

Xpert®
C. difficile
BT



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



Xpert® *C. difficile* BT

Detection of *Clostridium difficile* in 47 minutes.

CE IVD In Vitro Diagnostic Medical Device

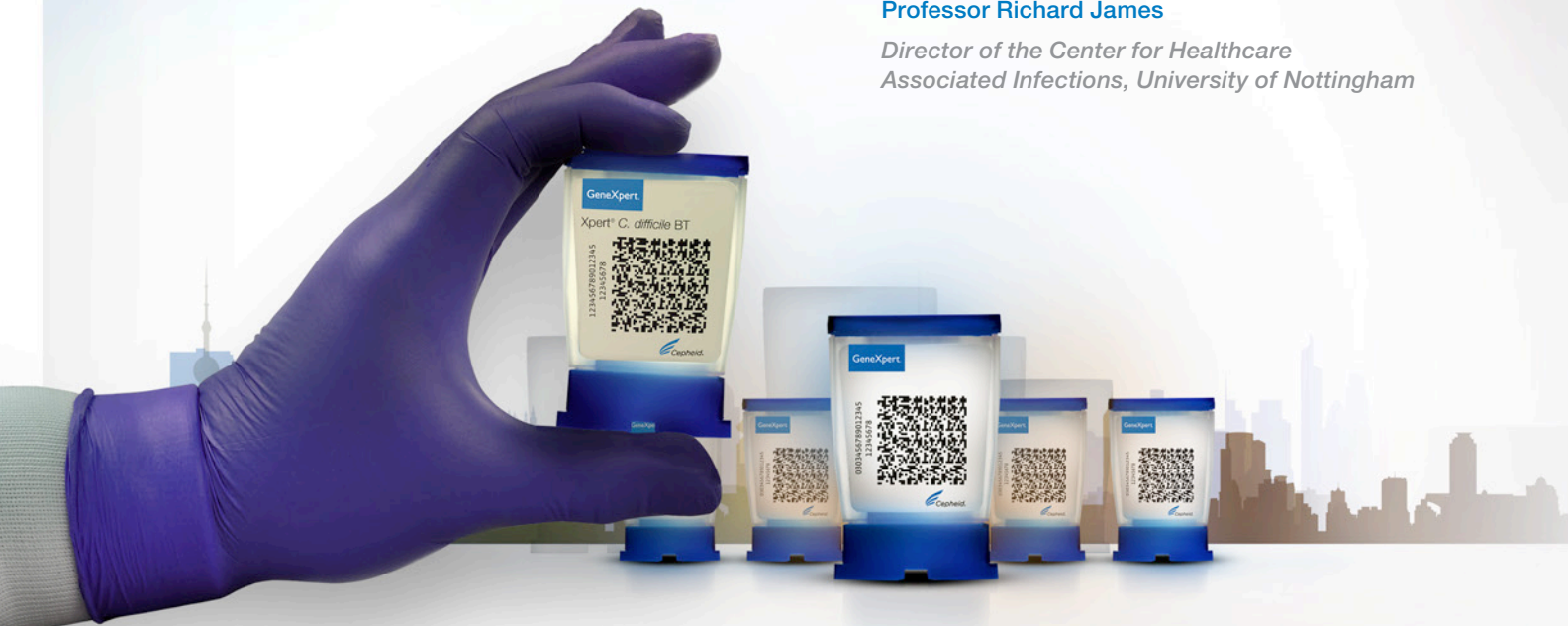
 **Cepheid®**
A better way.



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 accurate results in 47 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

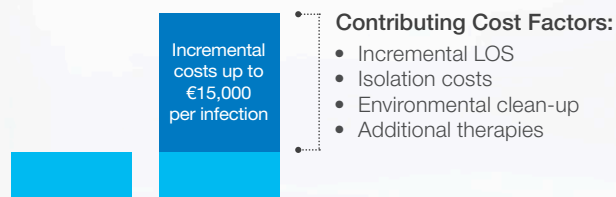


THE NEED

C. difficile infections (CDI) have been increasing in incidence and severity, and are associated with an increase in length of hospital stay, costs, morbidity and mortality.¹

- Highly virulent (O27-NAP1-BI) strains have caused outbreaks of severe disease in Europe and North America — with mortality rates above 50%²
- Binary toxin (BT) may be important because of:
 - Links to both disease severity and outcome^{3,4}
 - Strains, such as O33, are positive only for binary toxin and not toxins A and B yet have been reported to cause CDI^{5,6}

Incremental costs associated with *C. difficile* infection⁷



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



THE SOLUTION

Xpert® *C. difficile* BT detects the presence of toxin-producing *Clostridium difficile* in 47 minutes. Detection of three targets: toxin B (*tcdB*), binary toxin (*cdtA*), and a *tcdC* deletion at nucleotide 117, offers presumptive identification of the O27/NAP/BI epidemic strain and an independent call-out of binary toxin results. This new solution delivers both speed and accuracy, and eliminates the need for additional 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* BT test can be significant: with 47-minute detection, clinicians can now initiate therapy and appropriate infection prevention and control measures sooner, supporting better patient management.



THE IMPACT

With Xpert® *C. difficile* BT:

- Clinicians can promptly administer therapy to support improved patient outcomes
- Timely infection control initiatives can be implemented to reduce spread of infection within an institution⁸
- Speed and accuracy eliminates the need for additional testing
- Identify the presence of the gene encoding binary toxin, which has been linked with increased disease severity and poorer patients outcomes
- Detect strains of *C. difficile* that only produce binary toxin, which may still be associated with CDI



PERFORMANCE

Performance characteristics of Xpert® *C. difficile* were determined in a prospective investigation by comparing Xpert *C. difficile* on the GeneXpert® System with broth-enriched toxigenic culture. These data were then re-analyzed with the Xpert *C. difficile* BT product.

Performance Characteristics of Xpert *C. difficile* BT

REFERENCE CULTURE & PCR-RIBOTYPING

| | Toxin B+ 027 + | Toxin B+ 027 - | Negative |
|----------------|-------------------|-------------------|----------|
| Toxin B+ 027 + | 89 | 5 | 31 |
| Toxin B+ 027 - | 0 | 217 | 86 |
| Negative | 1 | 21 | 1841 |

Sensitivity: 93.4%
Specificity: 94.0%



COMPREHENSIVE TARGETS

Pathogenicity Locus



cdt Locus



TARGETED GENES



WORKFLOW:

3 EASY STEPS

Total hands-on time: <1 Minute

1

Insert swab into stool specimen, then into elution reagent vial and break at score



2

Vortex and dispense sample into port S



3

Insert cartridge and start test



> Xpert® *C. difficile* BT is a rapid PCR test that detects the presence of toxin-producing *Clostridium difficile* in 47 minutes. Detection of three targets: toxin B (*tcdB*), binary toxin (*cdtA*), and a *tcdC* deletion at nucleotide 117, offers presumptive identification of the 027/NAP/BI epidemic strain and an independent call-out of binary toxin results.

CATALOG NUMBER

Xpert *C. difficile* BT (10 tests) GXCDIFFBT-CE-10

References:

1. Zilberberg, et al. Emerging Infectious Diseases. 2008;(14);6.
2. Mundy, et al. Infection. 2007;(35):300-7.
3. Bacci, et al. Emerg Infect Dis. Jun. 2011.
4. Stewart, et al. J Gastrointest Surg. 2013;(17):118-25.
5. Eckert, et al. New Microbes New Infect. 2014;(8):3:12-7.
6. Androga, et al. J Clin Microbiol. 2015;(53):973-5.
7. Kuijper, et al. European Society of Clinical Microbiology & Infectious Diseases, CMI. 12;(6):2-18.
8. National Prevalence Study of Clostridium Difficile in U.S. Healthcare Facilities. www.apic.org.

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