



Solana[®]

C. difficile ASSAY

C. difficile molecular testing with connectivity for easy results monitoring

The Solana C. difficile Assay is an *in vitro* diagnostic test for the direct, qualitative detection of toxigenic *Clostridium difficile* in unformed stool specimens of patients suspected of having *Clostridium difficile*-infection (CDI). Change the way you monitor *C. difficile* results with Virena[®]. Virena provides an electronic patient de-identified data management system to monitor results on a daily basis. This allows healthcare providers and healthcare facilities the ability to quickly track *C. difficile* infections in their patient population and facilities.

Prompt initiation of patient management and therapy

- Results in just 35 minutes
- High volume throughput capabilities; Batch up to 12 tests per runs
- Monitor results in near real-time

Ease and Affordability

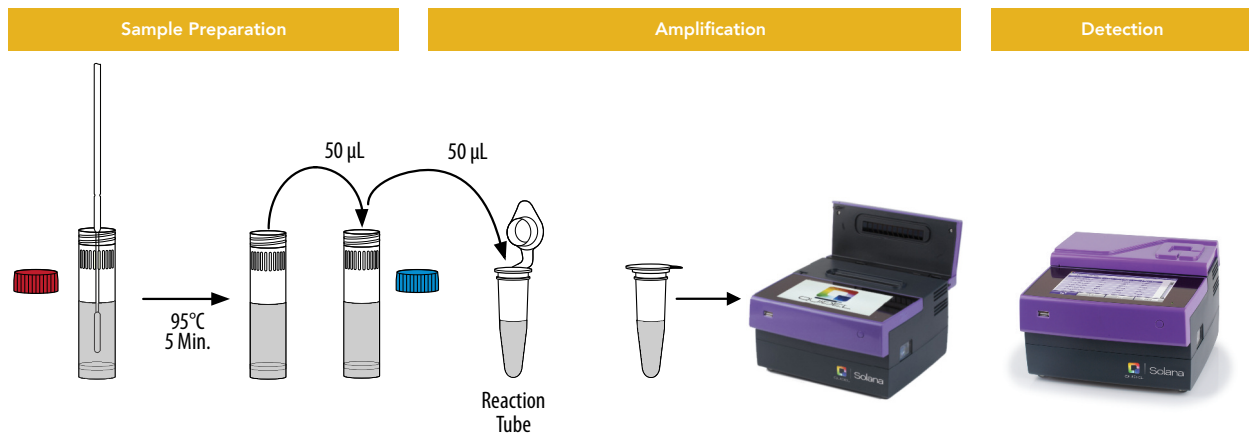
- Simple procedure
- Sustainable reagent pricing
- Flexible instrument placement options

The Accurate. Sustainable.
Molecular *C. difficile* Solution.

Solana C. difficile Assay run with the Solana bench top instrument a mere 9.4" x 9.4" x 5.9"



Procedure



Clinical Performance

Performance Characteristics of the Solana *C. difficile* Assay Compared to Broth Enhanced Toxigenic Bacterial Culture (Combined Sites – Raw Specimen)

		Enhanced Toxigenic Culture			Sensitivity	93.0%
		POS	NEG	Total		
Solana <i>C. difficile</i>	POS	107	6*	113	Specificity	99.2%
	NEG	8**	731	739		
	Total	115	737	852		

*Three (3) of the six (6) specimens were positive for *C. difficile* toxin gene DNA by an alternative molecular device, three (3) were negative.

**Six (6) of eight (8) specimens were found positive for *C. difficile* toxin gene DNA by an alternative molecular device, two (2) were negative.

Refer to Package Insert for additional performance claims.

Performance Characteristics of the Solana *C. difficile* Assay Compared to FDA-cleared molecular device (Combined Sites – Raw Specimen)

		FDA-cleared Molecular Device			Sensitivity	97.0%
		POS	NEG	Total		
Solana <i>C. difficile</i>	POS	97	16*	113	Specificity	97.9%
	NEG	3**	736	739		
	Total	100	752	852		

*Twelve (12) of the sixteen (16) specimens were positive for *C. difficile* toxin gene DNA by an alternative molecular device, four (4) were negative.

**Two (2) of three (3) specimens were found positive for *C. difficile* toxin gene DNA by an alternative molecular device, one (1) was negative.

Refer to Package Insert for additional performance claims.

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Solana *C. difficile* Assay – 48 Test Kit: Cat. #M307
 Quidel Molecular *C. difficile* Control Set – 40-Reaction Kit: Cat. #M108
 Solana *C. difficile* Assay Startup Kit – Cat. #M923
 Solana Instrument – Cat. #20278

