

C. difficile



For the qualitative detection and identification of toxigenic *Clostridium difficile* bacterial DNA using real time PCR

- Less than 70 minute turn-around time from sample to answer
- 3 step sample preparation
 - ▶ No heat step
 - ▶ No timed step
 - ▶ No vortexing or centrifugation
- For use on the Applied Biosystems® 7500 series of instruments, QuantStudio™ Dx Real-Time PCR Instrument, and Cepheid SmartCycler® II

Workflow benefits of Lyra Direct real-time PCR assays

Feature	Benefit
Three-step sample prep	No timed, heat or vortexing steps
One step reagent set-up	Rehydration solution is simply added to the lyophilized master mix
Speed	Results in less than 70 minutes
Easy training	Simplified and uniform workflow with standard pipetting volumes
Refrigerated storage	No freezer needed. 2°C to 8°C storage
Long shelf life	2-year shelf life from date of manufacture
Room temperature set-up	No ice or cooling block required
Flexible 96-test format	Kit includes vials of 12x8 master mix, rehydration solution and liquid process controls. Sample preparation kit includes all consumables

Clinical performance

Lyra Direct C. difficile Assay on the QuantStudio Dx	Tissue Culture Cytotoxin				Sensitivity	95% CI		
		POS	NEG	Total		93.3%	86.9%	96.7%
	POS	98	45*	143	Specificity	93.4%	91.3%	95.0%
	NEG	7**	638	645				
	Total	105	683	788				

*Of the forty-five (45) discordant specimens (Quidel Molecular Positive/Direct Culture Negative) reported, forty-four (44) were tested with a FDA-cleared molecular device. Thirty-five (35) of these specimens were positive for *C. difficile*, and nine (9) were negative. The remaining specimen was unavailable for testing.

**Seven (7) discordant specimens (Quidel Negative/Direct Culture Positive) reported were tested with a FDA-cleared molecular device. Two (2) of these specimens were found positive for *C. difficile*, and five (5) were negative.

Lyra Direct C. difficile Assay on the QuantStudio Dx	Enriched Toxigenic Culture				Sensitivity	95% CI		
		POS	NEG	Total		87.3%	81.1%	91.6%
	POS	137	8*	145	Specificity	98.7%	97.5%	99.4%
	NEG	20**	626	646				
	Total	157	634	791				

*Eight (8) discordant specimens (Quidel Molecular Positive/Enriched Toxigenic Culture Negative) reported were tested with a FDA-cleared molecular device. Two (2) of these specimens were positive for *C. difficile*, and six (6) were negative.

**Seventeen (17) out of twenty (20) discordant specimens (Quidel Negative/ Enriched Toxigenic Culture Positive) reported, were tested with a FDA-cleared molecular device. Three (3) specimens were unavailable for testing. Eleven (11) of these specimens were found negative for *C. difficile*, and six (6) were positive.