Poster number 433

Comparison of Simplexa™ *C. difficile* Direct Assay and BD MAX™ Cdiff Assay For Identification of *Clostridium difficile*

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Abstract

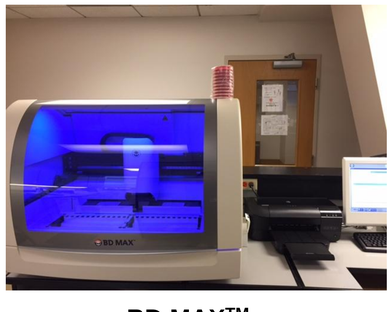
Background: *Clostridium difficile* is the major causative agent of nosocomial- and community-acquired diarrhea, posing increasing threat to global public health and economy. Accurate and rapid diagnosis improves patient outcome and facilitates infection control. Molecular assays have been shown to be more sensitive and specific compared to conventional enzyme immunoassays targeting glutamate dehydrogenase or *C. difficile* toxins. This study compared the performance of a new PCR assay, the Simplexa™ *C. difficile* Direct assay (DiaSorin Molecular LLC, Cypress, California) to the BD MAX™ Cdiff Assay (BD Diagnostic Systems, Hunt Valley, Maryland).

Methods: One hundred seventy-nine unpreserved stool specimens were tested prospectively (November 2016 to January 2017) using two platforms in parallel: the Integrated Cycler of Focus Diagnostics and the BD MAX™ System. Specimens with discordant results were repeated using the Xpert® C difficile assay on the GeneXpert® Systems (Cepheid, Sunnyvale, California).

Results: Of 179 clinical samples tested using BD MAX™ Cdiff Assay, 33 were positive, 145 were negative and 1 was indeterminate for *C. difficile* toxin B gene (*tcdB*). The observed agreement between the BD MAX™ Cdiff Assay assays and the Simplexa™ *C. difficile* Direct assay was 97.2%, whereas 3 of the 4 discrepant results from the latter concurred with the results by the Xpert® C difficile assay. After resolving discrepancies, the sensitivity and specificity of the Simplexa™ *C. difficile* Direct assay are 97.1% (95% CI, 85.1 – 99.5%) and 100% (95% CI, 97.4 – 100%), respectively.

Conclusions: Our data suggest that the new Simplexa™ *C. difficile* Direct assay is comparable to commercial PCR assays currently available for diagnosing *C. difficile* infection.

Focus Integrated Cycler



BD MAX™

Performance of *C. difficile* assays

Before resolving discrepancies

		BD MAX™		
		Positives	Negatives	Total
Simplexa®	Positives	31	2	33
	Negatives	2	143	145
	Total	33	145	178

Resolving discrepant results

		Xpert®		
		Positives	Negatives	Total
Simplexa®	Positives	2	0	2
	Negatives	1	1	2
	Total	3	1	4

After resolving discrepancies

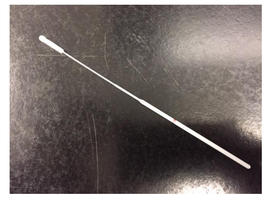
		BD MAX™		
		Positives	Negatives	Total
Simplexa®	Positives	33	0	33
	Negatives	1	144	145
	Total	34	144	178

The sensitivity and specificity of the Simplexa™ *C. difficile* Direct assay are 97.1% (95% CI, 85.1 – 99.5%) and 100% (95% CI, 97.4 – 100%), respectively.

Comparison of operational parameters

Assay	Target	Max number of specimens per run	Sample preparation time	Run time	Hands-on time
Simplexa®	*tcd*B	8	<2 min per specimen	60 min regardless of the number of specimen	<10 min
BD MAX™	*tcd*B	24	<2 min per specimen	Varies depending on number of specimens and other assays being run simultaneously. Minimum 85 min	<10 min

Specimen inoculation



Simplexa® *C. difficile* Direct Assay

BD MAX™ *C. difficile* Assay

Results

- The sensitivity and specificity of the Simplexa™ *C. difficile* Direct assay are 97.1% (95% CI, 85.1 – 99.5%) and 100% (95% CI, 97.4 – 100%), respectively.
- Depending on the test volume and staffing, the Simplexa™ *C. difficile* Direct assay can reduce turnaround time for diagnosis.

Conclusions

- The new Simplexa™ *C. difficile* Direct assay is comparable to commercial PCR assays currently available for diagnosing *C. difficile* infection.

Acknowledgement

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