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

Kazantaki Ekaterini, Kiliddar Zainab, Randell Paul, Morkowska Anna, Deugi Dipika, Rebec Monica

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 F40/F41, 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).

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).

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 assay) 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.