



Xpert® *C. difficile*

Datasheet — US-IVD

Test Reagent Kit	Xpert <i>C. difficile</i>
Catalog Number	GXCDIFFICILE-10 GXCDIFFICILE-120
Technology	Real-time RT-PCR
Targets	<i>tcdB</i> gene
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	In about 40 minutes*
Controls: Process	Sample Processing Control
Controls: Probe Function/Detection	Probe Check Control
Sensitivity[^]	93.5%
Specificity[^]	94.0%
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

US-IVD. For *In Vitro* Diagnostic Use.

* For positive results with early assay termination (EAT). Full run time is 43 minutes.

[^] Xpert *C. difficile* was compared to Reference Broth Enriched Culture.

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