

AmpliVue®

Anytime, Anywhere Molecular Assays

C. difficile



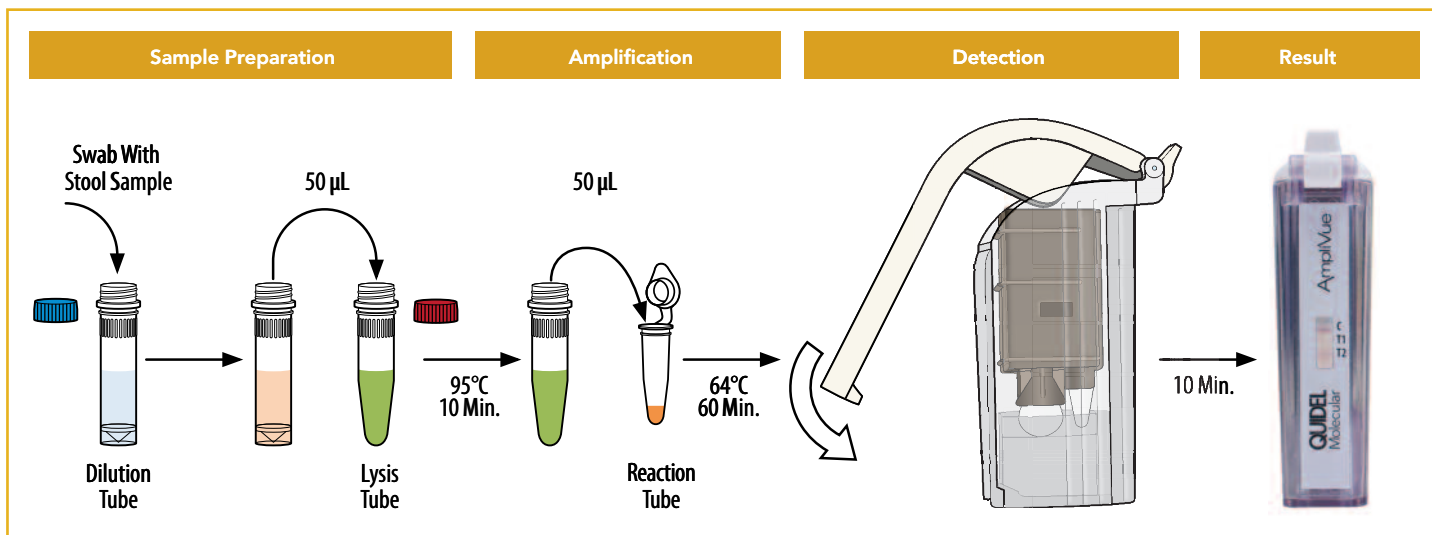
For the qualitative detection and identification of toxigenic *Clostridium difficile* bacterial DNA

- Easy-to-read disposable cassette-based molecular testing
- No capital investment
- Minimal hands-on time
- Uniform pipetting volumes
- Total assay time approximately 80 minutes
- Lyophilized reagents

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Procedure



Why Test?

- Nucleic acid amplification tests can be as much as twice as sensitive as enzyme immunoassays.¹
- *C. difficile* infection (CDI) can range in severity from asymptomatic to life-threatening, especially among the elderly (most often nosocomially infected in hospitals, nursing homes or other medical institutions).²
- Relapses of *C. difficile* have been reported in up to 20% of cases.³ Increases to 40% and 60% with subsequent recurrences.⁴
- *C. difficile* infection often mimics some flu-like symptoms and can mimic disease flare in patients with inflammatory bowel disease associated colitis.⁵

Clinical performance

C. difficile			
Fresh Stool Specimens Received for CDAD Testing (N=835)	Tissue Culture Cytotoxin		
	Positive	Negative	Total
AmpliVue C. difficile Assay			
Positive	102	43*	145
Negative	7**	683	690
Total	109	726	835
	95% CI		
Sensitivity	93.6%	87.3%	96.9%
Specificity	94.1%	92.1%	95.6%

*Of these 43 discordant specimens (AmpliVue Positive/Tissue Culture Cytotoxin Negative) reported, 37 were positive for *C. difficile* by an FDA-cleared molecular device, and 6 were negative.

**Of these 7 discordant specimens (AmpliVue Negative/Tissue Culture Cytotoxin positive) reported, 2 were positive for *C. difficile* by an FDA-cleared molecular device, and 5 were negative. Only 4 specimens were invalid upon initial testing and only one specimen was invalid upon repeat testing.

AmpliVue C. difficile Assay – 16 Test Kit: Catalog #M201
 Quidel Molecular C. difficile Control Set – 10-Reaction Kit: Catalog #M108

¹Vital Signs: Preventing *Clostridium difficile* Infections Weekly, March 9, 2012:61(09):157-62.

²Clabots CR, Johnson S, Olson MM, Peterson LR, Gering DN. Acquisition of *Clostridium difficile* by hospitalized patients: evidence for colonized new admissions as a source of infection. *J. Infect Dis.* Sept 1992;166 (3):561-7.

³Ryan KJ, Ray CG (ed). *Sherris Medical Microbiology* (4th ed.) McGraw Hill. pp. 322-4.

⁴Kelly CP, LaMont JT. *Clostridium difficile*—more difficult than ever. *N. Engl. J. Med.* Oct 2008;359 (18):1932-40.

⁵Binion DG. *Clostridium difficile* and IBD. *Inflam. Bowel Dis. Mon.* 2010;11 (1):7-14.



For more information on AmpliVue C. difficile, visit our website, call your Quidel Account Manager at 858.552.1100 (outside the U.S.), or your local distributor.

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