QIAstat-Dx gastrointestinal diagnostic test shows strong performance in prospective multicenter pivotal clinical trial

Key takeaways

- The QIAstat-Dx Gastrointestinal Panel showed robust performance with a positive percent agreement (sensitivity) and negative percent agreement (specificity) of 98.2% and 99.9% respectively
- The QIAstat-Dx Gastrointestinal Panel proved to be an effective tool for identifying co-infection with 32.5% of the positive patient samples tested being positive for more than one pathogen
- Authors discussed the potential positive impact of using Ct values to determine the validity of co-detections, confirming *C. difficile* infection, and mitigating the potential risk of false positives.

Acute gastroenteritis (AGE) causes an estimated 1.4 million deaths worldwide every year. While most AGE infections are self-limited, they may result in more severe illness requiring hospitalization. A wide variety of pathogens can cause AGE, with viruses and bacteria predominance in the developed world and parasite-caused illness in resource-restricted regions.

The diagnostic landscape has changed dramatically with the availability of highly multiplexed PCR stool tests, leading to important new insights on AGE epidemiology. This valuable clinical input has been associated with fewer imaging studies, reduced antibiotic prescribing, and shorter hospital stays. The QIAstat-Dx® Gastrointestinal Panel is a new rapid, highly multiplexed PCR assay which detects 24 gastrointestinal targets in about an hour. The authors of this study report their findings from a multicenter study comparing the QIAstat-Dx Gastrointestinal Panel to the FilmArray GI assay.

Study design:

In this multicenter, prospective-retrospective study, 385 stool samples were tested to evaluate the QIAstat-Dx Gastrointestinal Panel. The 163 prospective samples were collected at the Copenhagen University Hospital Hvidovre (Denmark) and the 222 preselected, frozen retrospective specimens were evaluated at University Hospital of Bonn (Germany).

All samples were compared to the FilmArray® GI Panel, with discordant results retested using the Seegene® Allplex™ GI Panels 1-4. Additionally, Allplex GI panel 1 was also used to differentiate Norovirus GI from Norovirus GII detections, a differentiation not available using the Biofire® FilmArray GI Panel.

Results:

A QIAstat-Dx Gastrointestinal Panel result was considered a true positive (TP) or true negative (TN) when it agreed with the result from the comparator method or was confirmed by discrepant analysis. The QIAstat-Dx Gastrointestinal Panel detected at least one pathogen in 311 of the 385 tested samples. Additionally, the QIAstat-Dx GI Panel detected coinfections in 32.5% (101/311) of positive samples, which is consistent with the expected rate of coinfection. There were 24 pathogen results for each of the 385 stool samples for a total of 9240.

Table 1: Performance of the QIAstat-Dx Gastrointestinal Panel compared to FilmArray GI Panel

QIAstat-Dx Gastrointestinal Panel performance	
Overall Positive Percent Agreement	98.2% (447/455)
Overall Negative Percent Agreement	99.9% (8777/8785)

In this study, the QIAstat-Dx Gastrointestinal Panel demonstrated robust performance with less than 1% (45/9240) of the total results discordant. Upon discrepancy testing, 64.4% of discordant results were confirmed to be QIAstat-Dx Gastrointestinal Panel true results. Reliable performance was also presented in this study, with a 4.2% failure rate, and 99.7% of samples yielding valid results on the first or second attempt.

Table 2: Total number of QIAstat-Dx Gastrointestinal Panel-positive specimens by number of detections

Number of pathogens	Number of specimens	Percent of total specimens	Percent of total positive specimens
Detected at least one	311	80.8%	(100%)
1	210	54.5%	67.5%
2	66	17.1%	21.2%
3	28	7.3%	9.0%
4	6	1.6%	1.9%
5	1	0.3%	0.3%

Discussion:

Verifying findings of co-detected pathogens

Several reports have highlighted that the high co-infection rates and emerging pathogens newly detected by highly multiplexed PCR methods has created a clinical challenge which current guidelines do not address. The authors mention that Ct values, such as those provided by the QIAstat-Dx Gastrointestinal Panel, may be of help to assess whether co-detected pathogens are true findings.

Confirming of *C. difficile* positive samples

As labs are receiving more Cary-Blair stool specimens, the important parameter for *C. difficile* testing and treatment, stool density, is not always available. When an unexpected *C. difficile* result is reported, the authors suggest that Ct values could potentially support the lab in assessing the appropriateness and quality of the sample.

Mitigating the risk of false positives

The consequences of a false positive result are not insignificant. Inappropriate treatment could lead to adverse drug effects and the selection of antimicrobial resistance, unnecessary public health investigations, and premature closure of the diagnostic work-up. The authors mention the need for quantitation when using highly multiplexed PCR panels, and the pathogen Ct values reported by the QIAstat-Dx Gastrointestinal Panel maybe a step in this direction.

References:

1. Hannet, I., Engsbro, A.L., Pareja, J., Schneider, U.V., Lisby, J.G., Pružinec-Popovic, B., Hoerauf, A., Parcina, M. (2019) Multicenter evaluation of the new QIAstat Gastrointestinal Panel for the rapid syndromic testing of acute gastroenteritis. European Journal of Clinical Microbiology & Infectious Diseases. https://doi.org/10.1007/s10096-019-03646-4

This study was performed with the DiagCORE Analyzer and DiagCORE Gastrointestinal Panel V2. Currently available as QIAstat-Dx.
Not available in all countries.

The QIAstat-Dx Analyzer and the QIAstat-Dx Gastrointestinal Panel are intended for in vitro diagnostic use.

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