Cepheid
A better way.

Xpert® *C. difficile* BT

Detection of toxigenic C. difficile with binary toxin call out and presumptive identification of the epidemic 027 strain in 43 minutes

The Need

- *Clostridioides difficile* (*C. difficile*) is amongst the **most frequently reported** micro-organisms in healthcare associated infections in Europe[1]
- It is associated with an **increase in length of hospital stay, high morbidity and mortality** resulting in both societal and financial burden[2]
- Highly virulent (027-NAP1-BI) strains have caused outbreaks of severe diseasae in Europe and North America and are often resistant to fluoroquinolones[3]
- Although the **accurate and rapid diagnosis** of *C. difficile* is essential for effective and timely treatment, this remains an unmet clinical need[4]

The Solution

- **Xpert *C. difficile* BT** provides **detection and differentiation** of *Clostridioides difficile* & the epidemic 027 strain, with a callout for binary toxin, in 43 minutes from unformed stool specimens
- Rapid detection and differentiation of *Clostridioides difficile* & the epidemic 027 strain **optimizes patient management** decisions, enables timely and appropriate treatment, and **supports infection control** and outbreak prevention measures[4]

The Impact

- Rapid and accurate detection of toxigenic *C. difficile* is essential to diagnose CDI to implement **optimized therapy and bed management** and to help **prevent transmission** and outbreaks:
  - **45%** reduced empiric therapy[5]
  - **48%** reduced isolation days[6]

1 Viprey, V. F., Granata, G., & Vendrik, K. (n.d.). European survey on the current surveillance practices, management ... https://www.journalofhospitalinfection.com/article/S0195-6701(22)00365-6/fulltext.

2 Tschudin-Sutter S, et al. Guidance document for prevention of C. difficile infection in acute healthcare settings. Clin Microbiol Infect 2018;24:1051

3 Markovska, R et al. Clostridioides difficile, a new suberbug, Microorganisms 2023, 11, 845. https://doi.org/10.3390/microorganisms11040845

4 Bai Y, Hao Y, Song Z, Chu W, Jin Y, Wang Y. Evaluation of the Cepheid Xpert C. difficile diagnostic assay: an update meta-analysis. Braz J Microbiol. 2021 Dec;52(4):1937-1949.

5 Peppard W, et al. Implementation of polymerase chain reaction to rule out C. difficile infection is associated with reduced empiric antibiotic duration of therapy. Hosp Pharm. 2014 Jul;49(7):639-43.

6 Casari E, et al. Reducing rates of Clostridium difficile infection by switching to a stand-alone NAAT with clear sampling criteria. Antimicrob Resist Infect Control. 2018 Mar;7(40).

Xpert® *C. difficile* BT

Product Reference Sheet — CE-IVD

Test Reagent Kit	Xpert *C. difficile* BT	
Catalog Number	GXCDIFFBT-CE-10	
Technology	Real-time RT-PCR	
Targets	*tcdB*, *cdt*, *tcdC*Δ117	
Batch or On-Demand	On-demand	
Minimum Batch Size	1	
Sample Type	Unformed (liquid or soft) stool specimen	
Sample Extraction	Automated/Integrated	
Precision Pipetting	Not required	
TAT	43 minutes	
Control: Process	Sample Processing Control	
Controls: Probe Function/Detection	Probe Check Control	
	Toxigenic *C. difficile*	**Toxigenic *C. difficile* 027/NAP1/BI**
Sensitivity	93.4%	**Positive Agreement:** 98.9%
Specificity	94%	**Negative Agreement:** 98.4%
Sample Stability	2-8°C for 5 days Room temperature 20-30°C for 24 hours	
Kit Storage	2–28 °C	
Commercial Controls	Refer to Package Insert or Contact Cepheid Technical Support	

Xpert® *C. difficile* BT Package Insert n° 301-6190, Rev. D, March 2023

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

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