

# Evaluation of clinical performance and usability of a new automatic assay for gastrointestinal syndromic testing

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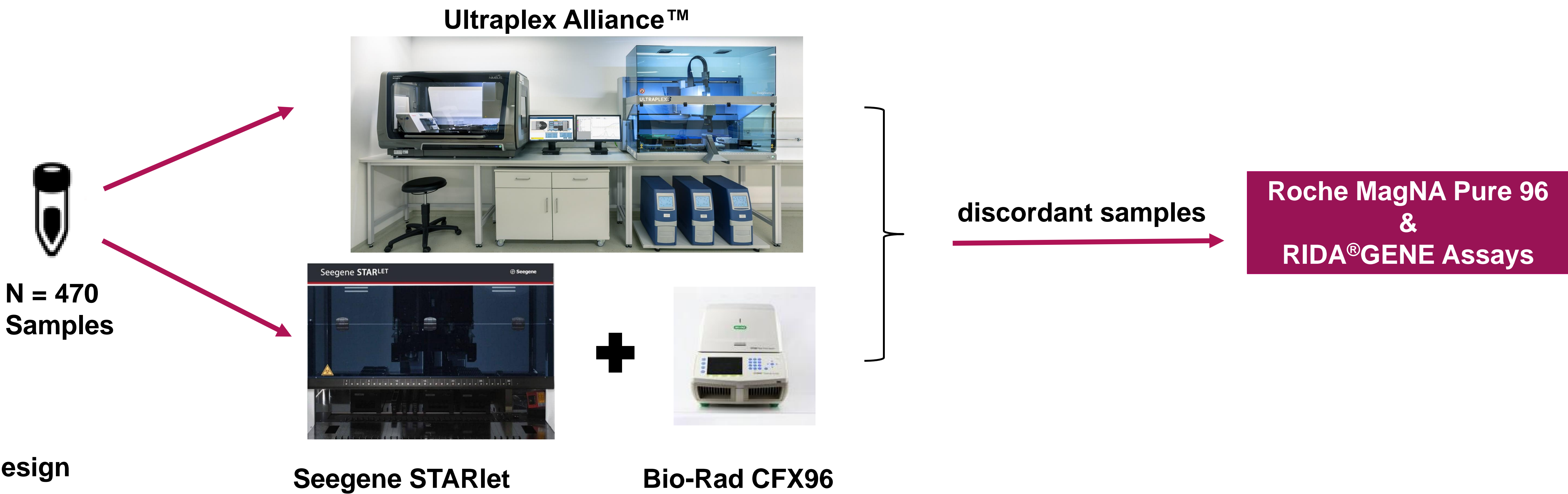
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## Introduction

Gastrointestinal infections are a common global health problem. A wide variety of pathogens can cause similar symptoms and are usually diagnosed by different methods. A syndromic molecular testing approach allows fast detection of the relevant pathogens, thus resulting in sooner and more appropriate patient treatment. The study evaluated the Faecal Pathogen M 16-well Assay on the Ultrplex Alliance™ (AusDiagnostics). The results were compared to the Allpex GI-Parasite Assay, Allpex GI-Virus Assay, and Allpex GI-EB Assay (Seegene).

## Methods

The Faecal Pathogen M assay is based on the multiplex-tandem PCR technology for the simultaneous and differentiated detection of 16 pathogens of viral, bacterial, and parasitic gastroenteritis. A total of 470 prospectively collected stool samples were extracted and analysed using the Ultrplex Alliance™. As a comparison, the sample were extracted using the Seegene STARlet system and analysed using the CFX96 Cycler (Bio-Rad). Discrepant results were analysed with the RIDA®GENE assays (R-Biopharm AG) on the LightCycler®480 II (Roche) after extraction on the MagNA Pure 96 System (Roche).



## Results

A total of 470 samples were tested with both assays. Two samples were repeatedly invalid and were excluded from the analysis. After analyzing the discrepancies, the results showed excellent agreement between the Ultrplex Alliance™ test and the Seegene assays. The Faecal Pathogen M 16-well Assay achieved a PPA of 80% for Shiga toxin type 1/2, 77.8% for Rotavirus and 100% for the other pathogens (Table 1). The NPA for all pathogens was between 98.2% and 100% for the Faecal Pathogen M 16-well Assay.

Pathogen		PPA		NPA	Cohen's kappa
Salmonella spp.	5/5	100% (47.8% - 100%)	463/463	100% (99.2% - 100%)	1.0 (1.00 - 1.00)
Shigella spp./EIEC	3/3	100% (29.2% - 100%)	465/465	100% (99.2% - 100%)	1.0 (1.00 - 1.00)
Campylobacter spp.	20/20	100% (83.2% - 100%)	444/448	99.1% (97.7% - 99.8%)	0.9 (0.81 - 1.00)
C. difficile tcdA/tcdB	22/22	100% (84.6% - 100%)	438/446	98.2% (96.5% - 99.2%)	0.84 (0.73 - 0.95)
Yersinia enterocolitica	2/2	100% (15.8% - 100%)	465/466	99.8% (98.8% - 100%)	0.80 (0.41 - 1.00)
Shiga toxin type 1/2	12/16	80% (51.9% - 95.7%)	450/452	99.6% (98.4% - 99.9%)	0.82 (0.67 - 0.97)
Sapovirus G1/G2	8/8	100% (63.1% - 100%)	459/460	99.8% (99.8% - 100%)	0.94 (0.82 - 1.00)
Rotavirus A	7/9	77.8% (40% - 97.2%)	454/459	98.9% (97.5% - 99.6%)	0.66 (0.42 - 0.90)
Norovirus GI	6/6	100% (54.1% - 100%)	460/462	99.6% (98.4% - 99.9%)	0.86 (0.66 - 1.00)
Norovirus GII	10/10	100% (69.2% - 100%)	456/458	99.6% (98.4% - 99.9%)	0.91 (0.78 - 1.00)
Adenovirus Gruppe F	1/1	100% (2.5% - 100%)	461/467	98.7% (97.2% - 99.5%)	0.25 (-0.15 - 0.64)
Astrovirus	3/3	100% (29.2% - 100%)	458/465	98.5% (96.9% - 99.4%)	0.46 (0.12 - 0.79)
Gardia lamblia	2/2	100% (15.8% - 100%)	466/466	100% (99.2% - 100%)	1.0 (1.00 - 1.00)
Cryptosporidium spp.	4/4	100% (39.8% - 100%)	464/464	100% (99.2% - 100%)	1.0 (1.00 - 1.00)
Entamoeba histolytica	2/2	100% (15.8% - 100%)	466/466	100% (99.2% - 100%)	1.0 (1.00 - 1.00)

Table 1: Results of the clinical performance evaluation after resolution of discrepant results

## Conclusion

The Faecal Pathogen M 16-well Assay showed a very good performance and comparable results in comparison to the used Seegene assays. Due to the excellent performance the Faecal Pathogen M 16-well Assay on the Ultrplex Alliance™, this test offers an excellent and suitable addition to routine molecular diagnostics.