January 16, 2026

Cepheid
Karen Otrupchak
Manager, Regulatory Affairs, New Product Development
904 Caribbean Drive
Sunnyvale, California 94089

Re: K251721
Trade/Device Name: Xpert GI Panel
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointenstinal Microorganism Multiplex Nucleic Acid-Based Assay
Regulatory Class: Class II
Product Code: PCH, OOI
Dated: December 9, 2025
Received: December 9, 2025

Dear Karen Otrupchak:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bryan M. Grabias -S
2026.01.16 11:02:15 -05'00'

Bryan Grabias
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251721

Device Name
Xpert GI Panel

Indications for Use *(Describe)*
The Xpert GI Panel, performed on the GeneXpert® Instrument Systems, is a qualitative multiplexed in vitro diagnostic test that is capable of the simultaneous detection and identification of DNA and RNA from multiple bacteria, parasites and/or virus directly from stool samples in Cary Blair transport media obtained from individuals with signs and symptoms of gastrointestinal infection. The test utilizes automated, qualitative real time polymerase chain reaction (PCR). The following bacteria (including several diarrheagenic E. coli/Shigella pathotypes), parasites, and virus are identified using the Xpert GI Panel:

Pathogens Detected:

Bacteria: Campylobacter (C. jejuni/C. coli), Shiga toxin-producing Escherichia coli (STEC) stx1/stx2, Salmonella, Shigella/Enteroinvasive Escherichia coli, Yersinia enterocolitica, Vibrio parahaemolyticus, Vibrio cholerae

Parasites: Giardia (also known as G. intestinalis, G. duodenalis & G. lamblia), Cryptosporidium

Virus: Norovirus GI/GII

Pathogens Reported:

Bacteria: Campylobacter, STEC stx1, STEC stx2, Salmonella, Shigella EIEC, Yersinia, V. parahaemolyticus, V. cholerae

Parasites: Giardia, Cryptosporidium

Virus: Norovirus

Results are meant to be used in conjunction with other clinical, laboratory and epidemiological data and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive results do not rule out co-infection with pathogens not included in the Xpert GI Panel. The pathogen detected may not be the definite cause of the disease. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
for
Xpert GI Panel

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1. 510(K) SUMMARY

As required by 21 CFR Section 807.92(c).

Submitted by: Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089
215-388-5491

Contact: Karen J. Otrupchak

Date of Preparation: 01/14/2026

Device:

Trade name:	Xpert® GI Panel
Common name:	Xpert GI Panel
Type of Test:	Qualitative real-time reverse transcription polymerase chain reaction (RT-PCR) and detection test
Regulation number:	21 CFR 866.3990
Classification name:	Gastrointestinal microorganism multiplex nucleic acid-based assay
Product code(s):	PCH, OOI (Secondary)
Classification Advisory Panel:	Microbiology
Prescription Use:	Yes

Predicate Device Assay: FilmArray Gastrointestinal (GI) Panel (K140407)

1.1. Device Description

The Xpert Gastrointestinal (GI) Panel test, performed on Cepheid GeneXpert® Instrument Systems equipped with 10-color modules, is an automated *in vitro* diagnostic test for qualitative detection and differentiation of eleven (11) pathogens in stool in Cary Blair specimens collected from individuals suspected of gastrointestinal infection (GI). The results from the Xpert GI Panel test will be available in approximately 74 minutes.

The Xpert GI Panel is performed on the Cepheid GeneXpert® Instrument Systems equipped with GeneXpert 10-color modules running software version 6.4 and higher (GeneXpert Dx), software version Xpertise 7.1 or higher (GeneXpert Infinity) or software version COS 2.1 or higher (GeneXpert with Touchscreen). The GeneXpert® Instrument Systems automate and integrate sample purification, nucleic acid amplification, and detection of the target sequences from clinical specimens using reverse transcription (conversion of RNA template into DNA) followed by real-time polymerase chain reaction (real-time PCR) and melt curve analysis. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. Each test requires the use of a single-use disposable GeneXpert cartridge that contains target-specific reagents and carries out the reverse transcription and PCR processes.

The Xpert GI Panel test includes reagents needed: (i) for sample preparation and (ii) to detect the different bacteria, parasites, and virus. A Sample Processing Control (SPC), an Internal Control (IC) and a Probe Check Control (PCC) are also included in the cartridge. The PCC verifies reagent rehydration, PCR tube filling in the cartridge, probe integrity, and dye stability. The IC is present to ensure adequate processing of RNA targets and monitor the presence of inhibitor(s) in the PCR reaction. The SPC is present to control for adequate extraction and processing of the target sequences in the PCR reaction. The SPC also acts as a control for functionality of melt curve analysis.

The Xpert GI Panel test results are interpreted by GeneXpert Instrument Systems from measured fluorescent signals and embedded calculation algorithms and will be reported as positive or negative for each of the targets.

1.2. Device Intended Use

The Xpert GI Panel, performed on the GeneXpert® Instrument Systems, is a qualitative multiplexed *in vitro* diagnostic test that is capable of the simultaneous detection and identification of DNA and RNA from multiple bacteria, parasites and/or virus directly from stool samples in Cary Blair transport media obtained from individuals with signs and symptoms of gastrointestinal infection. The test utilizes automated, qualitative real time polymerase chain reaction (PCR). The following bacteria (including several diarrheagenic *E. coli/Shigella* pathotypes), parasites, and virus are identified using the Xpert GI Panel:

Pathogens Detected		Pathogens Reported
Bacteria	*Campylobacter (C. jejuni/C. coli)*	*Campylobacter*
	Shiga toxin-producing *Escherichia coli* (STEC) *stx1/stx2*	STEC stx1
		STEC stx2
	Salmonella	*Salmonella*
	Shigella/Enteroinvasive *Escherichia coli*	*Shigella EIEC*
	Yersinia enterocolitica	*Yersinia*
	Vibrio parahaemolyticus	*V. parahaemolyticus*
	Vibrio cholerae	*V. cholerae*
Parasites	*Giardia* (also known as *G. intestinalis, G. duodenalis & G. lamblia)*	*Giardia*
	Cryptosporidium	*Cryptosporidium*
Virus	Norovirus GI/GII	Norovirus

Results are meant to be used in conjunction with other clinical, laboratory and epidemiological data and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive results do not rule out co-infection with pathogens not included in the Xpert GI Panel. The pathogen detected may not be the definite cause of the disease. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

1.3. Substantial Equivalence

Table 1 shows the similarities and differences between the subject device and the predicate device.

Table 1: Comparison of Similarities and Differences Between Subject and Predicate Device

Attribute	Subject Device	Predicate Device
	Xpert® GI Panel	**BioFire FilmArray GI Panel (K140407)**
Regulation	Same	**21 CFR 866.3990** Gastrointestinal microorganism multiplex nucleic acid-based assay
Product Code	Same	PCH, OOI
Device Class	Same	II (Special Controls)
Technology/ Detection	Nested multiplex real-time reverse transcription polymerase chain reaction (RT-qPCR) with detection by amplification and melt curve analysis.	Nested multiplex RT-PCR followed by high resolution melting analysis to confirm identity of amplified product
Intended Use	The Xpert GI Panel, performed on the GeneXpert® Instrument Systems, is a qualitative multiplexed *in vitro* diagnostic test that is capable of the simultaneous	The FilmArray Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based in vitro diagnostic test intended for use with the FilmArray Instrument. The

<table>
<tr><th rowspan="2">Attribute</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><th>Xpert® GI Panel</th><th>BioFire FilmArray GI Panel (K140407)</th></tr>
<tr><td></td><td>detection and identification of DNA and RNA from multiple bacteria, parasites and/or virus directly from stool samples in Cary Blair transport media obtained from individuals with signs and symptoms of gastrointestinal infection. The test utilizes automated, qualitative real time polymerase chain reaction (PCR). The following bacteria (including several diarrheagenic E. coli/Shigella pathotypes), parasites, and virus are identified using the Xpert GI Panel:

<table>
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<tr><td rowspan="8">Bacteria</td><td>Campylobacter (C. jejuni/C. coli)</td><td>Campylobacter</td></tr>
<tr><td rowspan="2">Shiga toxin-producing Escherichia coli (STEC) stx1/stx2</td><td>STEC stx1</td></tr>
<tr><td>STEC stx2</td></tr>
<tr><td>Salmonella</td><td>Salmonella</td></tr>
<tr><td>Shigella/Enteroinvasive Escherichia coli</td><td>Shigella EIEC</td></tr>
<tr><td>Yersinia enterocolitica</td><td>Yersinia</td></tr>
<tr><td>Vibrio parahaemolyticus</td><td>V. parahaemolyticus</td></tr>
<tr><td>Vibrio cholerae</td><td>V. cholerae</td></tr>
<tr><td rowspan="2">Parasites</td><td>Giardia (also known as G. intestinalis, G. duodenalis & G. lamblia)</td><td>Giardia</td></tr>
<tr><td>Cryptosporidium</td><td>Cryptosporidium</td></tr>
<tr><td>Virus</td><td>Norovirus GI/GII</td><td>Norovirus</td></tr>
</table>

Results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Positive results do not rule out co-infection with pathogens not included in the Xpert GI Panel. The pathogen detected may not be the definite cause of the disease. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test of other non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Chrohn’s disease.</td><td>FilmArray G1 Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection. The FilmArray GI Panel is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. The following bacteria (including several diarrheagenic E- coli/Shigella pathotypes), parasites, and viruses are identified using the FilmArray GI Panel:

* Campylobacter (C. jejuni/C. coli/C. upsaliensis)
* Clostridium djfficile (C. difficile) toxin A/B
* Plesiomionas shigelloides
* Salmonella
* Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae) including specific identification of Vibrio cholerae
* Yersinia enterocolitica
* Enteroaggregative Escherichia coli (EAEC)
* Enteropathogenic Escherichia coli (EPEC)
* Enterotoxigenic Escherichia coli (ETEC) lt/st
* Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2 (including specific identification of the E. coli O157 serogroup within STEC)
* Shigella/Enteroinvasive Escherichia coli (FIEC)
* Cryptosporidium
* Cyclospora cayetanensis
* Entamoeba histolytica
* Giardia lamblia (also known as G. intestinalis and G. duodenalis)
* Adenovirus F 40/41
* Astrovirus
* Norovirus GI/GlI
* Rotavirus A
* Sapovirus (Genogroups I, II, IV, and V)
Pathogens reported:
Campylobacter</td></tr>
</table>

Attribute	Subject Device	Predicate Device
	Xpert® GI Panel	**BioFire FilmArray GI Panel (K140407)**
		E. coli 0157 *Plesiomonas shigelloides* *Salmonella* *Vibrio* and *V. cholerae* *Yersinia enterocolitica* STEC (*stx1/2*) ETEC EPEC EIEC/*Shigella* EAEC Adenovirus F 40/41 Astrovirus Norovirus Gl/Gll Rotavirus A Sapovirus *Clostridium difficile* toxin A/B *Cryptosporidium* *Giardia lamblia* *Cyclospora cayetanensis* *Entamoeba histolytica* Positive results do not rule out co-infection with organisms not included in the FilmArray GI Panel. The agent detected may not be the definite cause of the disease.
Assay Targets	*Campylobacter (C. jejuni/C. coli),* Shiga toxin-producing *Escherichia coli* (STEC) *stx1 and* STEC *stx2* (separate callouts), *Salmonella, Shigella/*Enteroinvasive *Escherichia coli, Yersinia enterocolitica, Vibrio parahaemolyticus, Vibrio cholerae, Giardia*, *Cryptosporidium,* Norovirus GI/GII	Campylobacter species: *C. jejuni/C. coil/C. upsaliensis*. *Clostridioides* (Clostridium) *difficile* (toxin A/B) Salmonella *Yersinia enterocolitica* *Cryptosporidium* *Giardia lamblia* *Enterotoxigenic E. coli (ETEC) lt/st* *Shiga-like toxin-producing E. coli (STEC) stx1/stx2, E. coli O157* callout *Shigella/Enteroinvasive E. coli (EIEC)* *Norovirus* *Plesiomonas shigelloides*. Vibrio (*V. parahaemolyticus/V. vulnificus/V. cholerae*), *V. cholerae callout* *Yersinia enterocolitica* Adenovirus F40/41, Rotavirus A Astrovirus, Sapovirus (Genogroups I, II, IV, and V), *Cyclospora cayetanensis*, *Entamoeba histolytica*, Enteropathogenic *E. coli* (EPEC), and Enteroaggregative *E. coli* (EAEC).
Specimen Type	Same	Stool in Cary Blair transport media

Attribute	Subject Device	Predicate Device
	Xpert® GI Panel	**BioFire FilmArray GI Panel (K140407)**
Transport Media	Same	Cary Blair
Test Format	Same	Single Use
Automation	Automated Nucleic Acid Extraction, Detection and Results Interpretation	Automated Nucleic Acid Extraction, Melt curve analysis, Detection and Results Interpretation
Assay Results	Same	Qualitative
Non-Determinate Results Text	INVALID ERROR NO RESULT	Not Applicable (N/A) Invalid
Internal Control	Sample Processing Control (SPC) Internal Control (IC) Probe Check Control (PCC)	Two controls (RNA Process Control and PCR2 Control) are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.
Instrument Systems	Cepheid GeneXpert® Instrument Systems	FilmArray Instrument
GeneXpert Software	GeneXpert Dx 6.4 or higher GeneXpert Infinity Xpertise 7.1 or higher Cepheid OS 2.1 or higher	BIOFIRE® FILMARRAY® Software
Time to Result	≤90 mins	≤75 mins

The following performance data (analytical and clinical) were provided in support of the substantial equivalence determination.

1.4. Performance Studies

1.4.1 Analytical Performance

Analytical Sensitivity (Limit of Detection)

Studies were performed to determine the analytical limit of detection (LoD) of the Xpert GI Panel test. The LoD was estimated for two strains per Xpert GI Panel target pathogen respectively. Each Xpert GI Panel target pathogen strain was serially diluted and tested using two reagent lots across three testing days. The highest observed LoD, as determined by Probit regression analysis (95th Percentile), for each target pathogen strain from the two reagent lots was selected for LoD verification. Verification and confirmation of the estimated LoD for each Xpert GI Panel target pathogen strain was performed using one reagent lot across three testing days with a minimum of 20 replicates. All LoD testing was performed using Xpert GI Panel target pathogens prepared in clinical stool matrix. The verified LoD was determined as the titer with a positive reported result greater than or equal to 95%. The verified LoD was confirmed by levels tested below and above the verified LoD with reported results of <95% and 100% respectively. The verified and confirmed LoD values for each Xpert GI Panel target pathogen strain are presented in **Table 2**.

Table 2. Limit of Detection (LoD) for Xpert GI Panel Analytes

Target	Strain	Strain ID	Confirmed LoD
Campylobacter	*Campylobacter coli*	CCUG 11283T	46 CFU/mL
	Campylobacter jejuni	CCUG 41359	183 CFU/mL
Shigella/EIEC	*Shigella sonnei*	CCUG 68726T	82 CFU/mL
	Enteroinvasive *Escherichia coli* (EIEC)	CCUG 46406	204 CFU/mL
Salmonella	*Salmonella bongori*	CCUG 30042T	261 CFU/mL
	Salmonella enterica	NCTC 13171	1,242 CFU/mL
STEC stx1/stx2	STEC stx1	Statens Serum Institut MHI813	624 CFU/mL
	STEC stx2	Statens Serum Institut 31	3,010 CFU/mL
	STEC stx1_2	Statens Serum Institut EDL933	565 (stx1) CFU/mL 683 (stx2) CFU/mL
Vibrio cholerae	*Vibrio cholerae*	NCTC 8457	136 CFU/mL
	Vibrio cholerae	CCUG 67718	459 CFU/mL
Vibrio parahaemolyticus	*Vibrio parahaemolyticus*	CCUG 14474T	127 CFU/mL
	Vibrio parahaemolyticus	CCUG 67711	489 CFU/mL
Yersinia enterocolitica	*Yersinia enterocolitica*	CCUG 52867T	348 CFU/mL
	Yersinia enterocolitica	CCUG 12369T	106 CFU/mL
Cryptosporidium	*Cryptosporidium hominis*	Waterborne Inc. TU502	72 oocysts/mL
	Cryptosporidium parvum	Waterborne Inc. P102C, Iowa	246 oocysts/mL
Giardia	*Giardia lamblia*	Waterborne Inc. P101, H3	246 cysts/mL
	Giardia intestinalis	ATCC 30957	0.36 cysts/mL
Norovirus	Norovirus GI	Clinical sample GI.3[P3]	298 cp/mL
	Norovirus GII	Clinical sample GII.4 Sydney	27 cp/mL

Analytical Reactivity (Inclusivity)

Studies were performed to evaluate the analytical reactivity (inclusivity) of the Xpert GI Panel test. For each Xpert GI Panel target pathogen, multiple clinically relevant strains, representative of genotypic differences from various geographical regions, were evaluated using the Xpert GI Panel test. All strains were tested at ≤3x LoD with a minimum of five replicates using the Xpert GI Panel test, except for one strain which was assessed using *in silico* analysis against the Xpert GI Panel primer and probe sequences. If a target pathogen strain reported negative results for one replicate or more at ≤3x LoD, the strain was subsequently tested at a higher concentration. A strain was considered detected when all replicates at a test level were reported positive. **Tables 3 to 13** present the evaluated strains, test levels and the results for detection.

Table 3. *Campylobacter* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Campylobacter coli	CCUG 10960	549	3x LoD	Positive
	CCUG 53138	549	3x LoD	Positive
	ATCC 43478	549	3x LoD	Positive
	CCUG 36766	549	3x LoD	Positive
Campylobacter jejuni	CCUG 59141	549	3x LoD	Positive
	CCUG 10259	549	3x LoD	Positive
	Zeptometrix 0801650	549	3x LoD	Positive
Campylobacter jejuni subsp. *doylei*	CCUG 24567T	549	3x LoD	Positive
Campylobacter jejuni subsp. *jejuni*	CCUG 11284T	549	3x LoD	Positive
	CCUG 14541	549	3x LoD	Positive
	CCUG 33057	549	3x LoD	Positive
	CCUG 6824	549	3x LoD	Positive
	ATCC 33560	549	3x LoD	Positive
Campylobacter fetus	CCUG 71557	24,000	131x LoD	Negative
Campylobacter lari	CCUG 15031	24,000	131x LoD	Negative
Campylobacter upsaliensis	CCUG 14913T	24,000	131x LoD	Negative
	CCUG 24191	24,000	131x LoD	Negative

Table 4. *Cryptosporidium* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (oocysts/mL or cp/mL for Synthetic DNA)	Multiple of LoD	Reported Results
Cryptosporidium parvum	IDT Synthetic DNA, L25642	3,690	3x LoD	Positive
Cryptosporidium meleagridis	IDT Synthetic DNA, EF179381	3,690	3x LoD	Positive
Cryptosporidium canis	IDT Synthetic DNA, AF112576	3,690	3x LoD	Positive
Cryptosporidium ubiquitum	IDT Synthetic DNA, QZWX01000067	3,690	3x LoD	Positive
Cryptosporidium hominis	IDT Synthetic DNA, JIBM01000066	3,690	3x LoD	Positive
Cryptosporidium muris	Waterborne Inc. P104, RN66	480,000	390x LoD	Negative[a]
	IDT Synthetic DNA, AB089284	100,000	81xLoD	Positive[b]

Target Pathogen Strain	Strain ID	Test Concentration (oocysts/mL or cp/mL for Synthetic DNA)	Multiple of LoD	Reported Results

[a]Two out of 5 replicates and 1 out of 5 replicates were detected at 134x LoD and 390x LoD respectively.
[b]Three out of 5 replicates, 8 out of 10 replicates and 9 out of 10 replicates were detected at 8.1x LoD, 33x LoD and 57x LoD respectively.

Table 5. STEC Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
STEC stx1 (O103)	NCTC 13782	1,872	3x LoD	Positive
STEC stx1 (O45)	Microbiologics 01098P (CDC 00-3039)	1,872	3x LoD	Positive
STEC stx2 (O121)	Statens Serum Institute D6088	9,030	3x LoD	Positive
STEC stx2 (O145)	NCTC 13797	9,030	3x LoD	Positive
STEC stx2 (O113)	Statens Serum Institute D5586	9,030	3x LoD	Positive
STEC stx2 (O104)	NCTC 13796	9,030	3x LoD	Positive
STEC stx1/stx2 (O26)	NCTC 13733	1,872	3x LoD (stx1)	Positive
			0.6x LoD	Positive
STEC stx1/stx2 (O111)	NCTC 13794	1,872	3x LoD (stx1)	Positive
			0.6x LoD	Positive
STEC stx1/stx2 (O157)	Microbiologics 0617P (ATCC 35150)	1,872	3x LoD (stx1)	Positive
			0.6x LoD	Positive

Table 6. Norovirus Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (cp/mL)	Multiple of LoD	Reported Results
Norovirus GII.4	Clinical Specimen, DLS0113053, CerbaXpert France	60	0.2x LoD	Positive[a]
Norovirus GI.3[P3]	Clinical Specimen, 460878, Precision for Medicine U.S.	298	1x LoD	Positive
Norovirus GI.6	Clinical Specimen 13CA514199, Karolinska Hospital Sweden	298	1x LoD	Positive
		3	0.01x	
Norovirus GII.3[P12]	Clinical Specimen 435625, Precision for Medicine U.S.	894	3x LoD	Positive
		9	0.03x	
Norovirus GII.6[P6]	Clinical Specimen 487208, Precision for Medicine U.S.	894	3x LoD	Positive
Norovirus GII.7[P6]	Clinical Specimen 461526, Precision for Medicine U.S.	894	3x LoD	Positive
Norovirus GIX.1[GII.P15]	Clinical Specimen 487198, Precision for Medicine U.S.	894	3x LoD	Positive

Target Pathogen Strain	Strain ID	Test Concentration (cp/mL)	Multiple of LoD	Reported Results
Norovirus GI	Clinical Specimen GI 1, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GI E, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
Norovirus GII	Clinical Specimen GII 1, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GII 2, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GII 3, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen, GII 4 Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GII 5, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GII A, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GII B, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GII C, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
	Clinical Specimen GII D, Karolinska Hospital Sweden	Unknown[b]	NA	Positive
Norovirus GI.1	IDT Synthetic RNA, NC-001959	12,600	4x LoD	Positive
Norovirus GI.2	IDT Synthetic RNA, NMZ223426	25,200	8x LoD	Positive
Norovirus GI.4	IDT Synthetic RNA, MH393671	12,600	4x LoD	Positive
Norovirus GI.5	IDT Synthetic RNA, MT908122	9,390	3x LoD	Positive
Norovirus GI.7	IDT Synthetic RNA, MT357994	25,200	8x LoD	Positive
Norovirus GII.2	IDT Synthetic RNA, KJ407074	9,390	3x LoD	Positive
Norovirus GII.4	IDT Synthetic RNA, X86557	9,390	3x LoD	Positive
Norovirus GII.10	IDT Synthetic RNA, MT501863	9,390	3x LoD	Positive
Norovirus GII.12	IDT Synthetic RNA, HQ449728	18,800	6x LoD	Positive
Norovirus GII.15	IDT Synthetic RNA, OK247589	18,800	6x LoD	Positive
Norovirus GII.17	IDT Synthetic RNA, KT190704	9,390	3x LoD	Positive

[a]The strain is considered detected since 19 from 20 replicates were reported positive at <1 LoD.
[b]Clinical specimens with unknown titers and one replicate tested per specimen.

Table 7. *Salmonella* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Salmonella bongori	CCUG 63587	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *salamae*	CCUG 30039T	2,400	1.9x LoD	Positive

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Salmonella enterica subsp. *arizonae*	CCUG 6322T	2,400	1.9x LoD	Positive
	CCUG 63588	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *diarizonae*	CCUG 63589	2,400	1.9x LoD	Positive
	CCUG 30040T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *houtenae*	CCUG 30041T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *indica*	CCUG 30038T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Agona	CCUG 21287	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Anatum	CCUG 21243	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Bareilly	CCUG 12616	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Berta	CCUG 27106	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Blockely	CCUG 21263	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Branderup	CCUG 50923	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Derby	CCUG 21276	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Enteritidis	CCUG 34136T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Hadar	CCUG 21271	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Heidelberg	CCUG 21289	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* serotype Typhimurium 4,5,12: i: 1,2	CCUG 18375	2,400	1.9x LoD	Positive
	ATCC 14028	2,400	1.9x LoD	Positive
	CCUG 42060T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Infantis	CCUG 12615	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Javiana	CCUG 21235	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Litchfield	NCTC 6028	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Mbandaka	CCUG 21272	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Mississippi	Clinical Specimen S027019, Public Health Agency of Sweden	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Montevideo	CCUG 21239	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Muenchen	CCUG 21254	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Newport	CCUG 21283	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Oranienburg	CCUG 12649	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Panama	CCUG 21275	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Parathyphi A	NCTC 5702	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Poona	CCUG 39842	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Reading	NCTC 5720	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Saintpul	CCUG 21282	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Sandiego	NCTC 6024	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Schwarzengrund	CCUG 21280	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Senftenberg	CCUG 37886	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Stanley	CCUG 26623	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Thompson	CCUG 12652	2,400	1.9x LoD	Positive

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Salmonella enterica subsp. *enterica* Typhi	Clinical Specimen 22-00912, Public Health Agency of Sweden	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Typhimurium	CCUG 35118	2,400	1.9x LoD	Positive

Table 8. *Shigella* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Shigella boydii (Subgroup C, serotype 8)	CCUG 37892	612	3x LoD	Positive
Shigella boydii (Subgroup C, serotype 10)	CCUG 9564	612	3x LoD	Positive
Shigella boydii (Subgroup C, serotype 11)	ATCC 12031	612	3x LoD	Positive
Shigella dysenteriae (Subgroup A, serotype 1)	NCTC 4837[a]	204	1x LoD	Positive
	NCTC 8217[a]	612	3x LoD	Positive
	NCTC 8571[a]	612	3x LoD	Positive
Shigella dysenteriae (Subgroup A, serotype 8)	NCTC 9345	612	3x LoD	Positive
Shigella dysenteriae (Subgroup A, serotype 9)	NCTC 9348	612	3x LoD	Positive
Shigella flexneri (Subgroup B, serotype 2a)	CCUG 56439T	1,224	6x LoD	Positive
Shigella flexneri (Subgroup B, serotype 3)	CCUG 21251	612	3x LoD	Positive
Shigella flexneri (Subgroup B, serotype 4a)	CCUG 37906	612	3x LoD	Positive
Shigella flexneri (Subgroup B, serotype 6)	CCUG 39080	612	3x LoD	Positive
	ATCC 15391	612	3x LoD	Positive
Shigella sonnei (Subgroup D)	CCUG 9567	612	3x LoD	Positive
Shigella dysenteriae (Subgroup A, serotype 9)	ATCC 49547	*In silico* analysis	NA	100% match with primer and probe sequences

[a]*Shigella* strains carrying STEC stx1 gene.

Table 9. Enteroinvasive *Escherichia coli* (EIEC) Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Enteroinvasive *Escherichia coli* (EIEC)	CCUG 38092	204	1x LoD	Positive
	CCUG 38094	612	3x LoD	Positive
	NCTC 9013	70,000	343x LoD	Negative [a]

[a]Secondary PCR assay confirm the absence of the EIEC target gene *ipaH* in strain NCTC 9013, i.e., target gene loss confirmed.

Table 10. *Vibrio cholerae* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Vibrio cholerae O:139	CCUG 34707	1,200	2.6x LoD	Positive
Vibrio cholerae O:1	CCUG 9118T	1,200	2.6x LoD	Positive

Table 11. *Vibrio parahaemolyticus* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Vibrio parahaemolyticus	CCUG 19113	1,467	3x LoD	Positive
	CCUG 15657T	1,467	3x LoD	Positive
	CCUG 43362	1,467	3x LoD	Positive

Table 12. *Yersinia enterocolitica* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiple of LoD	Reported Results
Yersinia enterocolitica biotype 1	CCUG 33055	1,044	3x LoD	Positive
Yersinia enterocolitica biotype 2	CCUG 8239A	1,044	3x LoD	Positive
Yersinia enterocolitica biotype 2 (O:5, 27)	NCTC 10463	1,044	3x LoD	Positive
Yersinia enterocolitica biotype 4	CCUG 34604	1,044	3x LoD	Positive

Table 13. *Giardia* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (cysts/mL)	Multiple of LoD	Reported Results
Giardia intestinalis	ATCC 30888	1	3x LoD	Positive
	ATCC 50114	1	3x LoD	Positive

Analytical Specificity (Exclusivity) and Microbial Interference

Studies were performed to evaluate the analytical specificity (exclusivity), microbial interference and the in-assay cross reactivity of the Xpert GI Panel test. A total of 136 non-target microorganisms commonly found in stool and rectal flora were either tested with the Xpert GI Panel test (131 microorganisms) or assessed using *in silico* analysis directed against the Xpert GI Panel probe and primer sequences (five microorganisms). The non-target microorganisms evaluated using the Xpert GI Panel test were diluted into clinical stool matrix at high concentrations and tested in absence of target pathogens using three replicates, and in presence

of target pathogens diluted to ≤ 3x LoD using six replicates. Non-target bacteria were tested at 1E6 CFU/mL and non-target viruses and parasites/yeast were tested at ≥ 1E4 units/mL.

The in-assay cross reactivity was evaluated using a subset of target pathogen strains, individually tested at high concentrations using six replicates, to determine potential cross-reactivity with the primers and probes included in the Xpert GI Panel test. Target pathogen strains evaluated for in-assay cross reactivity were tested at 1E6 units/mL, except for *Cryptosporidium parvum* which was tested at 9.94E4 oocysts/mL.

No cross-reactivity or microbial interference were observed for any of the tested non-target microorganisms using the Xpert GI Panel test. The risk for cross reactivity or interference with the Xpert GI Panel test was assessed low using *in silico* analysis for five of the non-target microorganisms. No in-assay cross reactivity was observed for any of the Xpert GI Panel target pathogens tested at high concentrations. **Tables 14, 15 and 16** present the bacteria, viruses, parasites/yeast evaluated in the Xpert GI Panel analytical (exclusivity) and microbial interference study. **Table 17** presents the target pathogen strains evaluated for in-assay cross reactivity of the Xpert GI Panel test.

Table 14. Non-Target Bacteria Evaluated in the Xpert GI Panel Analytical Specificity and Microbial Interference Study

Bacteria		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Abiotrophia defectiva	CCUG 27639	1E6 CFU/mL
Acinetobacter baumannii	CCUG 19096T	1E6 CFU/mL
Acinetobacter lwoffii	ZeptoMetrix 0801909	1E6 CFU/mL
Aeromonas caviae	CCUG 25939	1E6 CFU/mL
Aeromonas salmonicida (Aeromonas hydrophila)	ATCC 7965	1E6 CFU/mL
Aeromonas schubertii	CCUG 27820	1E6 CFU/mL
Aeromonas sobria	CCUG 14830	1E6 CFU/mL
Aeromonas veronii	CCUG 27821T	1E6 CFU/mL
Alcaligenes faecalis subsp. *faecalis*	CCUG 1814T	1E6 CFU/mL
Anaerococcus tetradius	CCUG 46590T	1E6 CFU/mL
Arcobacter butzleri	CCUG 30485	1E6 CFU/mL
Arcobacter cryaerophilus	CCUG 17801	1E6 CFU/mL
Bacillus cereus	ZeptoMetrix 0801823	1E6 CFU/mL
Bacteroides caccae	ATCC 43185	1E6 CFU/mL
Bacteroides fragilis	ZeptoMetrix 0801583	1E6 CFU/mL
Bacteroides stercoris	ATCC 43183	1E6 CFU/mL
Bacteroides thetaiomicron	CCUG 10774	1E6 CFU/mL
Phocaeicola vulgatus (Bacteroides vulgatus)	ATCC 8482	1E6 CFU/mL
Bifidobacterium adolescentis	CCUG 18363T	1E6 CFU/mL
Bifidobacterium bifidum	CCUG 45217	1E6 CFU/mL
Bifidobacterium longum subsp. *longum*	ATCC 15707	1E6 CFU/mL
Brevundimonas diminuta	CCUG 2031	1E6 CFU/mL

Bacteria		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Cedecea davisae	CCUG 12370	1E6 CFU/mL
Chlamydia trachomatis	ZeptoMetrix 0801775	1E6 CFU/mL
Citrobacter amalonaticus	CCUG 4860A	1E6 CFU/mL
Citrobacter freundii	ZeptoMetrix 0801563	1E6 CFU/mL
Citrobacter koseri	CCUG 4859	1E6 CFU/mL
Citrobacter sedlakii	CCUG 30794	1E6 CFU/mL
Clostridium difficile	ZeptoMetrix 0801619	1E6 CFU/mL
Hathewaya histolytica (Clostridium histolyticum)	ATCC 19401	1E6 CFU/mL
Clostridium novyi	ATCC 17861	1E6 CFU/mL
Clostridium perfringens	ATCC 13124	1E6 CFU/mL
Thoamsclavelia ramose (Clostridium ramosum)	CCUG 24038	1E6 CFU/mL
Clostridium septicum	ATCC 12464	1E6 CFU/mL
Paeniclostridium sordellii (Clostridium sordellii)	DSMZ 2141	1E6 CFU/mL
Clostridium tetani	ATCC 19406	1E6 CFU/mL
Collinsella aerofaciens	CCUG 28087	1E6 CFU/mL
Corynebacterium genitalium	CCUG 65575	1E6 CFU/mL
Corynebacterium lipophiloflavum	CCUG 37336	1E6 CFU/mL
Desulfovibrio piger	NA	*In silico* analysis
Edwardsiella tarda	CCUG 1638	1E6 CFU/mL
Eggerthella lenta	ATCC 43055	1E6 CFU/mL
Klebsiella aerogenes (Enterobacter aerogenes)	ZeptoMetrix 0801518	1E6 CFU/mL
Enterobacter cancerogenus	ATCC 35316	1E6 CFU/mL
Enterobacter cloacae subsp. *cloacae*	ZeptoMetrix 0801830	1E6 CFU/mL
Enterococcus faecalis	ZeptoMetrix 0801637	1E6 CFU/mL
Enterococcus faecium	ZeptoMetrix 0804210	1E6 CFU/mL
Enteroaggregative *E. coli* EAEC	ZeptoMetrix 0801919	1E6 CFU/mL
Enteropathogenic *E. coli* EPEC	ZeptoMetrix 0801938	1E6 CFU/mL
Enterotoxigenic *E. coli* ETEC	ZeptoMetrix 0801624	1E6 CFU/mL
Escherichia fergusonii	CCUG 18766	1E6 CFU/mL
Escherichia hermannii	CCUG 15714	1E6 CFU/mL
Pseudescherichia vulneris (Escherichia vulneris)	CCUG 15715	1E6 CFU/mL
Fusobacterium varium	ATCC 8501	1E6 CFU/mL
Gardnerella vaginalis	ZeptoMetrix 0801894	1E6 CFU/mL
Gemella morbillorum	CCUG 18164	1E6 CFU/mL
Hafnia alvei	CCUG 41547T	1E6 CFU/mL
Helicobacter fennelliae	CCUG18820	1E6 CFU/mL
Helicobacter pylori	ZeptoMetrix 0804383	1E6 CFU/mL
Klebsiella oxytoca	ZeptoMetrix 0801881	1E6 CFU/mL

Bacteria		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Klebsiella pneumoniae subsp. *pneumoniae*	CCUG 225T	1E6 CFU/mL
Lactobacillus acidophilus	ATCC 314	1E6 CFU/mL
Limosilactobacillus reuteri	CCUG 33624	1E6 CFU/mL
Lactococcus lactis subsp. lactis	CCUG 32211	1E6 CFU/mL
Leminorella grimontii	CCUG 20909B	1E6 CFU/mL
Listeria monocytogenes	ZeptoMetrix 0801534	1E6 CFU/mL
Megamonas hypermegale	CCUG 5856	1E6 CFU/mL
Megasphaeara elsdenii	ATCC 25940	1E6 CFU/mL
Morganella morganii subsp. *morganii*	ZeptoMetrix 0804010	1E6 CFU/mL
Neisseria gonorrhoeae	ZeptoMetrix 0801482	1E6 CFU/mL
Parabacteroides merdae	CCUG 38734	1E6 CFU/mL
Peptoniphilus asaccharolyticus	ATCC 14963	1E6 CFU/mL
Peptostreptococcus anaerobius	CCUG 7835	1E6 CFU/mL
Photobacterium damselae subsp. *damselae*	CCUG 13626	1E6 CFU/mL
Pleisomonas shigelloides	CCUG 410T	1E6 CFU/mL
Porphyromonas asaccharolytica	CCUG 7834T	1E6 CFU/mL
Prevotella melaninogenica	ATCC 25845	1E6 CFU/mL
Proteus mirabilis	ZeptoMetrix 0801544	1E6 CFU/mL
Proteus penneri	CCUG 15722	1E6 CFU/mL
Proteus vulgaris	ZeptoMetrix 0801898	1E6 CFU/mL
Providencia alcalifaciens	ZeptoMetrix 0801906	1E6 CFU/mL
Pseudomonas aeruginosa	CCUG 551T	1E6 CFU/mL
Ruminococcus bromii	ATCC 27255	1E6 CFU/mL
Serratia fonticola	CCUG 14186	1E6 CFU/mL
Serratia liquefaciens	CCUG 9285T	1E6 CFU/mL
Serratia marcescens subsp. *marcescens*	ZeptoMetrix 0801723	1E6 CFU/mL
Shewanella algae	CCUG 39064	1E6 CFU/mL
Shimwellia blattae	CCUG 14803BT	1E6 CFU/mL
Staphylococcus aureus subsp. *aureus*	ATCC 25923	1E6 CFU/mL
Staphylococcus epidermidis	ZeptoMetrix 0801651	1E6 CFU/mL
Stenotrophomonas maltophilia	ZeptoMetrix 0801569	1E6 CFU/mL
Streptococcus agalactiae	CCUG 4208	1E6 CFU/mL
Streptococcus intermedius	ZeptoMetrix 0801895	1E6 CFU/mL
Streptococcus pyogenes	CCUG 4207	1E6 CFU/mL
Streptococcus salivarius subsp. *salivarius*	ZeptoMetrix 0801896	1E6 CFU/mL
Streptococcus suis	CCUG 7984	1E6 CFU/mL
Trabulsiella guamensis	ATCC 49492	1E6 CFU/mL
Veillonella parvula	ATCC 10790	1E6 CFU/mL
Vibrio vulnificus	CCUG 48492	1E6 CFU/mL
Yersinia bercovieri	CCUG 26329T	1E6 CFU/mL
Yersinia frederiksenii	CCUG 11293	1E6 CFU/mL

Bacteria		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Yersinia intermedia	CCUG 11292T	1E6 CFU/mL
Yersinia kristensenii	CCUG 11294	1E6 CFU/mL
Yersinia mollaretii	CCUG 26331	1E6 CFU/mL
Yersinia rohdei	CCUG 38833	1E6 CFU/mL

Table 15. Non-Target Viruses Evaluated in the Xpert GI Panel Analytical Specificity and Microbial Interference Study

Viruses		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Adenovirus Type 1	ZeptoMetrix 0810050CF	1E6 $TCID_{50}$/mL
Adenovirus Type 3	ZeptoMetrix 0810062CF	5E5 $TCID_{50}$/mL[a] 1E4 $TCID_{50}$/mL[b]
Adenovirus Type 4	ZeptoMetrix 0810070CF	5E4 $TCID_{50}$/mL[a]
Adenovirus Type 5	ZeptoMetrix 0810020CF	1E6 $TCID_{50}$/mL
Adenovirus Type 8	ZeptoMetrix 0810069CF	2E4 $TCID_{50}$/mL[a] 1E4 $TCID_{50}$/mL[b]
Adenovirus Type 14	ZeptoMetrix 0810108CF	1E5 $TCID_{50}$/mL
Adenovirus Type 18	NA	*In silico* analysis
Adenovirus Type 31	ZeptoMetrix 0810073CF	1E5 $TCID_{50}$/mL
Adenovirus Type 40	ZeptoMetrix 0810084CF	1E5 $TCID_{50}$/mL
Adenovirus Type 41	ZeptoMetrix 0810085CF	1E5 $TCID_{50}$/mL
Astrovirus	ATCC VR-1936	1E6 $TCID_{50}$/mL
Parvovirus	ZeptoMetrix 0810064C	1E6 IU/mL
Cytomegalovirus	ATCC VR-538	5E5 $TCID_{50}$/mL
Enterovirus	ATCC VR-836	5E5 $TCID_{50}$/mL
Haemophilus influenzae	ZeptoMetrix 0801679	1E6 CFU/mL
Hepatitis A virus	ATCC VR-1541	5E5 $TCID_{50}$/mL
Herpes Simplex Virus Type 2	ZeptoMetrix 0810006CF	5E5 $TCID_{50}$/mL
Human coxsackievirus	ZeptoMetrix 0810074CF	5E5 $TCID_{50}$/mL
Rhinovirus	ZeptoMetrix 0810012CFN	2E4 $TCID_{50}$/mL[a] 1E5 $TCID_{50}$/mL[b]
Rotavirus	ATCC VR-2551	1E6 $TCID_{50}$/mL
Sapovirus	ATCC VR-3237SD	1E7 genome copies/mL[a] 1E6 genome copies/mL[b]

[a]Concentration of the non-target microorganism tested with *Salmonella enterica, Giardia lamblia, Vibrio cholerae* and negative sample.
[b]Concentration of the non-target microorganism tested with *Campylobacter jejuni,* STEC stx1 and stx2, EIEC*, Yersinia enterocolitica, Vibrio parahaemolyticus, Cryptosporidium parvum* and Norovirus GI and GII.

Table 16. Non-Target Parasites/Yeast Evaluated in the Xpert GI Panel Analytical Specificity and Microbial Interference Study

Parasites/Yeast		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Blastocystis hominis	NA	*In silico* analysis

Parasites/Yeast		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Candida albicans	ZeptoMetrix 0801504	1E6 CFU/mL
Cyclospora cayetanensis	ATCC PRA-3000SD	1E7 copies/mL[a] 1E6 copies/mL[b]
Encephalitozoon cuniculi	NA	*In silico* analysis
Encephalitozoon hellum	NA	*In silico* analysis
Entamoeba dispar	ATCC PRA-368	N/A[c]
Entamoeba histolytica	ATCC 30459	2E4 cells/mL[a] 1E4 cells/mL[b]
Entamoeba invadens	ATCC 30994	5E4 cells/mL
Pentatrichomonas hominis	ATCC 30000	1E6 cells/mL
Trichomonas vaginalis	ZeptoMetrix 0801805	1E5 trophozoites/mL

[a]Concentration of the non-target microorganism tested with *Salmonella enterica, Giardia lamblia, Vibrio cholerae* and negative sample.
[b]Concentration of the non-target microorganism tested with *Campylobacter jejuni,* STEC stx1 and stx2, EIEC*, Yersinia enterocolitica, Vibrio parahaemolyticus, Cryptosporidium parvum* and Norovirus GI and GII.
[c]For *Entamoeba dispar*, ATCC PRA-368, no titer or cell count was available according to vendor ATCC. According to the Certificate of Analysis, the microorganism was released based on visual observation methods.

Table 17. Target Pathogen Strains Evaluated in the Xpert GI Panel In-assay Cross Reactivity Study

Target Pathogen	Strain ID	Concentration Tested
Campylobacter coli	CCUG 53138	1E6 CFU/mL
	ATCC 43478	1E6 CFU/mL
	CCUG 36766	1E6 CFU/mL
Shigella boydii (Subgroup C, serotype 8)	CCUG 37892	1E6 CFU/mL
Shigella boydii (Subgroup C, serotype 10)	CCUG 9564	1E6 CFU/mL
Shigella flexneri (Subgroup B, serotype 2a)	CCUG 56439T	1E6 CFU/mL
Shigella flexneri (Subgroup B, serotype 4a)	CCUG 37906	1E6 CFU/mL
Enteroinvasive *Escherichia coli* (EIEC)	CCUG 38094	1E6 CFU/mL
Escherichia coli (STEC), O111	NCTC 13794	1E6 CFU/mL
Escherichia coli (STEC), O113	D5586	1E6 CFU/mL
Escherichia coli (STEC), O104	NCTC 13796	1E6 CFU/mL
Salmonella bongori	CCUG 63587	1E6 CFU/mL
Salmonella enterica subsp. *indica*	CCUG 30038T	1E6 CFU/mL
Salmonella enterica subsp. enterica Parathyphi A	NCTC 5702	1E6 CFU/mL
Vibrio cholerae, O:139 (non-O:1)	CCUG 34707	1E6 CFU/mL
Vibrio cholerae, O:1	CCUG 9118T	1E6 CFU/mL
Vibrio parahaemolyticus	CCUG 43362	1E6 CFU/mL
	CCUG 19113	1E6 CFU/mL
	CCUG 15657T	1E6 CFU/mL

Target Pathogen	Strain ID	Concentration Tested
Norovirus GI.3 [P3]	Clinical Specimen, 460878, Precision for Medicine U.S.	1E6 cp/mL
Norovirus GII.7	Clinical Specimen, 461526, Precision for Medicine U.S.	1E6 cp/mL
Yersinia entercolitica, subsp. *enterocolitica*, biotype 1 (serotype O:8)	CCUG 33055	1E6 CFU/mL
Yersinia entercolitica, subsp. *enterocolitica*, biotype 2 (serotype O:5,27)	NCTC 10463	1E6 CFU/mL
Yersinia entercolitica, subsp. *enterocolitica*, biotype 4 (serotype O:3)	CCUG 34604	1E6 CFU/mL
Cryptosporidium parvum	Waterborne Inc. P102C Iowa	9.94E4 oocysts/mL
Cryptosporidium hominis	Waterborne Inc. TU502	1E6 oocysts/mL
Giardia intestinalis	ATCC 30888	1E6 cysts/mL
	ATCC 50114	1E6 cysts/mL

Competitive Inhibition Study

Competitive inhibition of the Xpert GI Panel test, caused by clinically relevant co-infections, was evaluated by testing 12 target pathogen combinations using a total of seven target pathogens, i.e., *Campylobacter jejuni*, *Salmonella enterica*, *Giardia lamblia*, *Yersinia enterocolitica*, STEC *stx1*, STEC *stx2* and Norovirus GI. The target pathogens were tested at low concentrations, i.e., ≤3x LoD in presence of one or more additional target pathogen(s) at a high concentration in negative clinical stool matrix. The high test concentrations were 1E6 CFU/mL for bacterial pathogens, 1E5 cysts/mL for *Giardia lamblia*, and 1E5 cp/mL for Norovirus GI. All target pathogen combinations were diluted in clinical stool matrix and tested with six replicates. The study results showed no competitive inhibition for common gastrointestinal co-infections with the Xpert GI Panel test. **Table 18** presents the target pathogen combinations and the reported results.

Table 18. Target Pathogen Combinations Evaluated in the Xpert GI Panel Competitive Inhibition Study

High Titer Target Pathogen	Low Titer Target Pathogen	Low Titer Testing Concentration (≤3x LoD)	Reported Result for Low Titer Target Pathogen
STEC stx1 (1E6 CFU/mL) STEC stx2 (1E6 CFU/mL)	*Campylobacter jejuni*	549 CFU/mL	Positive
	Salmonella enterica	1,863 CFU/mL	Positive
Yersinia enterocolitica (1E6 CFU/mL)	*Campylobacter jejuni*	549 CFU/mL	Positive
	Salmonella enterica	1,863 CFU/mL	Positive
Norovirus GI (1E5 cp/mL)	*Campylobacter jejuni*	549 CFU/mL	Positive
	Salmonella enterica	1,863 CFU/mL	Positive
Campylobacter jejuni (1E6 CFU/mL) *Salmonella enterica* (1E6 CFU/mL)	STEC stx1	1,872 CFU/mL	Positive
	STEC stx2	9,030 CFU/mL	Positive
	STEC stx1	1,872 CFU/mL	Positive

High Titer Target Pathogen	Low Titer Target Pathogen	Low Titer Testing Concentration (≤3x LoD)	Reported Result for Low Titer Target Pathogen
Yersinia enterocolitica (1E6	STEC stx2	9,030 CFU/mL	Positive
Norovirus GI (1E5 cp/mL)	STEC stx1	1,872 CFU/mL	Positive
	STEC stx2	9,030 CFU/mL	Positive
Campylobacter jejuni (1E6 CFU/mL) *Salmonella enterica* (1E6 CFU/mL)	*Yersinia enterocolitica*	1,044 CFU/mL	Positive
STEC stx1 (1E6 CFU/mL) STEC stx2 (1E6 CFU/mL)	*Yersinia enterocolitica*	1,044 CFU/mL	Positive
Campylobacter jejuni (1E6 CFU/mL) *Salmonella enterica* (1E6 CFU/mL)	Norovirus GI	894 cp/mL	Positive
Giardia lamblia (1E5 cysts/mL) *Yersinia enterocolitica* (1E6 CFU/mL)	Norovirus GI	894 cp/mL	Positive
STEC stx1 (1E6 CFU/mL) STEC stx2 (1E6 CFU/mL)	Norovirus GI	894 cp/mL	Positive
Norovirus GI (1E5 cp/mL)	*Giardia lamblia*	738 cysts/ml	Positive
	Yersinia enterocolitica	1,044 CFU/mL	Positive

Potentially Interfering Substances Study

A total of seven endogenous and 29 exogenous substances, that may be encountered in clinical stool specimens, as well as four method-specific substances for collecting and storing clinical specimens, were evaluated for potential interference with the Xpert GI Panel test performance. **Table 19** presents the evaluated substances and the corresponding test concentration in raw stool. Each potentially interfering substance was tested individually in clinical negative stool matrix in absence and in presence of representative Xpert GI Panel target pathogens respectively at a concentration of 3x LoD using six replicates. The representative target pathogens included EIEC, *Yersinia enterocolitica*, *Cryptosporidium parvum* and Norovirus and they were selected to include at least one of each pathogen type (bacteria, parasite, virus), covering both detection methods (amplification and melt analysis).

None of the substances tested showed interference with the Xpert GI Panel test performance at the concentration levels evaluated. However, overfilling of stool sample above the Cary Blair medium transport vial max fill line resulted in five pressure errors, two false negative results for *Cryptosporidium parvum* and delayed Ct values for the amplification targets (EIEC, *Cryptosporidium parvum* and Norovirus). Thus, overfilling stool in the Cary Blair medium vial may be a potential risk for non-determinate results or false negative results at low target pathogen levels. These results highlight the importance of performing the stool sample collection correctly and according to the Cary Blair manufacturer´s instructions.

Table 19. Substances Evaluated in the Xpert GI Panel Potential Interfering Substances Study

Type of Substance	Substance	Concentration Tested in Raw Stool
Endogenous Substances	Human whole blood	10% v/v
	Mucin	5% w/v
	Fecal fat – triglycerides	5% v/v
	Fecal fat – cholesterol	5% w/v
	Human stool (overfill of Cary Blair vial)	Filled above vial max fill line
	Bile Salts	9 mg/g
	Human urine	50% v/v
Exogenous Substances	Amoxicillin	5% w/v
	Ampicillin	5% w/v
	Aspartame	5% w/v
	Azithromycin	1% w/v
	Bacitracin	50% w/v
	Ceftriaxone	16 mg/mL
	Ciprofloxacin	5% w/v
	Doxycycline	1% w/v
	Fluvastatin	1% w/v
	Glycerin	50% v/v
	Nystatin	50% w/v
	Metronidazole	60.8 mg/mL
	Vancomycin	12.5 mg/mL
	Naproxen sodium	10% w/v
	Bisacodyl	5% w/v
	Bismuth subsalicylate	1% w/v
	Calcium carbonate	5% w/v
	Docusate sodium	50% w/v
	Hydrocortisone	50% w/v
	Loperamide hydrochloride	5% w/v
	Magnesium hydroxide	10% w/v
	Phenylephrine hydrochloride	30% w/v
	Sodium phosphate	5% w/v
	Nonoxynol-9	50% v/v
	Steric acid	5% w/v
	Palmitic acid	5% w/v
	Bleach 10%	50% v/v
	Ethanol	0.2% v/v
	Mineral Oil	50% v/v
Method Specific Substances (Cary Blair medium)	Remel Cary Blair	N/A
	Para-Pak C&S	N/A
	MCC C&S Medium Transport	N/A

Carry-over Contamination Study

A study was conducted to demonstrate that the single-use, self-contained Xpert GI Panel cartridge prevents carry-over contamination. The carry-over contamination evaluation was conducted by testing a negative sample immediately after testing a positive sample at high concentration in the same GeneXpert module. This procedure was repeated until 10 high positive and 11 negative replicates had been alternately tested for two GeneXpert modules respectively. The positive sample consisted of representative target pathogens at high concentrations in clinical stool matrix, i.e., EIEC at 1E6 CFU/mL, *Giardia lamblia* at 1E5 cysts/mL and Norovirus at 1E5 cp/mL. The target pathogens were selected to include at least one of each pathogen type (bacteria, parasite, virus). The negative sample consisted of negative clinical stool matrix without any target pathogens. All 20 replicates of the positive sample (10 replicates for each GeneXpert module) were correctly reported as POSITIVE for the target pathogens included. All 22 replicates of the negative sample (11 replicates for each GeneXpert module) were correctly reported as NEGATIVE**.** Thus, no carry-over contamination in the GeneXpert modules was observed.

Reproducibility and Precision

The reproducibility and precision of the Xpert GI Panel was established through a multicenter (3 sites) blinded study utilizing a multi-factor nested design consisting of three contrived panels composed of low positive (~1x LoD), moderate positive (~3x LoD), and negative samples. The negative samples were pooled negative clinical stool matrix.

The positive samples were contrived by diluting target pathogen into pooled negative clinical stool matrix across three panels. Testing was conducted to assess reproducibility over days, lots of Xpert GI Panel cartridges, sites, and operators at each site. The percent agreement of the correct results compared to the expected results analyzed by each of the operators across site is shown in **Table 20**. In addition, the overall percent agreement for each sample (% total agreement) and the two-sided Wilson Score confidence intervals (CI) are presented in the last column.

Low and moderate *V. parahaemolyticus* positives were tested fresh within the 4-day window of specimen stability (2 - 8°C) as part of Panel 3. Panel 3 consisted of low and moderate positive *V. parahaemolyticus* and negative panel members. The results from the study are summarized in **Table 20**.

Table 20. Summary of Reproducibility Results - % Agreement

Panel	Sample	Site 1			Site 2			Site 3			% Total Agreement [95% CI]
		OP 1	OP2	Site	OP 1	OP 2	Site	OP 1	OP 2	Site	
Panel 1	*Campylobacter* Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 1	*Campylobacter* Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 1	STEC *stx2* Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	

Panel	Sample	Site 1			Site 2			Site 3			% Total Agreement [95% CI]
		OP 1	OP2	Site	OP 1	OP 2	Site	OP 1	OP 2	Site	
Panel 1	STEC *stx2* Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 1	Negative	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	*Salmonella* Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	*Salmonella* Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	*Salmonella* Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (143/143) [97.4-100.0]
		24/24	24/24	48/48	23/23[b]	24/24	47/47	24/24	24/24	48/48	
Panel 2	*Yersinia* Low Pos	100%	100%	100%	100%	96%	98%	100%	100%	100%	99.3% (143/144) [96.2-99.9]
		24/24	24/24	48/48	24/24	23/24	47/48	24/24	24/24	48/48	
Panel 2	*Yersinia* Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (143/143) [97.4-100.0]
		24/24	24/24	48/48	23/23[b]	24/24	47/47	24/24	24/24	48/48	
Panel 2	*Cryptosporidium* Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	*Cryptosporidium* Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (143/143) [97.4-100.0]
		24/24	24/24	48/48	23/23[b]	24/24	47/47	24/24	24/24	48/48	
Panel 2	*Giardia* Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	*Giardia* Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	*Shigella* EIEC Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	*Shigella* EIEC Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	Norovirus Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	Norovirus Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144) [97.4-100.0]
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	
Panel 2	Negative	100%	96%	98%	100%	96%	98%	100%	100%	100%	98.6% (142/144) [95.1-99.6]
		24/24	23/24	47/48	24/24	23/24	47/48	24/24	24/24	48/48	
Panel 3	*V. parahaemolyticus* Low Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (108/108) [96.6-100.0]
		18/18	18/18	36/36	18/18	18/18	36/36	18/18	18/18	36/36	
Panel 3	*V. parahaemolyticus* Mod Pos	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (108/108) [96.6-100.0]
		18/18	18/18	36/36	18/18[a]	18/18	36/36	18/18	18/18	36/36	
Panel 3	Negative	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (108/108) [96.6-100.0]
		18/18	18/18	36/36	18/18	18/18	36/36	18/18	18/18	36/36	

Panel	Sample	Site 1			Site 2			Site 3			% Total Agreement [95% CI]
		OP 1	OP2	Site	OP 1	OP 2	Site	OP 1	OP 2	Site	

[a] One moderate positive sample (02-03-12-A) tested positive for *V. parahaemolyticus* and *V. cholerae*. This sample was considered concordant for *V. parahaemolyticus*.
[b] One sample was non-determinate on both initial and retest and was excluded from the analyses.

The evaluation of reproducibility and within-laboratory precision of the underlying analyte response (Ct, melt peak (MP), or melt valley (MV) values) for the Xpert GI Panel was analyzed using nested Analysis of Variance (ANOVA). The mean response (Ct, MP or MV), standard deviation (SD), and coefficient of variation (CV) between-sites, between-operators, between-lots, between-days, between-runs and within-run for each panel member are presented in **Table 21**.

Table 21. Summary of Nested ANOVA by Coefficient of Variation

Sample	Response	N	Mean Ct, MP, or MV	Variance Source													
				Site		Operator		Lot		Day		Run		Within-Run		Total	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Campylobacter Low Pos	MP	144	15.6	0.6	3.6	0.0	0.0	1.2	7.6	0.7	4.4	0.0	0.0	1.9	12.2	2.4	15.4
	MV	144	-13	0.4	3.3	0.0	0.0	0.9	7.2	0.6	4.3	0.0	0.0	1.5	11.6	1.9	14.7
Campylobacter Mod Pos	MP	144	16.4	0.6	3.5	0.0	0.0	0.6	3.8	0.6	3.7	0.0	0.0	1.6	9.9	1.9	11.8
	MV	144	-13.7	0.6	4.3	0.0	0.0	0.5	3.8	0.5	3.5	0.0	0.0	1.3	9.5	1.6	11.6
STEC *stx2* Low Pos	MP	144	12.9	0.9	6.6	0.0	0.0	0.7	5.7	0.0	0.0	0.1	0.9	1.7	13.0	2.0	15.7
	MV	144	-12.1	0.7	6.0	0.0	0.0	0.7	5.7	0.3	2.2	0.0	0.0	1.7	13.9	2.0	16.3
STEC *stx2* Mod Pos	MP	144	14.1	1.1	8.0	0.0	0.0	0.5	3.2	0.8	5.7	0.4	3.2	1.8	12.7	2.3	16.7
	MV	144	-13.4	1.0	7.4	0.0	0.0	0.4	2.9	0.7	5.3	0.5	3.9	1.8	13.5	2.3	17.0
Salmonella Low Pos	Ct	144	34.6	0.4	1.0	0.2	0.4	0.0	0.0	0.3	0.8	0.0	0.0	0.7	1.9	0.8	2.3
Salmonella Mod Pos	Ct	143[a]	33.7	0.2	0.7	0.2	0.5	0.3	0.8	0.0	0.0	0.2	0.7	0.6	1.8	0.8	2.2
Yersinia Low Pos	MP	143[b]	14.2	0.4	2.8	0.0	0.0	0.0	0.0	0.0	0.0	0.7	5.0	1.4	10.0	1.6	11.5
	MV	143	-11.7	0.4	3.6	0.0	0.0	0.0	0.0	0.0	0.0	0.6	4.8	1.2	9.9	1.4	11.6
Yersinia Mod Pos	MP	143[a]	14.7	0.6	3.7	0.0	0.0	0.5	3.2	0.0	0.0	0.0	0.0	1.8	12.0	1.9	12.9
	MV	143[a]	-12.3	0.5	4.0	0.0	0.0	0.4	3.0	0.0	0.0	0.2	1.4	1.4	11.1	1.5	12.2
Cryptosporidium Low Pos	Ct	144	23.3	0.6	2.6	0.0	0.0	0.0	0.0	0.5	2.1	0.0	0.0	1.6	6.8	1.8	7.5
Cryptosporidium Mod Pos	Ct	143[a]	22.3	0.5	2.0	0.0	0.0	0.0	0.0	0.4	1.6	0.5	2.2	1.0	4.4	1.2	5.5
Giardia Low Pos	Ct	144	27.4	1.3	4.6	0.0	0.0	1.2	4.4	0.7	2.4	1.2	4.3	1.6	5.7	2.7	9.9
Giardia Mod Pos	Ct	144	26.6	1.2	4.5	0.0	0.0	1.4	5.4	0.4	1.6	1.1	4.2	1.3	4.9	2.6	9.7

Sample	Response	N	Mean Ct, MP, or MV	Variance Source													
				Site		Operator		Lot		Day		Run		Within-Run		Total	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Shigella EIEC Low Pos	Ct	144	32.8	0.4	1.1	0.1	0.3	0.2	0.5	0.1	0.4	0.0	0.0	0.8	2.3	0.9	2.7
Shigella EIEC Mod Pos	Ct	144	31.9	0.1	0.4	0.2	0.6	0.0	0.0	0.0	0.1	0.0	0.0	0.7	2.3	0.8	2.5
Norovirus Low Pos	Ct	144	33.2	0.3	0.9	0.0	0.0	0.2	0.6	0.3	0.8	0.3	0.8	0.6	2.0	0.8	2.5
Norovirus Mod Pos	Ct	144	32	0.3	0.9	0.0	0.1	0.1	0.4	0.1	0.4	0.1	0.3	0.6	1.8	0.7	2.1
V. parahaemolyticus Low Pos	MP	108	15.5	1.3	8.4	0	0	0.9[d]	5.8[c]	NA[c]	NA[c]	0.8	5.1	2	12.9	2.7	17.2
	MV	108	-13.5	1.1	8.1	0	0	0.8[d]	5.7[c]	NA[c]	NA[c]	0.8	6.2	1.8	13.5	2.4	17.9
V. parahaemolyticus Mod Pos	MP	108	16.2	1.1	6.7	0	0	0.8[d]	5.1[c]	NA[c]	NA[c]	0.2	1.5	2.2	13.4	2.6	15.9
	MV	108	-14.1	0.9	6.2	0	0	0.8[d]	5.6[c]	NA[c]	NA[c]	0.1	0.8	2	14.1	2.3	16.4

Abbreviations: Ct, cycle threshold; CV, coefficient of variation; Low Pos, low positive ~1x LoD; MP, melt peak; Mod Pos, moderate positive ~3xLoD; MV, melt valley; SD, standard deviation

[a] One sample excluded due to a non-determinate result.

[b] One sample excluded due to negative *Yersinia* result with missing melt peak and melt valley values.

[c] In the Panel 3 study, the variation of lot and day are confounded and cannot be separated. Therefore, the values in the lot column represent the combined variance of both lot and day for *Vibrio parahaemolyticus* samples.

Expected Values

Expected values for each analyte as determined by Xpert GI Panel in prospectively collected fresh specimens from individuals suspected of gastrointestinal infection stratified by age group (years) are presented in **Table 22**.

The number and percentage of positive cases per analyte calculated for each age group are presented in **Table 22**.

Table 22. Expected Values per Analyte by Age Group in Prospective Specimens as Determined by the Xpert GI Panel

Analyte	Overall[a]	<18 years	18-21 years	22-49 years	50-64 years	≥65 years
Campylobacter	4.3% (67/1568)	5.9% (11/185)	17.2% (5/29)	4.6% (18/394)	3.9% (13/336)	3.2% (20/624)
Salmonella	3.3% (51/1568)	6.5% (12/185)	6.9% (2/29)	4.1% (16/394)	3.3% (11/336)	1.6% (10/624)
V. parahaemolyticus	0.0% (0/1505)	0.0% (0/179)	0.0% (0/29)	0.0% (0/377)	0.0% (0/321)	0.0% (0/599)
V. cholerae	0.1% (1/1568)	0.0% (0/185)	0.0% (0/29)	0.3% (1/394)	0.0% (0/336)	0.0% (0/624)
Yersinia	1.6% (25/1568)	2.2% (4/185)	0.0% (0/29)	1.0% (4/394)	1.5% (5/336)	1.9% (12/624)
Shigella EIEC	2.4% (38/1568)	3.2% (6/185)	0.0% (0/29)	4.3% (17/394)	2.4% (8/336)	1.1% (7/624)
STEC *stx1*	0.4% (6/1497)	0.6% (1/173)	0.0% (0/25)	0.3% (1/374)	0.6% (2/320)	0.3% (2/605)

Analyte	Overall[a]	<18 years	18-21 years	22-49 years	50-64 years	≥65 years
STEC *stx2*	0.2% (3/1497)	0.0% (0/173)	0.0% (0/25)	0.0% (0/374)	0.3% (1/320)	0.3% (2/605)
Cryptosporidium	2.2% (34/1568)	5.4% (10/185)	0.0% (0/29)	3.8% (15/394)	2.1% (7/336)	0.3% (2/624)
Giardia	1.5% (24/1568)	1.6% (3/185)	0.0% (0/29)	3.8% (15/394)	0.9% (3/336)	0.5% (3/624)
Norovirus	4.7% (72/1521)	7.2% (13/181)	0.0% (0/29)	5.0% (19/381)	3.4% (11/327)	4.8% (29/603)

[a] Includes prospectively collected clinical specimens with valid results for both the Xpert GI Panel and the comparator method. Each denominator in this column shows the number of specimens included by analyte. For analytes where the comparator method was a composite of 3 FDA-cleared NAATs, specimens with valid results for Xpert GI Panel and NAAT 1 were included.

Expected Values for Analytes in Multi-analyte Detections

The prevalence of multi-analyte combinations detected by the Xpert GI Panel is presented in **Table 23**. The Xpert GI Panel detected a total of 25 specimens with co-detections among the 1429 prospectively collected specimens with valid test results for all 11 analytes by both Xpert GI Panel and the comparator method. This represents 1.7% of all prospectively collected specimens with valid test results for all 11 analytes.

Table 23. Expected Values for Analytes in Multi-analyte Detections by Xpert GI Panel

Multianalyte Detection Combinations[a]	Number of Specimens with Mixed Infections (n/N)	Prevalence of Mixed infections (%)
Cryptosporidium and Norovirus	1/25	4.0%
Cryptosporidium and *Giardia*	1/25	4.0%
Yersinia and Norovirus	2/25	8.0%
Shigella EIEC and Norovirus	2/25	8.0%
Shigella EIEC and *Giardia*	1/25	4.0%
STEC *stx1* and *Cryptosporidium*	1/25	4.0%
STEC *stx1* and *Shigella* EIEC	1/25	4.0%
STEC *stx1* and STEC *stx2*	1/25	4.0%
Salmonella and Norovirus	2/25	8.0%
Salmonella, *Giardia*, and Norovirus	1/25	4.0%
Salmonella and *Yersinia*	1/25	4.0%
Salmonella, STEC *stx1*, and STEC *stx2*	1/25	4.0%
Campylobacter and Norovirus	2/25	8.0%
Campylobacter and *Cryptosporidium*	1/25	4.0%
Campylobacter and *Yersinia*	2/25	8.0%
Campylobacter and *Shigella* EIEC	3/25	12.0%
Campylobacter, *Shigella* EIEC, and Norovirus	1/25	4.0%
Campylobacter and *Salmonella*	1/25	4.0%

[a] Includes 1429 specimens with valid test results for all 11 target analytes by both Xpert GI Panel and comparator method. For analytes where the comparator method was a composite of 3 FDA-cleared NAATs, specimens with valid results for Xpert GI Panel and NAAT 1 were included.

1.4.2. Clinical Performance

The clinical performance of the Xpert GI Panel was evaluated in a multicenter study at nineteen (19) geographically diverse clinical sites within (13) and outside (6) of the United States. Clinical specimens were prospectively collected between July 2023 and December 2023. The clinical study utilized leftover, de-identified stool specimens in Cary Blair media collected from individuals suspected of GI infection.

A total of 1658 prospectively collected fresh stool specimens in Cary Blair media were initially enrolled in the study of which 66 did not meet eligibility criteria and were excluded. All clinical specimen testing (initial and repeat runs) using the Xpert GI Panel were performed by trained operators at 14 clinical testing sites.

Due to the low prevalence observed for specific analytes in the prospective study cohort, the sample size for this study was supplemented with pre-selected archived specimens sourced from sites within the United States. To minimize bias, pre-selected specimens were randomized and tested in a blinded manner at 5 of the 19 clinical sites. Pre-selected specimens were identified by standard of care results and confirmed using comparator test results prior to testing with the Xpert GI Panel. Of the pre-selected specimens, 45 were excluded from the analysis of clinical performance because specific analyte results on the comparator test could not be confirmed. Therefore, a total of 103 pre-selected specimens were included in the clinical performance analysis. In addition, if sufficient prospective and pre-selected archived specimens were not obtained for specific analytes, the sample size was supplemented with contrived samples for those analytes.

Overall initial and final non-determinant rates for this study were 3.4% (74/2150) and 0.2% (4/2150), respectively.

Prospective Specimens

Demographic information (sex, age, and healthcare setting) of the eligible prospective specimens is presented in **Table 24**.

Table 24. Demographic Information of Eligible Prospective Specimens

Prospectively Collected Fresh Specimens (N=1592)	Number of Specimens (%)
Sex	
Female	907 (57.0%)
Male	685 (43.0%)
Age (years)	
<18	187 (11.7%)
18-21	29 (1.8%)
22-49	398 (25.0%)
50-64	344 (21.6%)
>=65	634 (39.8%)
Healthcare Setting	
ER Patient	133 (8.4%)

Inpatient/Hospitalized	338 (21.2%)
Outpatient	569 (35.7%)
Unknown	552 (34.7%)

A total of 1658 prospective fresh specimens were enrolled with 1592 specimens deemed eligible for inclusion in the study. Of the 1592 prospective fresh specimens eligible for the study, 13 were excluded due to problems with sample shipping, testing not completed per Xpert GI Panel instructions for use, or a valid external control not completed on the day of testing.

Of the 1579 eligible prospective fresh specimens, 33 (2.1%, 33/1579) specimens yielded a non-determinate result on the Xpert GI Panel on the initial test. After retest, 4 (0.3%, 4/1579) specimens yielded a non-determinate result. A total of 1575 prospective specimens yielded valid results by Xpert GI Panel.

The clinical performance of each Xpert GI Panel analyte was compared to those of an FDA cleared molecular assay for most analytes. A composite of three FDA-cleared molecular assays was used for *Campylobacter* and *Yersinia.* Specimens were considered positive if at least two of the three comparator assays had positive results. Specimens were considered negative if at least two of three comparator assays had negative results. A composite of PCR assays followed by bi-directional sequencing was used for Norovirus. For STEC *stx1*, STEC *stx2*, and *V. parahaemolyticus* analytes, if the FDA cleared molecular assay was positive, a second FDA cleared molecular assay was performed to provide species differentiation. Specimens with discrepant results were investigated on an independent FDA cleared molecular assay. For each analyte in the Xpert GI Panel, the performance (Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), and the 95% confidence interval (CI)) of the Xpert GI Panel as compared to the comparator method in prospective specimens is presented in **Table 25**. The number of specimens included in the performance calculations for each analyte were based on availability of valid results for Xpert GI Panel and the comparator method for the analyte and are presented in **Table 25**.

Table 25. Clinical Performance of Xpert GI Panel in Prospectively Collected Specimens

Analyte	Total	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP+FN)	%	95%CI	TN/(TN+FP)	%	95%CI
Campylobacter	604	62/66[a]	93.9	85.4 - 97.6	533/538[a]	99.1	97.8 - 99.6
Salmonella	1568	49/54[b]	90.7	80.1 - 96.0	1512/1514	99.9	99.5 - 100.0
V. parahaemolyticus	1505	0/0	N/A	N/A	1505/1505	100.0	99.7 - 100.0
V. cholerae	1568	0/1[c]	0	0.0 - 79.3	1566/1567[c]	99.9	99.6 - 100.0
Yersinia	603	15/15	100.0	79.6 - 100.0	578/588[d]	98.3	96.9 - 99.1
Shigella EIEC	1568	34/37[e]	91.9	78.7 - 97.2	1527/1531[e]	99.7	99.3 - 99.9
STEC *stx1*	1497	6/6	100.0	61.0 - 100.0	1491/1491	100.0	99.7 - 100.0
STEC *stx2*	1497	2/2	100.0	34.2 - 100.0	1494/1495	99.9	99.6 - 100.0
Cryptosporidium	1568	32/32	100.0	89.3 - 100.0	1534/1536[f]	99.9	99.5 - 100.0
Giardia	1568	20/21[g]	95.2	77.3 - 99.2	1543/1547[g]	99.7	99.3 - 99.9
Norovirus GI/GII	1521	46/47	97.9	88.9 - 99.6	1448/1474	98.2	97.4 - 98.8

Abbreviations: CI, confidence interval; FN, false negative; FP, false positive; N/A, not available; NAAT, Nucleic Acid Amplification Test; NPA, negative percent agreement; PPA, positive percent agreement; TN, true negative; TP, true positive

[a] Of 4 specimens with FN *Campylobacter* results, 4 were positive by all 3 comparator NAAT tests. Of 5 specimens with FP *Campylobacter* results, 2 were negative by all 3 comparator NAAT tests and 3 were positive by only 1 of the 3 comparator NAATs. The sample size for NPA is smaller for *Campylobacter* as only a portion of the samples with negative results by Xpert GI Panel and NAAT 1 was tested with the complete composite comparator.

[b] Of 5 specimens with FN *Salmonella* results, 3 were also negative and 2 were not evaluable by the discrepant (NAAT 2).

[c] One specimen with FN *V. cholerae* was also negative by both discrepant tests (NAAT 2 and NAAT 4). One specimen with FP *V. cholerae* was negative by both discrepant tests (NAAT 2 and NAAT 4).

[d] Of 10 specimens with FP *Yersinia* results, 6 were negative by all 3 comparator NAATs and 4 were positive by only 1 of the 3 comparator NAATs. The sample size for NPA is smaller for *Yersinia* because only a portion of the samples with negative results by Xpert GI Panel and NAAT 1 was tested with the complete composite comparator.

[e] Of 3 specimens with FN *Shigella* EIEC results, 1 was also negative, 1 was positive, and 1 was not evaluable by the discrepant test (NAAT 2). Of 4 FP *Shigella* EIEC results, 1 was also positive, 2 were negative, and 1 was not evaluable by the discrepant test (NAAT 2).

[f] Of 2 specimens with FP *Cryptosporidium* results, both specimens were not evaluable by the discrepant test (NAAT 2).

[g] One specimen with FN *Giardia* result was also negative by the discrepant test (NAAT 2). Of 4 specimens with FP *Giardia* results, 3 were negative and 1 was not evaluable by the discrepant test (NAAT 2).

Multianalyte Detection - Mixed Infections

Table 26 presents only the number of specimens with multi-analyte detection by Xpert GI Panel. Each combination is listed, along with the total number of occurrences observed, and the number of instances where Xpert results for a given analyte were discrepant relative to the comparator.

Table 26. Multi-analyte Combinations Detected by Xpert GI Panel

Analyte 1	Analyte 2	Analyte 3	N of co-infections	N of discrepant co-	Discrepant analyte(s)
Cryptosporidium	Norovirus	N/A	1	1	Norovirus
Cryptosporidium	*Giardia*	N/A	1	0	N/A
Yersinia	Norovirus	N/A	2	2	Specimen 1: *Yersinia,* Norovirus; Specimen 2: *Yersinia,* Norovirus, *Shigella* EIEC [a]
Shigella EIEC	Norovirus	N/A	2	1	*Shigella* EIEC, Norovirus
Shigella EIEC	*Giardia*	N/A	1	1	*Shigella* EIEC
STEC *stx1*	*Cryptosporidium*	N/A	1	0	N/A
STEC *stx1*	*Shigella* EIEC	N/A	1	0	N/A
STEC *stx1*	STEC *stx2*	N/A	1	0	N/A
Salmonella	Norovirus	N/A	2	0	N/A
Salmonella	*Giardia*	Norovirus	1	1	Norovirus
Salmonella	*Yersinia*	N/A	1	0	N/A
Salmonella	STEC *stx1*	STEC *stx2*	1	0	N/A
Campylobacter	Norovirus	N/A	2	1	Norovirus
Campylobacter	*Cryptosporidium*	N/A	1	0	N/A
Campylobacter	*Yersinia*	N/A	2	0	N/A
Campylobacter	*Shigella* EIEC	N/A	3	1	*Campylobacter*
Campylobacter	*Shigella* EIEC	Norovirus	1	1	*Campylobacter,* Norovirus
Campylobacter	*Salmonella*	N/A	1	0	N/A
Total co-infections			25	9	N/A
Co-detection with 2 Analytes			22	7	
Co-detection with 3 Analytes			3	2	

[a] For specimen 2, *Yersinia* and Norovirus were not detected by the comparator method and *Shigella* EIEC was detected by the comparator method.

Of the 25 specimens with multi-analyte detections by Xpert GI Panel, 16 (64%; 16/25) agreed with the comparator. A total of 9 specimens (36%; 9/25) contained one or more analytes that were not concordant with the comparator test method.

Pre-selected Archived Specimens

Demographic information (sex, age, and healthcare setting) of the eligible pre-selected archived specimens is presented in **Table 27**.

Table 27. Demographic Information of Eligible Pre-selected Archived Specimens

Frozen Archived Specimens (N=103)	Number of Specimens (%)
Sex	
Female	51 (49.5%)
Male	52 (50.5%)
Age (years)	
<18	3 (2.9%)
18-21	2 (1.9%)
22-49	39 (37.9%)
50-64	21 (20.4%)
>=65	38 (36.9%)
Healthcare Setting	
ER Patient	21 (20.4%)
Inpatient/Hospitalized	14 (13.6%)
Outpatient	25 (24.3%)
Unknown	43 (41.7%)

Archived specimens (n=103) were pre-selected for *Salmonella*, *Shigella* EIEC, *Cryptosporidium*, *Giardia*, and Norovirus and deemed eligible for inclusion in the study. Out of the 103 eligible pre-selected archived specimens, 1 (1.0%; 1/103) specimen yielded a non-determinate result on the Xpert GI Panel on the initial test. After retest, no (0%; 0/103) specimens yielded a non-determinate result. A total of 103 pre-selected archived specimens with valid Xpert and comparator results were included in the performance evaluation.

The clinical performance of each Xpert GI Panel analyte was compared to that of an FDA cleared molecular assay and/or a composite of 2 PCR assays followed by bi-directional sequencing. Specimens with discrepant results were investigated on an independent FDA cleared molecular assay. For each analyte in the Xpert GI Panel, the performance (Positive Percent Agreement (PPA), Negative Percent Agreement (NPA), and the 95% confidence interval (CI)) of the Xpert GI Panel as compared to the comparator method in pre-selected archived specimens is presented in **Table 28**.

Table 28. Clinical Performance of Xpert GI Panel in Pre-selected Archived Specimens

Analyte	Total	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP+FN)	%	95%CI	TN/(TN+FP)	%	95%CI
Salmonella	68	6/7[a]	85.7	48.7 - 97.4	61/61	100.0	94.1 - 100.0
Shigella EIEC	68	15/15	100.0	79.6 - 100.0	52/53[b]	98.1	90.1 - 99.7
Cryptosporidium	68	3/4[c]	75.0	30.1 - 95.4	64/64	100.0	94.3 - 100.0
Giardia	68	13/13	100.0	77.2 - 100.0	55/55	100.0	93.5 - 100.0
Norovirus GI/GII	35	17/17	100.0	81.6 - 100.0	18/18	100.0	82.4 - 100.0

Abbreviations: CI, confidence interval; FN, false negative; FP, false positive; N/A, not available; NAAT, Nucleic Acid Amplification Test; TN, true negative; TP, true positive

[a] One specimen with FN *Salmonella* result was also negative by the discrepant test (NAAT 2).

[b] One specimen with FP *Shigella* EIEC result was negative by the discrepant test (NAAT 2).

[c] One specimen with FN *Cryptosporidium* result was also negative by the discrepant test (NAAT 2).

Contrived Samples

A total of 468 contrived samples were included in the study to supplement the sample size due to low prevalence for *V. parahaemolyticus*, *V. cholerae*, *Yersinia*, *Shigella* EIEC, STEC *stx1*, STEC *stx2*, *Cryptosporidium*, and *Giardia* in clinical specimens. The contrived samples were prepared by spiking representative strains (multiple strains per pathogen) at concentrations ranging from <3x the analytical limit of detection (LoD) to >800x LoD into unique negative clinical stool matrix that were confirmed negative by the Xpert GI Panel prior to preparation. Approximately 50% of the contrived positive samples were manufactured at concentrations up to 7x LoD, while the remaining positive samples spanned clinically relevant concentrations greater than 7x LoD. A total of 65 *V. parahaemolyticus*, 65 *V. cholerae*, 45 *Yersinia*, 15 *Shigella* EIEC, 65 STEC *stx1*, 65 STEC *stx2*, 32 *Cryptosporidium*, and 35 *Giardia* positive samples were contrived and tested with 81 negative samples in a blinded fashion.

Out of the 468 eligible contrived samples, 40 (8.5%; 40/468) samples yielded a non-determinate result on the Xpert GI Panel on the initial test. After retest, no (0%, 0/468) samples yielded a non-determinate result. A total of 468 contrived samples with valid Xpert were included in the performance evaluation

The performance of the Xpert GI Panel in contrived samples was calculated relative to the expected result and presented in **Table 29**.

Table 29. Performance of Xpert GI Panel in Contrived Samples

Analyte	Total	Positive Percent Agreement				Negative Percent Agreement			
		TP	FN	PPA (%)	95%CI	TN	FP	NPA (%)	95%CI
V. parahaemolyticus	146	63	2[a]	96.9	89.5 - 99.2	81	0	100.0	95.5 - 100.0
V. cholerae	146	65	0	100.0	94.4 - 100.0	81	0	100.0	95.5 - 100.0
Yersinia	126	45	0	100.0	92.1 - 100.0	81	0	100.0	95.5 - 100.0
Shigella EIEC	96	15	0	100.0	79.6 - 100.0	81	0	100.0	95.5 - 100.0
STEC *stx1*	146	65	0	100.0	94.4 - 100.0	81	0	100.0	95.5 - 100.0
STEC *stx2*	146	65	0	100.0	94.4 - 100.0	81	0	100.0	95.5 - 100.0
Cryptosporidium	113	32	0	100.0	89.3 - 100.0	81	0	100.0	95.5 - 100.0
Giardia	116	35	0	100.0	90.1 - 100.0	81	0	100.0	95.5 - 100.0

Analyte	Total	Positive Percent Agreement				Negative Percent Agreement			
		TP	FN	PPA (%)	95%CI	TN	FP	NPA (%)	95%CI

Abbreviations: CI, confidence interval; FN, false negative; FP, false positive; NPA, negative percent agreement; PPA, positive percent agreement; TN, true negative; TP, true positive

[a] Of 2 specimens with FN *V. parahaemolyticus* results, both were contrived samples spiked with the same strain that were not detected. It is possible that variability in test performance was due to variability of the clinical stool matrix composition.

1.5. Conclusions

The results of the analytical and clinical performance studies summarized above demonstrated that the Xpert GI Panel test is substantially equivalent to the predicate device.