Xpert® *C. difficile/Epi*

Detection and differentiation of C. difficile & the epidemic 027 strain in <45 minutes



The Need

- **55%** of the *C. difficile* cases are acquired in health care settings (Health care–associated *C. difficile* infection, HA-CDI)[1]
- It is associated with an **increase in length of hospital stay, high morbidity and mortality** resulting in both societal and financial burden[2]
- Although the **accurate and rapid diagnosis** of CDI is essential for effective and timely treatment, this remains an unmet clinical need or opportunity for future study in high risk patient populations[4]

The Solution

- The **Xpert *C. difficile/Epi*** test detects the toxin B (tcdB) gene sequence of toxigenic *Clostridioides difficile* & differentiates the presumptive 027/NAP1/BI-associated markers, in <45 minutes from unformed stool specimen
- Timely detection and differentiation of *Clostridioides difficile* (CDI) & the epidemic 027 strain **optimizes patient management** decisions and **supports infection control** and outbreak prevention measures

The Impact

- Rapid and accurate molecular PCR detection of toxigenic *C. difficile* is essential to aid **diagnostic assessment**, support **bed management** and help **reduce opportunities for transmission** and outbreaks. It has been associated with*:
  - **45%** reduction in empiric therapy[5]
  - **48%** reduction in contact precautions after a negative result[6]

1 Vered L, et al. Health care–associated Clostridioides difficile infection: Learning the perspectives of health care workers to build successful strategies. Am. Jour. of Infec. Con. Volume 52, Issue 3, March 2024, Pages 284-292

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 Guinta MM, et al. Clinical and economic impact of the introduction of a nucleic acid amplification assay for Clostridium difficile. Ann Clin Microbiol Antimicrob. 2017;16(1):77. Published 2017 Dec 4. doi:10.1186/s12941-017-0252-7

Xpert® *C. difficile/Epi*

Product Reference Sheet — US-IVD

Test Reagent Kit	Xpert *C. difficile/Epi*	
Catalog Number	GXCDIFF/EPI-10 GXCDIFF/EPI-120	
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	<45 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%	98.89%
Specificity	94%	98.36%
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	

* These outcomes have been reported in the literature. The Xpert® *C. difficile/Epi* test is intended as an aid in the diagnosis of CDI and is not intended to guide treatment or patient management decisions.

Xpert *C. difficile/Epi* Package Insert n° 300-9680, Rev J April 2020.

US-IVD. *In Vitro* Diagnostic Medical Device.

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