Introduction

Gastrointestinal disease accounts for significant mortality and morbidity globally and may be caused by multiple agents, including bacterial, viral, and parasitic pathogens (Steiner et al., 2016). Rapid molecular multiplex testing has recently been introduced into enteric diagnostics and is positively impacting patient diagnosis and treatment for diarrheal diseases. However, one needs to take cognizance of the suboptimal performance of molecular assays for detecting Salmonella when compared to the traditional selective enrichment workflow (MacArthur et al., 2017).

The enhancements of workflow direct from primary faecal collection devices which are “instrument ready” and require no further manipulation is the next logical progression. This coupled with pre-analytical automation could create a seamless workflow allowing for more efficient gains in large diagnostic laboratories. The inability to obtain a valid specimen at the time of the patient visit can delay the diagnostic process and contribute to inappropriate treatment. The suitability of liquid collection devices for rectal sampling can tackle this issue particularly among children where a high incidence of morbidity and mortality exist.

The MWE Fecal Transwab® comes in a tube with 2 ml of modified Cary-Biik medium and a faced or foam tip swab. While the Capill R.O.Q.a.d® is CEIVD approved for transport and use with the Serosep EntericBio® Gastro Panel 2, neither device has been validated in the Transwab®. The objective of this study was to evaluate the MWE Fecal Transwab for the simultaneous qualitative detection and identification of 6 GI pathogens, using the PCR EntericBio® Gastro Panel 2 (Serosep, Ireland) and the Roche LightCycler® 480 II system (Fig. 3).

Methods

A total of 50 fresh samples of stool which was collected from children residing in Africa (Nigeria, Tanzania, Malawi, and Kenya) by enteric medicine (EM) trainees who were enrolled in a study of Campylobacter and Salmonella species present in the stool. The samples were then transported to the EntericMedicine lab in Amsterdam, Netherlands where they were stored at 4°C. The study was approved by the Amsterdam University Medical Center, Department of Pediatrics, and the Ethics Committee of Amsterdam University Medical Center.

The study was conducted according to the following steps:

1. System using two different protocols to the standard of the Roche LightCycler® 480 II system.
2. A dual sample preparation of the standard protocol with this system.
3. A modified protocol was used to test the ability to detect Salmonella species in stool samples, which were obtained by the EntericMedicine lab.
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Results

At least four of the above pathogenic agents can be detected with the MWE Fecal Transwab® compared to the standard protocol with this system. Using the standard protocol with this system.

Concordant results were observed between the various methodologies with the exception of Salmonella and Campylobacter. The majority of discordant results were observed on the Serosep pocket insert method utilizing a Open FLOQ Swab when compared to the traditional culture enrichment methodology. The MWE Fecal Transwab® demonstrated the highest comparability with the Roche Gold standard.

Conclusions

Given the excellent sensitivity and negative predictive value of molecular testing as reported by many authors this study focused on the possible improvements in the pre-analytical phase of the analysis and any other potential benefits. The results did highlight reduced sensitivity for Salmonella in comparison to culture, which has been previously reported for the standard enrichment methodology. It recommends the use of a Serosep kit. Moreover, of note was that when the MWE Fecal Transwab was utilized an improvement in detection for Salmonella did occur reducing the number of false negatives from 4 to 1. Conclusively, the authors demonstrated the enhanced sensitivity of the culture method with a selective enrichment broth. The evaluation of the benefit of a selective broth enrichment step prior to multiplex PCR for enteric pathogens may be warranted. One can hypothesize that the bacterial load was greater when utilizing the MWE Fecal Transwab protocol as highlighted in this study which improved the detection limits of the assay for Salmonella.

The MWE Fecal Transwab is a convenient system for transporting faecal samples in small instrument ready tubes saving space and making it easier to transport to the laboratory. It enables rapid testing which has benefits particularly in paediatric patients. In addition, it simplifies and standardizes sample collection, transport and processing by converting solid or semi-solid specimens into liquid phase. In instrument ready tubes, to facilitate automated faecal sample processing. Further enhancements of the Serosep system should incorporate automated de-capping, sampling, inoculation of the SPS tube through and re-capping of the primary tube systems. Although parts of this pre-analytical automation is available currently further development is required to create a seamless front-end system. Additional benefits could incorporate the simultaneous inoculation of a selective liquid collection device in selected cases. Furthermore, it would allow for enhanced process traceability and standardization.

This study indicates that MWE Fecal Transwab® MW1665 can provide improved test results particular this study. Serosep has maintained its use for molecular test of enteric pathogens utilizing the Serosep EntericBio® system. The discordant results between the CE and “non CE” method need to be investigated further to fully understand the case. The MWE Fecal Transwab® system optimizes the collection and transport of gastrointestinal pathogens coupled with the rapid molecular diagnostics of gastrointestinal diseases.

References


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Improved sensitivity and workflow utilising a modified pre-analytical methodology with the Serosep PCR EntericBio Gastro Panel 2

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St George’s had recently installed a Serosep PCR EntericBio work station to assist with the processing of enteric specimens. They were concerned that SeroSep only endorsed the use of particular Copan swabs for inoculation of specimens into the system, and they had a suspicion they were missing some important pathogens. They also wanted to be able to have Fecal Transwabs as an option for the collection of specimens.

In this study they compared the performance of the system on a number of known positive samples, previously confirmed by conventional culture methods (including selenite enrichment), and by ELISA, when retested using Serosep’s procedure with Copan swabs, and with Fecal Transwabs (flock and foam).

From the 38 samples tested, the MWE swabs (flock and foam) correctly identified Salmonella where it was missed when the Copan swabs. There were no cases of MWE missing specimens that Copan swabs detected. There was also one case in which the MWE flock swab picked up a Campylobacter that Copan swab had missed. Campylobacter specimens are notoriously fickle, but it is interesting that at least one of the MWE swabs allowed it to be detected. There was one Salmonella that none of the swabs (Copan or MWE) detected – which may have been because the concentration was very low.

The study clearly demonstrates that Fecal Transwabs (foam or flock) are completely compatible with the SeroSep system, a fact which they have previously acknowledged in personal communications, but refuse for commercial reasons to refer to in their Instructions for Use. St George’s are concerned because of the risk of missing genuine cases of Salmonella, and have taken it up with the company.