Transitioning to molecular stool testing with the TaqPath Enteric Bacterial Select Panel

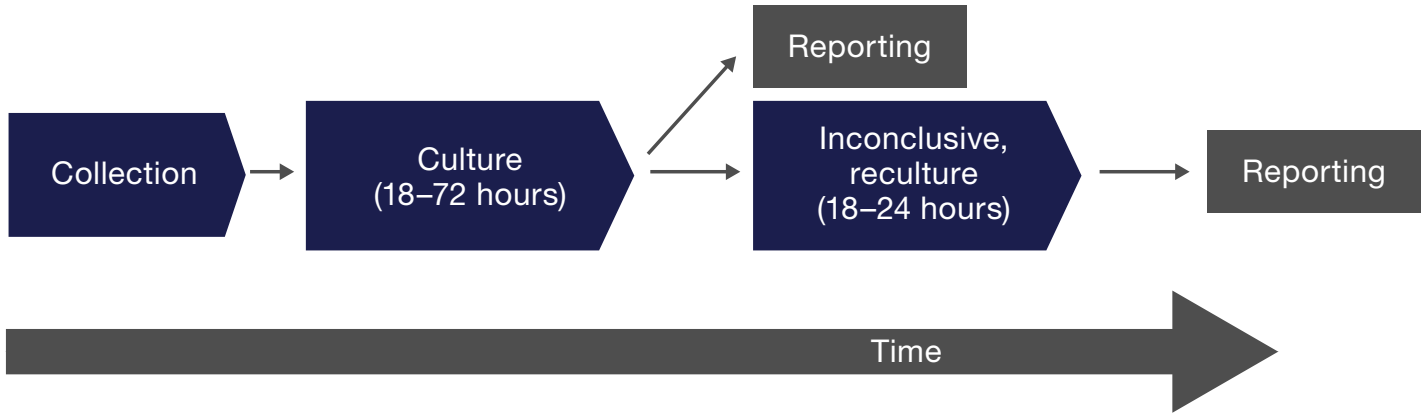
Traditional stool culture

The average time to obtain test results from gastrointestinal cultures is usually between one and three days.

Microbial culture and its interpretation can be challenging and often require highly skilled and experienced laboratory personnel.

Although stool culture testing is widely used, multiple factors can contribute to inaccurate results:

- Contamination in sample collection
- Lack of a controlled environment

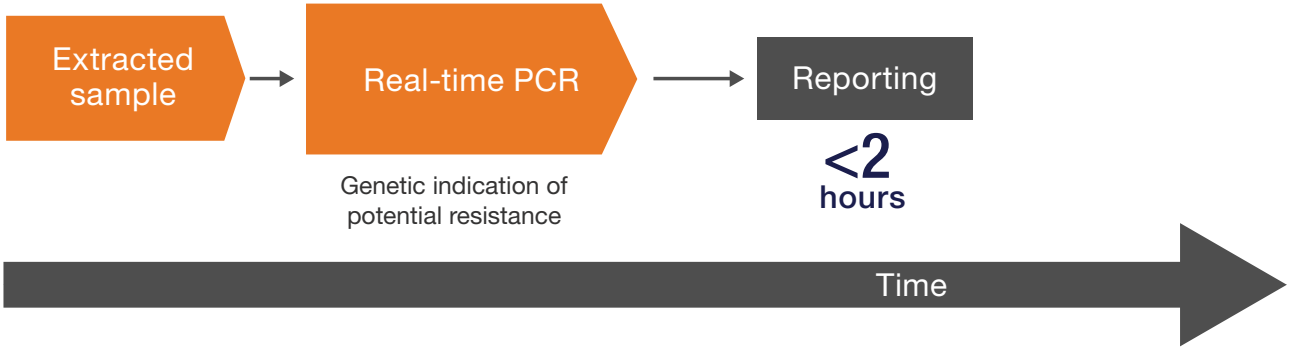


Molecular stool testing

Molecular tests target genetic material from pathogens. PCR-based molecular testing usually takes less than two hours from extracted sample to results. Interpretation of results can be automated using software-based solutions, helping reduce the chance of human interpretation error.

Benefits of molecular stool testing include:

- Faster time-to-results
- Higher sensitivity and specificity
- Multiple-pathogen testing using the same sample
- Detection of coinfections



Three gastrointestinal bacteria, one TaqPath panel

Introducing the TaqPath Enteric Bacterial Select Panel

The Applied Biosystems™ TaqPath™ Enteric Bacterial Select Panel is a molecular testing solution for detecting and differentiating common gastrointestinal (GI) bacteria: *Salmonella* spp.; *Shigella* spp./enteroinvasive *Escherichia coli* (EIEC);* and *Campylobacter jejuni*, *C. coli*, and *C. upsaliensis*.**

The TaqPath Enteric Bacterial Select Panel is a multiplex real-time PCR diagnostic test with high sensitivity, flexible sample throughput, limited hands-on time, and trusted PCR performance—all at an affordable price.

Interpretation of TaqPath Enteric Bacterial Select Panel results is automated using the Applied Biosystems™ Pathogen Interpretive Software CE-IVD Edition.

* *Shigella* spp. and EIEC are undifferentiated.
** *C. jejuni*, *C. coli*, and *C. upsaliensis* are undifferentiated.

Pre-clinical study

More details available in product IFU

Parallel analysis was performed using the TaqPath Enteric Bacterial Select Panel (CE-IVD), the Seegene™ Allplex™ GI-EB Screening Assay (CE-IVD), and the R-Biopharm™ RIDA™ GENE Bacterial Stool Panel 1 (CE-IVD).

Contrived samples were prepared by spiking a negative stool sample (characterized by PCR) with cultured organisms at 2 concentrations (which represent 3–5x LOD and 10x LOD of the TaqPath Enteric Bacterial Select Panel) each in 15 replicates.

Outcome of percent agreement between solutions (spiked specimens, 3–5x LOD, 10x LOD)

Target	TaqPath Enteric Bacterial Select Panel	Seegene Allplex GI-EB kit	RIDA GENE Bacterial Stool Panel 1
Campylobacter	100%	**43%**	100%
Salmonella	97%	**10%**	100%
Shigella	100%	100%	100%
Negative	100%	100%	100%

Results indicated superior sensitivity with the TaqPath panel compared to the Seegene kit in 2 of 3 targets.

2022 clinical study

Data to be presented as a poster at ASM Microbe 2023.

This study compares the TaqPath Enteric Bacterial Select Panel to the BD MAX™ Enteric Bacterial Panel for detection of *Campylobacter*, *Salmonella* spp., and *Shigella* spp./enteroinvasive *E. coli* (EIEC).

Results

- Positive percent agreement between both products was **100%** for *Shigella* spp./EIEC and *Campylobacter,* and **98.3%** for *Salmonella* spp.
- Negative percent agreement was **99.4%** for *Salmonella* spp., **96.9%** for *Campylobacter*, and **99.5%** for *Shigella* spp./EIEC

Insights

- 3 of 6 samples discordant between 2 tests were positive for *Campylobacter* using standard routine culture and in agreement with the TaqPath Enteric Bacterial Select Panel
- 2 of 62 samples that tested negative in routine stool culture were picked up as positive for *Campylobacter* and *Shigella* spp./EIEC with both molecular testing solutions

Conclusion

The TaqPath Enteric Bacterial Select Panel presents superior sensitivity compared to the Seegene Allplex GI-EB kit, and solid correlation with the BD MAX Enteric Bacterial Panel. The TaqPath Enteric Bacterial Select Panel also presents superior sensitivity to routine stool culture.

TaqPath Enteric Bacterial Select Panel Kit workflow

Receive samples

Samples from patients, including stool samples in preservative

Prep sample*

Thermo Scientific™ KingFisher™ Flex Purification System* with Applied Biosystems™ MagMAX™ Microbiome Ultra Nucleic Acid Isolation Kit, with bead plate or tubes*

Real-time PCR

(Required)

TaqPath Enteric Bacterial Select Panel

QuantStudio 5 system (96-well, 0.2 mL)

QuantStudio 5 Dx system (96-well, 0.2 mL)**

Analyze and report

(Required)

Report generated using Pathogen Interpretive Software CE-IVD Edition

* KingFisher Flex Purification System with MagMAX Microbiome Ultra Nucleic Acid Isolation Kit, with bead tubes was used for extraction during development. A sample prep methodology will need to be validated by the customer.
** The TaqPath Enteric Bacterial Select Panel is validated on the CE-IVDD version of the QuantStudio 5 Dx Real-Time PCR System; please contact your sales representative for more information.

Product specifications	
Control type	Internal: *Bacillus atrophaeus* Positive: Positive template control
Detection method	Primer-probe
No. of reactions	200
PCR method	qPCR
Sample type	Stool
Compatible instruments	Applied Biosystems™ QuantStudio™ 5 Real-Time PCR System, 96-Well, 0.2-mL Block; Applied Biosystems™ QuantStudio™ 5 Dx Real-Time PCR System
Product line	TaqPath products
Software	Applied Biosystems™ Pathogen Interpretive Software CE-IVD Edition
Target organism class	*Salmonella* spp. *Shigella* spp./enteroinvasive *Escherichia coli* (EIEC) *Campylobacter jejuni, Campylobacter coli, Campylobacter upsaliensis*
For use with (application)	Bacterial enteric diagnostic testing

Learn more about expanding your molecular testing menu at
thermofisher.com/taqpathentericselect