Evaluation and clinical suitability of enteric viral RT- PCR assay in diagnosis of infectious gastroenteritis in comparison to lateral flow test.

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EntericBio SEROSEP

BACKGROUND

Infectious gastroenteritis is a significant cause of mortality worldwide. The clinical symptoms span from mild diarrhoea to life-threatening dehydration. The most common agents of acute viral gastroenteritis in humans include Noroviruses, Rotavirus A, Adenoviruses F 40/41, Astroviruses and Sapoviruses.

OBJECTIVES

Evaluation and clinical suitability of **Serosep EntericBio® Viral Panel 3** in the routine Microbiology Laboratory in comparison to lateral flow kit- RIDA QUICK. We evaluated performance of the Serosep assay for detection of Norovirus, Rotavirus, Adenovirus, Sapovirus and Astrovirus;

METHODS

A Total of 181 faecal samples were tested. Positive faecal samples were collected and stored at -20 °C for a period from 2019 to 2022. Out of 181 specimens, 64 frozen samples were known positive for Norovirus, Adenovirus and Rotavirus. Samples were tested in parallel with RIDA QUICK immunochromatographic lateral flow assay (LFA).

Figure 1. Work flow shows preparation and detection of viral samples using EntericBio PCR

Discrepant samples were sent for confirmatory testing to the national reference laboratory. Specimens positive for Sapovirus or Astrovirus on the EntericBio® Viral Panel 3 were also submitted to reference laboratory for testing.

RESULTS

Number of samples that were positive by LFA and the EntericBio assay, discrepant results were confirmed by reference method (UKHSA).

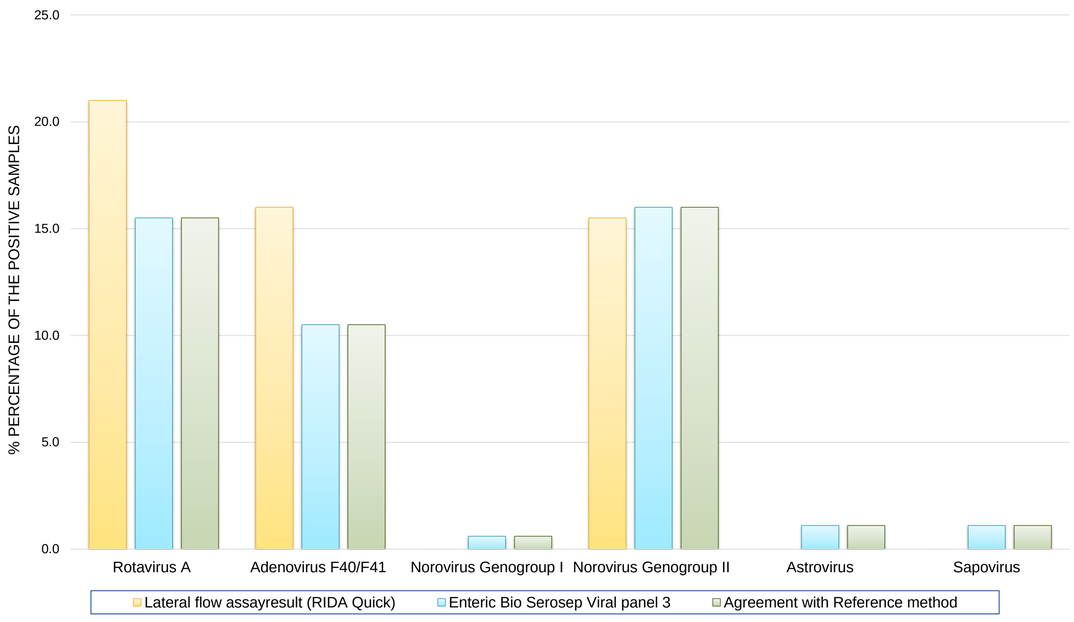

Figure 2. Number of samples that were positive by LFA and the EntericBio assay, discrepancy results were confirmed by reference method (UKHSA)

The PCR assay shown 100% concordance with reference laboratory results for Rotavirus.

Discrepancies were detected between the Rota RIDA Quick and Serosep, with 11 false positive samples.

We've detected discrepancies between the Adeno RIDA Quick and the Serosep (with an 80.3% concordance), however Serosep results shown 100% concordance with reference laboratory results.

Norovirus positive specimens: a very good agreement between Serosep and RIDA Quick 98% and 100% concordance with reference laboratory.

RESULTS (cont'd)

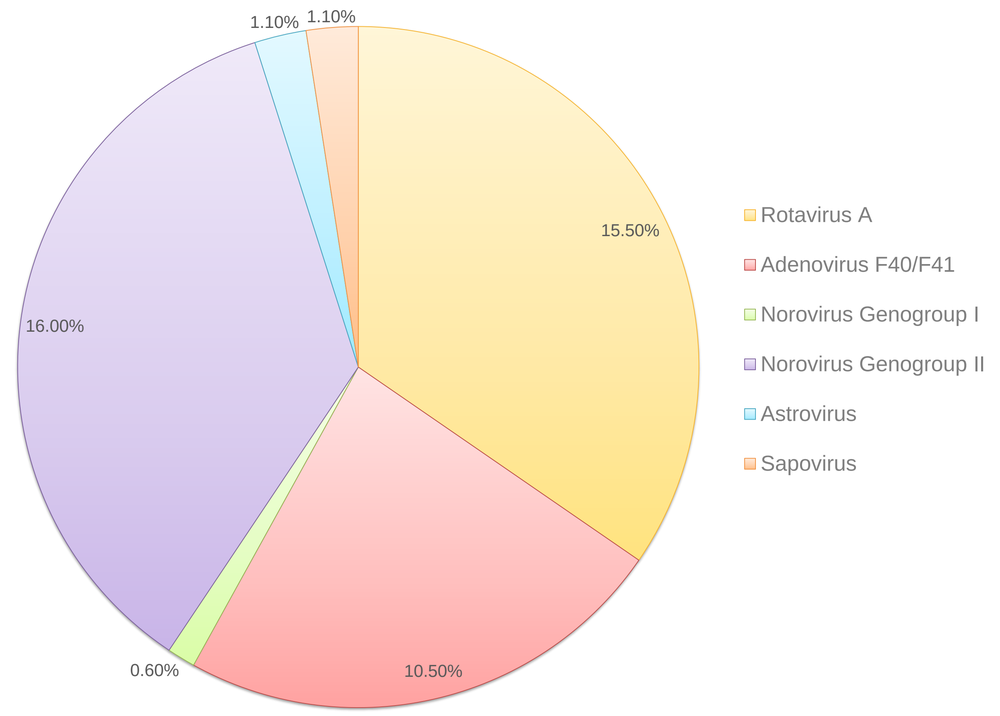

Figure 3. Percentage of the number of samples Enteric Bio Serosep agreement with Reference method

Table 1. Sensitivity and specificity of the results of the EntericBio® Viral Panel 3 assay agreement with the reference method

	Norovirus	Rotavirus	Adenovirus
True POSITIVE	30	28	19
True NEGATIVE	151	153	162
False POSITIVE	0	0	0
False NEGATIVE	0	0	0
Sensitivity	100.0	100.0	100.0
Specificity	100.0	100.0	100.0

Out of total 181 faecal samples:

- Two were positive for Astrovirus and two were positives for Sapovirus on the EntericBio® Viral Panel 3.
- One sample of Sapovirus was negative on EntericBio assay, but confirmed positive with reference lab. Sample was repeated twice on EntericBio, resulted negative.

Total of 21 external quality assurance samples were tested and showed 100% agreement.

There were 4 discrepant results (between the Serosep and RIDA Quick assays) that could not be tested at the reference laboratory and therefore removed from analysis:

- Two Rotavirus positive on RIDA were negative on Serosep.
- One Norovirus sample was negative on RIDA but produced weak positive result on Serosep.
- One Rotavirus sample tested negative twice on RIDA but positive on Serosep assay.

CONCLUSION

The internal validation study demonstrated that the Serosep assay performed well against the reference laboratory method and demonstrated improved diagnostic performance compared to the lateral flow assay (as anticipated for a molecular diagnostic assay). It was deemed to be suitable for use in our laboratory setting and is being introduced into the routine diagnostic pathway.

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