

CE-IVD

## Three gastrointestinal bacteria. One TaqPath panel.

### Transition to molecular testing with the new TaqPath Enteric Bacterial Select Panel

The new Applied Biosystems™ TaqPath™ Enteric Bacterial Select Panel is a highly sensitive testing solution for detecting and differentiating three common gastrointestinal (GI) bacteria: *Salmonella* spp.; *Shigella* spp./enteroinvasive *E. coli* (EIEC)\*; and *Campylobacter jejuni*, *C. coli*, and *C. upsaliensis*.\*\* Offering high sensitivity and fast time-to-results, this powerful PCR panel makes it easy and affordable for you to adopt a molecular diagnostic CE-IVD kit for gastrointestinal testing.

#### Panel selection

As the technological migration from culture to molecular testing continues, the need for expanded molecular testing remains beneficial for at-risk populations, including children, older adults, people with weakened immune systems, and travelers.<sup>1</sup> These populations are often at higher risk of severe disease and hospitalization and need clear answers. PCR testing delivers accurate results and aids in differential diagnosis, including coinfections, to assist with treatment or other patient management decisions.



#### Detect bacteria simultaneously

Enabling rapid detection of multiple enteropathogens simultaneously is critical to limiting transmission to humans in food, in water, and from person to person.<sup>2</sup>



#### Test efficiently

The TaqPath panel has a faster turnaround time and a simple workflow compared to culture; delivers consistent and reliable results from extracted sample (or purified nucleic acid) to result within ~2 hours.



#### Increased sensitivity

Multiplex PCR offers higher sensitivity and specificity rates than culture, increasing enteropathogenic bacteria detection.<sup>3</sup>

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

## Choose TaqPath panels

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



### Simple workflow

Save time with a simple workflow and automatic results interpretation



### Single tube

Detecting three bacteria and a process control, all in a single well, makes it easy to perform routine patient testing



### Affordable price

Easily adopt this panel and never overpay for the targets you need



### Confidence in results

Results from clinical evaluation show sensitivity  $\geq 98\%$  and specificity  $\geq 98\%$  so you can be confident in your results



### Controls included

*Bacillus atropheus* is used for sample internal control, and positive control for PCR reaction validity



### Flexible throughput

The workflow is scalable to fit your needs, allowing you to test 1 to 93 samples per run

## Performance characteristics

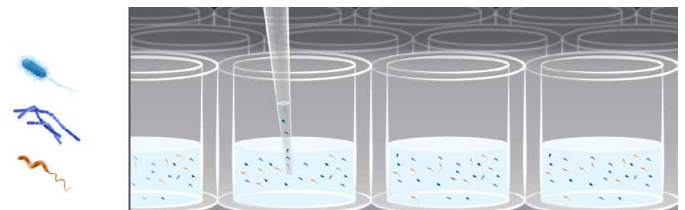
Analytical performance of the TaqPath Enteric Bacterial Select Panel assay was evaluated by determining limit of detection (LOD), characterizing the impact of competitive interference and endogenous/exogenous interfering substances, and assessing cross-reactivity, inclusivity, precision, and repeatability. Selected performance characteristics are detailed in Tables 1 and 2. Refer to the Instructions for Use (IFU) for full details.

Table 1. Limit of detection (LOD).

Bacteria	LOD (copies/rxn)*	LOD concentration (CFU/mL)**
<i>Campylobacter jejuni</i>	10.1	66
<i>Campylobacter coli</i>	10.6	150
<i>Campylobacter upsaliensis</i>	5.9	25
<i>Salmonella typhimurium</i>	4.1	500
<i>Salmonella typhi</i>	10.9	500
EIEC	0.7	20
<i>Shigella</i>	1.4	60

Table 2. Sensitivity/specificity of clinical evaluation.

Target	Sensitivity	Specificity
<i>Campylobacter</i>	98%	100%
<i>Salmonella</i>	100%	98%
<i>Shigella</i> /EIEC	100%	100%



\* Copies/rxn was generated using a conversion factor.

\*\* CFU/mL was used in clinical studies.

## Select Thermo Fisher Scientific

In a time when getting answers quickly is critical, Thermo Fisher Scientific, the global leader in COVID-19 testing, is leveraging its scale and resources to help the world move forward. With innovative solutions and a reliable supply chain already helping meet the unprecedented demand for trusted COVID-19 testing, we are continuing to expand our high-quality solutions and urgently accelerate innovation to address current and future challenges.



### Trusted technology

Applied Biosystems™ QuantStudio™ 5 or 5 Dx real-time PCR systems are part of an innovative family of platforms that combine modern hardware and software in an automatable, compact footprint, enabling molecular diagnostics workflows that operate with maximum efficiency and smarter productivity



### Service and support

Rely on one company for service and support of all steps of the workflow; our experts will help you get up and running and maintain your growing molecular menu



### Growing menu

Our expanding portfolio of Applied Biosystems™ CE-IVD panels, like the new Applied Biosystems™ TaqPath™ Respiratory Viral Select Panel, allows you to get more from your existing equipment

## Product details

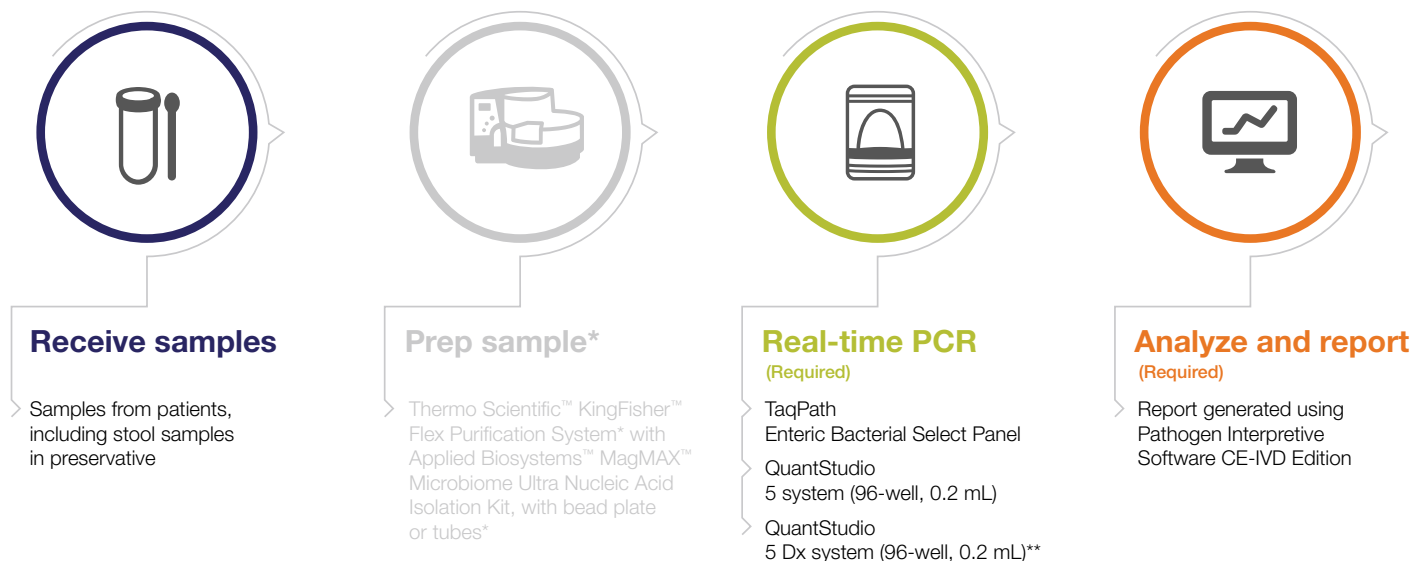
<b>Targets</b>	<ul style="list-style-type: none"> <li>• <i>Salmonella</i> spp.</li> <li>• <i>Shigella</i> spp./EIEC*</li> <li>• <i>Campylobacter jejuni</i>, <i>C. coli</i>, and <i>C. upsaliensis</i>**</li> </ul>
<b>Internal control</b>	Process control ( <i>Bacillus atrophaeus</i> )
<b>Positive control</b>	Included
<b>Sample type</b>	Stool
<b>Authorized kit</b>	TaqPath Enteric Bacterial Select Panel (Cat. No. A54714)
<b>Authorized real-time PCR systems</b>	<ul style="list-style-type: none"> <li>• QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL)</li> <li>• QuantStudio 5 Dx Real-Time PCR System (96-well, 0.2 mL)†</li> </ul>
<b>Turnaround time</b>	From extracted sample (or purified nucleic acid) to results in about 2 hours
<b>Software</b>	Applied Biosystems™ Pathogen Interpretive Software, CE-IVD edition
<b>Approval status</b>	CE-IVD

\* *Shigella* spp./EIEC are undifferentiated.

\*\* *C. jejuni*, *C. coli*, *C. upsaliensis* are undifferentiated.

† 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.

## TaqPath Enteric Bacterial Select Panel Kit workflow



\* 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.

### Ordering information

Description	Quantity	Cat. No.
<b>TaqPath Enteric Bacterial Select Panel</b> Components: TaqPath Enteric Bacterial Select Assay Multiplex TaqPath Enteric Bacterial Select Process Control TaqPath Enteric Bacterial Select Positive Control TaqPath 1-Step Enteric Master Mix (No ROX)	200 reactions	A54714

### References:

- Amjad M. An Overview of the Molecular Methods in the Diagnosis of Gastrointestinal Infectious Diseases. *Int J Microbiol.* 2020 Mar 24;2020:8135724. doi: 10.1155/2020/8135724. PMID: 32280346; PMCID: PMC7128059. [pubmed.ncbi.nlm.nih.gov/32280346/](https://pubmed.ncbi.nlm.nih.gov/32280346/)
- Salmonella (Non-Typhoidal) Key Facts. World Health Organization. [who.int/news-room/fact-sheets/detail/salmonella-\(non-typhoidal\)](https://who.int/news-room/fact-sheets/detail/salmonella-(non-typhoidal))
- Pouletty M, De Pontual L, Lopez M, Morin L, et al.. Multiplex PCR reveals a high prevalence of multiple pathogens in traveller's diarrhoea in children. *Arch Dis Child.* 2019 Feb;104(2):141-146. doi: 10.1136/archdischild-2017-314327. Epub 2018 Jul 7. PMID: 29982173. [pubmed.ncbi.nlm.nih.gov/29982173/](https://pubmed.ncbi.nlm.nih.gov/29982173/)



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