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A NEW MULTIANALYTE TEST FOR ACUTE GASTROENTERITIS

COMPARISON OF MARIPOC® GASTRO AND FIVE NOROVIRUS LATERAL FLOW TESTS

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Introduction

mariPOC® Gastro (now IVD CE marked) is a new automated multianalyte test for the detection of **norovirus GII.4, norovirus GI, rotavirus, adenovirus and *Campylobacter spp.*** antigens from stool samples. Hands-on time is few minutes per sample and includes stool suspension to mariPOC® Gastro Sample Buffer, filtration (**Figure**) and insertion of sample tube into analyser for automated analysis. The test system enables semi-quantitative results. We compared the new norovirus test to five commercial (IVD CE marked) lateral flow (LF) tests with leftover stool samples.

Conclusions

This study shows that there are significant differences in the performance of norovirus LF tests. Sampling, i.e. dipping the sampler into non-homogeneous stool sample, may affect results more than e.g. a freeze thaw cycle. The results suggest that automation and objective fluorescence readout may provide more accurate and precise results than traditional LF. Multianalyte testing should provide differentiation of pathogens with similar clinical signs at early stage of the symptoms. Prospective clinical evaluations are needed to assess the clinical performance of the new multianalyte Gastro test in more detail.

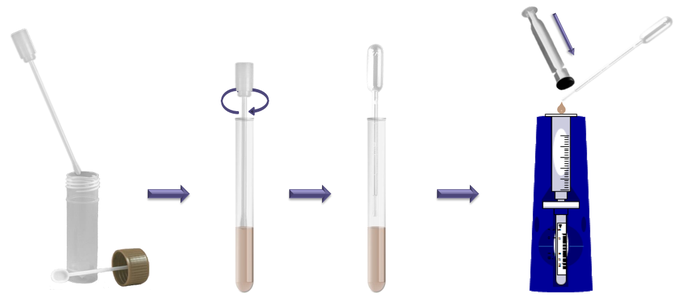

Figure. Sample pretreatment. Take stool with a swab. Suspend the sampe into Gastro Sample Buffer by vortexing. Filter the sampe with a 0.2 µm syringe filter.

Methods

Fresh stool samples (N=80) were analysed with LF1 as part of routine diagnostics in Turku, Finland during winter 2015. Initially 35 of the samples were positive with LF1. All the samples were analysed retrospectively with mariPOC® Gastro test and commercial LF2 and LF3. Two of the tests must coincide for true positivity. Discrepant results were resolved with PCR and sequencing. A subset of 48 and 74 of the samples were analysed with LF4 and LF5, respectively. The LF5 test was a combo test giving results for norovirus, adenovirus and rotavirus.

Results

Accuracy and specificity for the Gastro, LF1, LF2, LF3, LF4 and LF5 norovirus tests are shown in the **Table**. Sequenced samples (N=7) were norovirus GII.4 strain Sydney 2012. Norovirus GIs or adenoviruses were not found. Quantitative Gastro test results showed that several sample freeze and thaw cycles had no effect on the detection.

Table. Accuracy and specificity of the norovirus tests.

	Gastro	LF1	LF2	LF3	LF4	LF5
Accuracy	95%	88%	91%	94%	72%	93%
Specificity	100%	94%	98%	96%	89%	100%

The Gastro test was verified to detect adenovirus and norovirus GI.3, GI.4 and GI.6 from previously sequenced stool samples. The Gastro test was also verified to detect pure cultivated *C. jejuni*, *C. coli*, *C. hyolei and C. upsaliensis* suspended from plates into Gastro Sample Buffer. Among the 80 suspected norovirus samples in this study, one rotavirus and three *Campylobacter* positive samples were found using the mariPOC® Gastro test. These *Campylobacter* and rotavirus findings were single findings, showed very high antigen concentrations and matched with the results of IVD CE marked lateral flow tests. Specificity of mariPOC® gastro test for adenovirus, rotavirus and *Campylobacter* was 100%.

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