i> POS	NEGATIVE
Xpert <i>C. difficile</i>	Toxin B+	316	117
	NEGATIVE	22	1841

SENSITIVITY: 93.5%
SPECIFICITY: 94.0%

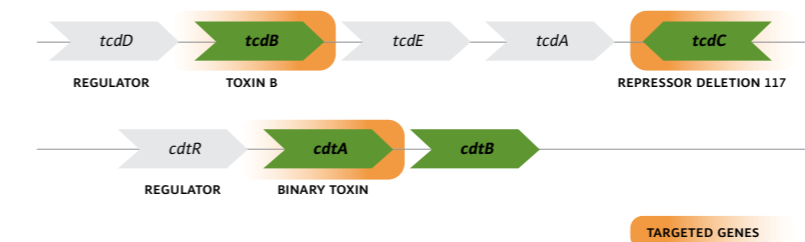
Broad Coverage

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

XPRT *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
	<i>C. difficile</i> POSITIVE	+	+	-	N/A
	Epidemic <i>C. difficile</i> POSITIVE	+	+	+	N/A

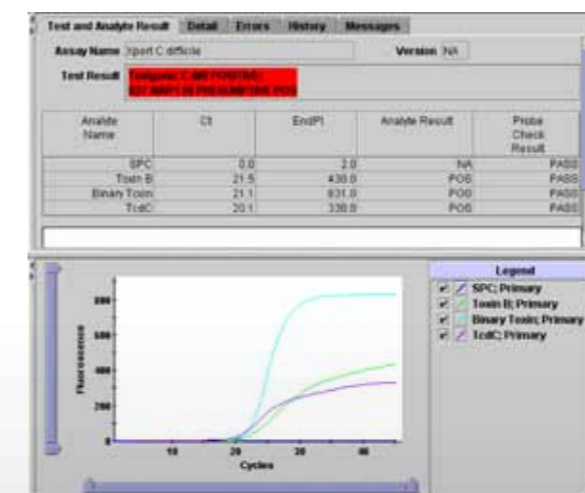
PATHOGENICITY LOCUS



Unique

Delivers immediate actionable results.

PRESUMPTIVE POSITIVE TOXIGENIC *C. DIFFICILE* 027/NAP1/B1



Rapid and Accurate. Xpert® *C. difficile*

- 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

WORKFLOW:

5 Easy Steps

Total hands-on time: 2 Minutes

<p>1</p> <p>Insert swab into Sample Reagent vial and break</p> 	<p>2</p> <p>Vortex and dispense Sample into Port 5</p> 	<p>3</p> <p>Dispense Reagent 1 into Port 1</p> 	<p>4</p> <p>Dispense Reagent 2 into Port 2</p> 	<p>5</p> <p>Insert Cartridge and start assay</p> 
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ORDERING INFORMATION

Xpert® *C. difficile* (10 Cartridges with reagents) Catalog No. GXCDIFFICILE-CE-10

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. National Prevalence Study of *Clostridium Difficile* in U.S. Healthcare Facilities. www. apic.org



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