Hvidovre Hospital

Evaluation of the *EasyScreen*™ Pan-Enteric Pathogen Detection Kit as a Replacement for a Laboratory-Developed Gastrointestinal PCR Test

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BACKGROUND

Rapid and accurate detection of gastrointestinal pathogens is essential for patient management, infection prevention, and public health surveillance. Syndromic multiplex PCR assays enable simultaneous detection of a broad range of viral, bacterial, and parasitic pathogens from a single specimen, reducing turnaround time while expanding pathogen coverage.

The Department of Clinical Microbiology, Copenhagen University Hospital Hvidovre (DCM HvH), serves a catchment population of approximately one million inhabitants and processes more than one million clinical specimens annually, including more than 28,000 faecal specimens.

OBJECTIVE

To compare the performance of a commercial test, the *EasyScreen*™ Pan-Enteric Pathogen Detection Kit from Genetic Signatures, validated for analysis of solid stool samples, with a routinely used laboratory-developed gastrointestinal PCR test (LDT) optimised for feacal swabs.

METHODS

STUDY DESIGN

Frozen faecal swap specimens previously analysed in the routine diagnostic workflow at the DCM HvH were retrieved from the biobank. We included ~20 positive specimens selected for each pathogen with a wide span of CT-values. Results obtained with the *Easy-Screen*™ Pan-Enteric Pathogen Detection Kit were compared with the routine laboratory-developed PCR assays. Concordance between methods was assessed with Positive Percent Agreement (PPA) for each pathogen. In addition, assay performance was evaluated using QCMD external quality assessment panels.

REFERENCE METHOD

The reference method consisted of LDT multiplex PCR assays routinely used for gastrointestinal pathogen detection at DCM HvH. Viral, bacterial and parasitic targets were analysed using the Roche platform with LightCycler 480's, while *Clostridioides difficile* was analysed on the Roche Cobas® 8800 system.

COMPARISON ASSAY

The comparison assay was the CE-IVD *EasyScreen*™ Pan-Enteric Pathogen Detection Kit (Genetic Signatures, NSW, Australia), an automated syndromic multiplex real-time PCR assay capable of detecting 24 viral, bacterial, and parasitic gastrointestinal pathogens using 3base® technology. Sample preparation and PCR setup were performed using the automated *EasyScreen*™ workflow.

CONCLUSION

The tests performed on clinical samples collected as faecal swabs demonstrated an acceptable high agreement between the *EasyScreen*™ Pan-Enteric Pathogen Detection Kit and the gastrointestinal LDT. Performance was further supported by high agreement with QCMD external quality assessment panels.

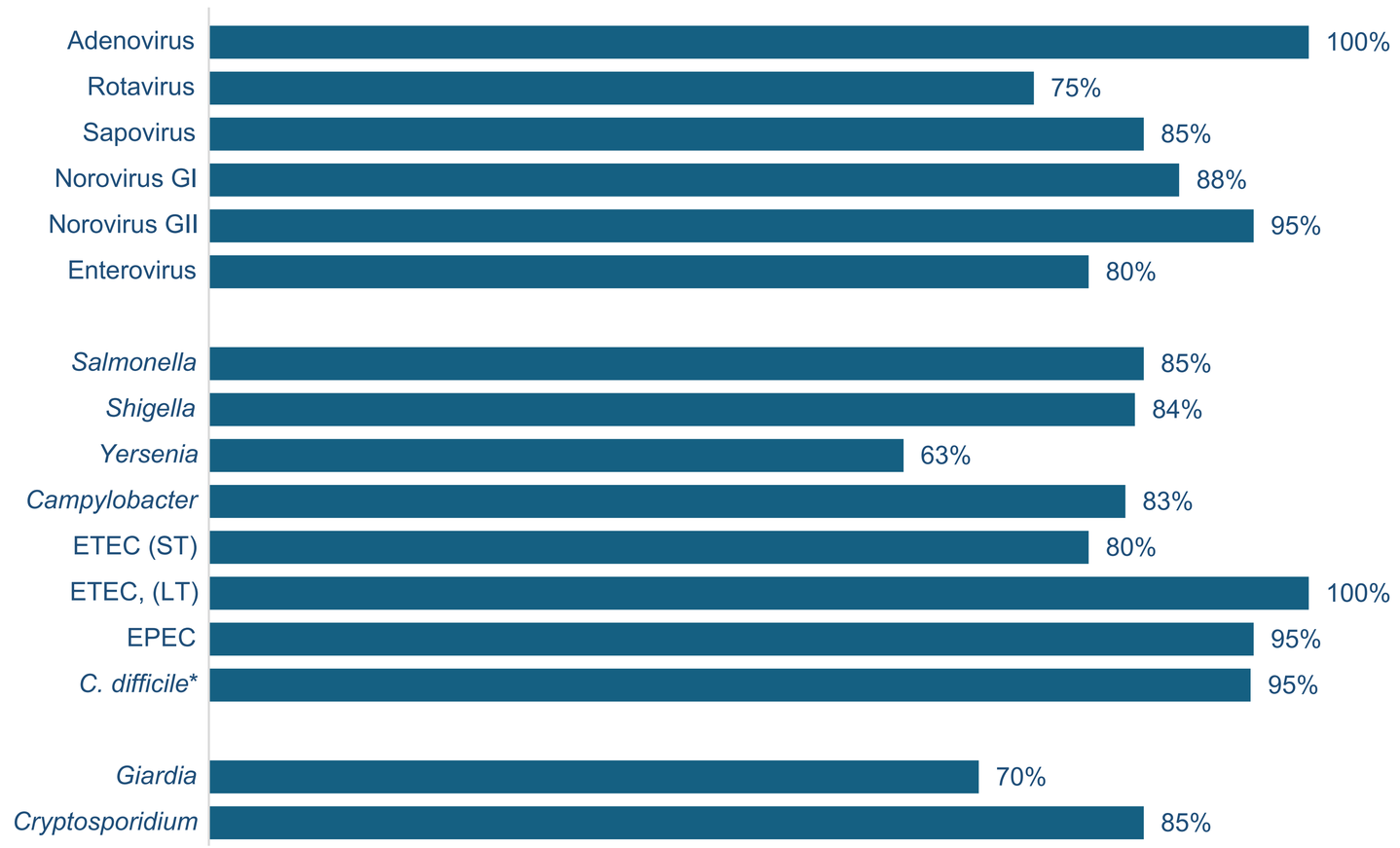
RESULTS

The *EasyScreen*™ Pan-Enteric Pathogen Detection Kit showed high agreement with the LDT for most gastrointestinal pathogens, thus PPA exceeded 80% for the majority of viral and bacterial targets. Lower agreement observed for Rotavirus, *Yersinia* and *Giardia lamblia*. All discrepancies between methods were observed in samples with high Ct values. Overall agreement in the QCMD external quality assessment panels was **90%** (54/60).

	In-house positive, n	GS positive, n	PPA, %
Virus	116	101	**87**
Bacteria*	173	136	**79**
Parasites	40	31	**78**

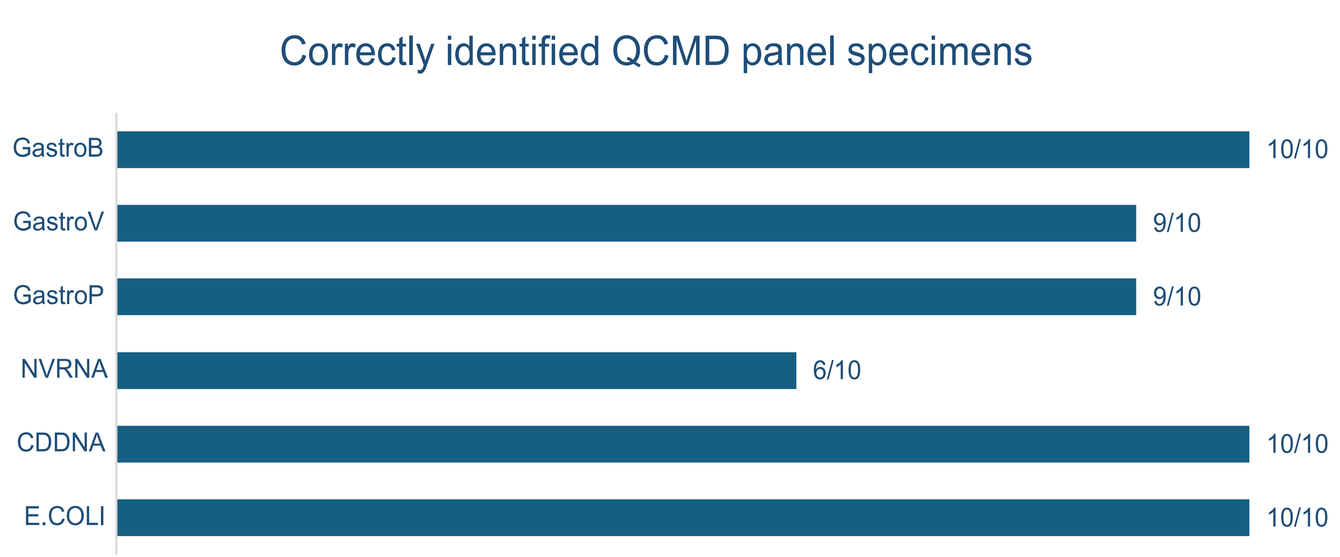
Positive Percent Agreement evaluated by pathogenic group
*ETEC EST and ELT are counted as individual samples, n = 39.
GS: Genetic Signatures; PPA: Positive Percentage Agreement

Positive Percent Agreement (PPA) by pathogen



*tcdA: 95% & tcdB: 90%

Correctly identified QCMD panel specimens



Performance in QCMD external quality assessment panels.
Six missed detections, evenly divided between Core and Educational specimens.

KEY POINTS

- **Good agreement in clinical samples**
- **QCMD panels supported assay performance**