P2037

Clinical performance of a fully automated real-time PCR assay for the detection of *Clostridium difficile* in human stool samples under IVDR

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Introduction

The RIDA®UNITY platform (R-Biopharm AG) is a fully automated system that enables a high sample throughput with low hands-on time. The study aimed to evaluate the clinical performance of the RIDA®UNITY C. difficile (R-Biopharm AG), which performs direct qualitative detection of DNA for *Clostridium difficile* and *Clostridium difficile* toxin A/B in untreated human stool samples from persons with signs and symptoms of acute gastritis on the RIDA®UNITY platform and in a manual workflow. The clinical performance of this assay was compared with that of the RIDASCREEN® Clostridium difficile (R-Biopharm AG) for GDH and with the Allplex™ GI-EB Screening Assay (Seegene) for toxin A/B detection.

Methods

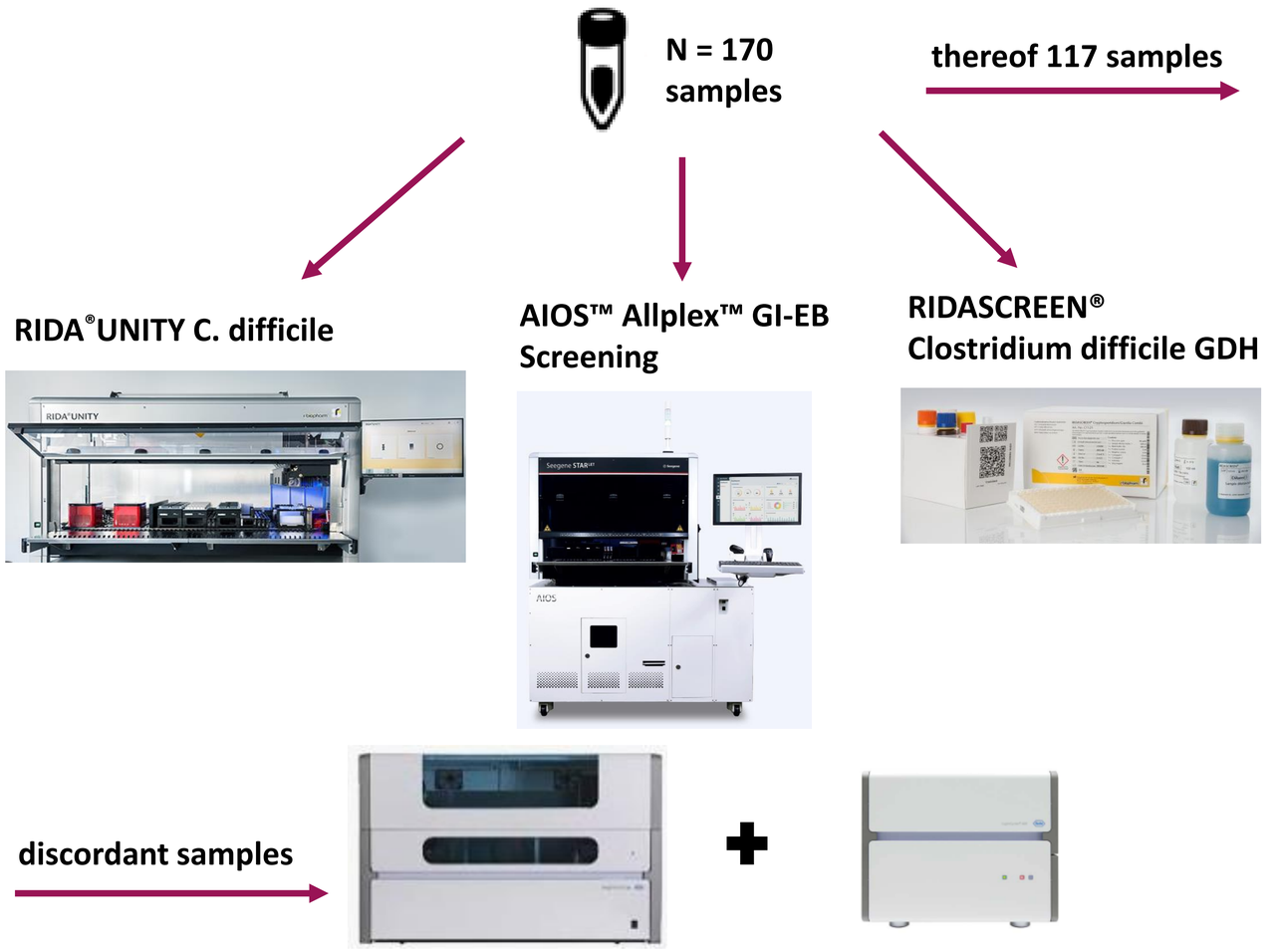

Figure 1: Study design

170 retrospective untreated human stool samples from persons with signs and symptoms of acute gastritis were tested with the RIDA®UNITY C. difficile assay on the fully automated RIDA®UNITY platform. The clinical performance characteristics of this assay were compared with the enzyme-linked immunosorbent RIDASCREEN® Clostridium difficile GDH assay and with the Allplex™ GI-EB Screening Assay (Seegene), which was tested on the fully automated AIOS™ system (Seegene).

Additionally, 117 samples were measured using the MagNa Pure 96 System (Roche) and the LightCycler® 480II (Roche) with the RIDA®UNITY C. difficile assay to evaluate the manual workflow of this assay. Discrepant results were subsequently measured using the RIDA®GENE Clostridium difficile assay in combination with the MagNa Pure 96 System (Roche) and the LightCycler® 480II (Roche).

Results

A total of 170 samples were tested as part of the automated RIDA®UNITY C. difficile workflow, of which 117 samples were also included in the manual RIDA®UNITY C. difficile workflow. During the study, one sample was invalid when using the automated RIDA®UNITY C. difficile assay due to a missing IC signal. After repeating the measurement, valid results were obtained.

After analyzing the discrepant results with the RIDA®GENE Clostridium difficile assay on the MagNa Pure 96 and the LightCycler® 480II, the following results were obtained: the automated workflow of the RIDA®UNITY assay compared to the RIDASCREEN® assay resulted in a sensitivity of 94.2% and a specificity of 98.0%. In comparison to the Allplex™ assay, a sensitivity of 92.0% and a specificity of 96.4% was achieved. The sensitivity of the manual workflow was 100% compared to the RIDASCREEN® and the Allplex™ assay. The specificity was 100% compared to the RIDASCREEN® and 91.0% compared to the Allplex™ assay (table 1).

Table 1: Results of the clinical performance after the resolution of discrepant results. a) RIDA®UNITY automated workflow b) RIDA®UNITY manual workflow.

a) Automated Workflow

		RIDASCREEN® C. difficile GDH & RIDA® GENE C. difficile			Allplex™ GI-EB Screening Assay & RIDA® GENE C. difficile		
		Positive	Negative	Total	Positive	Negative	Total
RIDA®UNITY C. difficile	Positive	113	1	114	80	3	83
	Negative	7	49	56	7	80	87
	Total	120	50	170	87	83	170
Sensitivity (95% CI)		**94.2%** (88.4% – 97.6%)			**92.0%** (84.1% - 96.7%)		
Specificity (95% CI)		**98.0%** (89.4% - 99.9%)			**96.4%** (89.8% - 99.2%)		

b) Manual Workflow

		RIDASCREEN® C. difficile GDH & RIDA® GENE C. difficile			Allplex™ GI-EB Screening Assay & RIDA® GENE C. difficile		
		Positive	Negative	Total	Positive	Negative	Total
RIDA®UNITY C. difficile	Positive	68	0	68	50	6	56
	Negative	0	49	49	0	61	61
	Total	68	49	117	50	67	117
Sensitivity (95% CI)		**100.0%** (94.7% – 100.0%)			**100.0%** (92.3% - 100.0%)		
Specificity (95% CI)		**100.0%** (92.7% - 100.0%)			**91.0%** (81.5% - 96.6%)		

Conclusion

In this study, the RIDA®UNITY C. difficile delivered excellent results, closely matching those of the reference methods. The comparison across all tests revealed nearly perfect sensitivity and specificity. The results from the automated and manual workflows were nearly identical, with the manual workflow showing slightly higher sensitivity. Due to the exceptional performance and high diagnostic value the RIDA®UNITY C. difficile is a valuable addition to diagnostic practice, whether in automated or manual workflow.

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