



Instructions for Use

Xpert® GI Panel

For use with GeneXpert® System with Touchscreen



Catalog Numbers

REF GXGI-10

303-4456 | Rev A | 2026-01

In Vitro Diagnostic Medical Device



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See [Revision History](#) for a description of changes.

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Getting Started

Product Information

Proprietary Name

Xpert® GI Panel

Common or Usual Name

Xpert GI Panel

Intended Use, Summary, and Principle of Procedure

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	<i>Campylobacter</i> (<i>C. jejuni</i> / <i>C. coli</i>)	<i>Campylobacter</i>
	Shiga toxin-producing <i>Escherichia coli</i> (STEC) <i>stx1/stx2</i>	STEC <i>stx1</i>
		STEC <i>stx2</i>
	<i>Salmonella</i>	<i>Salmonella</i>
	<i>Shigella</i> /Enteroinvasive <i>Escherichia coli</i>	<i>Shigella</i> EIEC
	<i>Yersinia enterocolitica</i>	<i>Yersinia</i>
	<i>Vibrio parahaemolyticus</i>	<i>V. parahaemolyticus</i>
Parasites	<i>Vibrio cholerae</i>	<i>V. cholerae</i>
	<i>Giardia</i> (also known as <i>G. intestinalis</i> , <i>G. duodenalis</i> & <i>G. lamblia</i>)	<i>Giardia</i>



Pathogens Detected		Pathogens Reported
	<i>Cryptosporidium</i>	<i>Cryptosporidium</i>
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.

Summary and Explanation

Gastrointestinal infections remain a significant problem globally for all age groups. It is a leading cause of outpatient visits and hospitalizations and is known to cause a decrease in the quality of life worldwide. Acute diarrheal infections are a common health issue globally and among individuals in the United States (US). In the US alone there are over 48 million cases of foodborne diseases, resulting in over 128,000 hospitalizations and 3,000 deaths per year. According to the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) there are about two billion cases of diarrheal disease worldwide every year and 1.9 million children under the age of 5 years old succumb to diarrheal infections each year. It is estimated that 9% of all deaths, of children under the age of five, are caused by acute diarrheal infections, with more than 1,200 children dying each day as a result. Of all the childhood related deaths from diarrhea, 78% occur in South-East Asian and African regions. The Xpert GI Panel test will simultaneously test for eleven of the most common pathogens ([Table 1](#)) directly from stool in Cary Blair medium.

Principle of the Procedure

The Xpert GI Panel test is an automated *in vitro* diagnostic test for qualitative detection and differentiation of 11 pathogens ([Table 1](#)). The test is performed on Cepheid GeneXpert Instrument Systems equipped with GeneXpert 10-color modules.

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 templates into DNA) followed by real-time PCR and melt curve analysis. The primers and probes in the Xpert GI Panel test are designed to amplify and detect unique sequences in the genes of the detected pathogens ([Table 1](#)). The test is performed on Cepheid GeneXpert Instrument Systems equipped with GeneXpert 10-color modules.

The system consists of an instrument, Touchscreen unit, and preloaded software for running tests and viewing the results. The system requires the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the system, refer to the *GeneXpert System with Touchscreen Operator Manual*.

The Xpert GI Panel test includes reagents for the detection of DNA or RNA from pathogens (listed in [Table 1](#)) in stool in Cary Blair media specimens. 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 the RNA targets and monitor the presence of inhibitor(s) in the PCR reactions. 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 following pathogens will be detected using melt curve analysis: *Campylobacter*, *Yersinia*, STEC *stx1*, STEC *stx2*, *V. cholerae* and *V. parahaemolyticus*, and the remaining targets are detected by amplification analysis ([Table 1](#)).



The stool specimen is collected and transferred to Cary Blair medium according to the Cary Blair manufacturer's instructions or institutional guidelines. If the incoming material to the lab is raw stool, the laboratory personnel can transfer raw stool into Cary Blair medium per Cary Blair supplier's package insert or institutional guidelines.

The stool specimen in Cary Blair medium will be mixed thoroughly. The user will then dip a transfer swab (provided) for 5 seconds into the specimen and then transfer the inoculated swab into the sample chamber of the Xpert GI Panel cartridge. The user will break the swab by snapping the shaft against the notch in the sample chamber opening leaving the swab tip in the sample chamber and closing the cartridge lid. The Xpert GI Panel cartridge is then loaded onto the GeneXpert instrument, which performs hands-off automated sample processing and real-time PCR for detection of the target DNA/RNA. After the melt curve analysis, software automatically calculates the melt peak temperature and melt peak height of the pathogens detected using melt curve analysis. Summary and detailed test results are obtained in approximately 74 minutes.

Table 1. Pathogens Detected by Xpert GI Panel

	Pathogen Detected	Reported Analyte Name	Detection Method
Bacteria	<i>Campylobacter</i> (<i>C. jejuni/C. coli</i>)	Campylobacter	Melt curve analysis
	Shiga toxin-producing <i>Escherichia coli</i> (STEC) <i>stx1/stx2</i>	STEC <i>stx1</i>	Melt curve analysis
		STEC <i>stx2</i>	Melt curve analysis
	<i>Salmonella</i>	Salmonella	Amplification analysis
	<i>Shigella/Enteroinvasive Escherichia coli</i>	Shigella EIEC	Amplification analysis
	<i>Yersinia enterocolitica</i>	Yersinia	Melt curve analysis
	<i>Vibrio parahaemolyticus</i>	<i>V. parahaemolyticus</i>	Melt curve analysis
Parasites	<i>Vibrio cholerae</i>	<i>V. cholerae</i>	Melt curve analysis
	<i>Giardia</i> (also known as <i>G. duodenalis</i> , <i>G. lamblia</i> and <i>G. intestinalis</i>)	Giardia	Amplification analysis
Virus	<i>Cryptosporidium</i>	Cryptosporidium	Amplification analysis
	Norovirus GI/GII	Norovirus	Amplification analysis

Reagents, Instruments, and Materials

Reagents

Materials Provided

The Xpert GI Panel test kit (GXGI-10) contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

Xpert GI Panel Panel Cartridges with Integrated Reaction Tubes 10 per kit

Bead 1, Bead 2, Bead 3, Bead 4, and Bead 5 (freeze-dried)	1 of each per cartridge
Lysis Reagent	1.4 mL per cartridge
Wash Reagent	2.5 mL per cartridge
Rinse Reagent	0.48 ml per cartridge
Elution Reagent	1.5 ml per cartridge

Disposable Transfer Swabs 10 per kit

Flyer (with instructions to website location) for: **1 per kit**

- Assay Definition File (ADF)
- Instructions to import ADF into GeneXpert software
- Instructions for Use

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **Support** tab.

Note The protein stabilizer of bovine origin in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post-mortem testing. During processing, there was no mixing of the material with other animal materials.

Materials Required but Not Provided

Specimen Collection Devices

- Stool specimens must be collected and transferred into Cary Blair media.



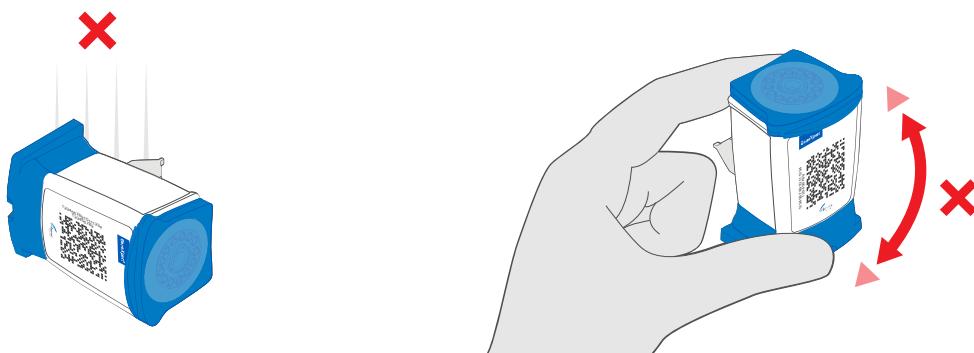
Instruments and Software

GeneXpert® Instrument Systems family of instruments, including GeneXpert Dx systems, GeneXpert Infinity systems and GeneXpert System with Touchscreen (catalog number varies by configuration).

- Instrument-associated computer or touchscreen with proprietary software, hand-held barcode scanner, and instrument operator manual
 - For GeneXpert Dx systems: GeneXpert Dx software version 6.4 or higher (use IFU PN 303-4454)
 - For GeneXpert Infinity systems: Xpertise software version 7.1 or higher (use IFU PN 303-4454)
 - For GeneXpert System with Touchscreen: Cepheid OS software version 2.1 or higher (use IFU PN 303-4456)
- Printer: If a printer is needed, contact Cepheid Technical Support to arrange for the purchase of a recommended printer.

Warning and Precautions

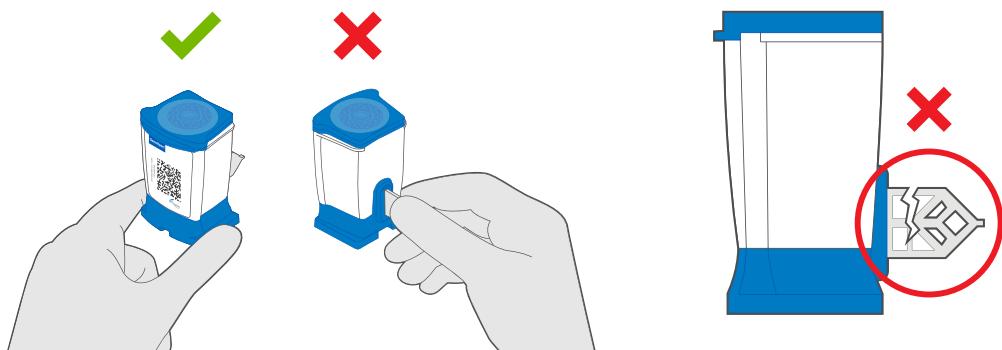
- For *In Vitro* diagnosis use
- For prescription use only
- Do not use a cartridge that has been dropped after removing from the kit or that has been shaken after the cartridge lid has been opened. Shaking or dropping the cartridge after opening the lid may yield false or non-determinate results.



- Do not place the sample ID label on the cartridge lid or on the barcode label.



- Hold the cartridge by the base. Do not touch the reaction tube at the rear of the cartridge as this could cause damage that would interfere with light passing through it during the test. Do not use a cartridge with a damaged reaction tube.



- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions.
- Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention¹ and the Clinical and Laboratory Standards Institute.²
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures. If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.
- Specimen collection and handling procedures require specific training and guidance.
- Cary Blair Medium for collection, transport and/or transfer of stool specimens.
- Specimens must be collected and tested before the expiration date of the Cary Blair Medium.
- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see [Specimen Collection Transport and Storage](#)). Specimen stability under shipping conditions other than those recommended has not been evaluated.
- Do not substitute Xpert GI Panel reagents with other reagents.
- Do not open the Xpert GI Panel cartridge lid except when adding sample.
- Do not use a cartridge that has a damaged reaction tube.
- Each single-use Xpert GI Panel cartridge is used to process one test. Do not reuse spent cartridges.
- A single-use disposable transfer swab is used to transfer one specimen. Do not reuse spent disposable swabs.
- Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.
- Good laboratory practices, including changing gloves between handling patient specimens, are recommended to avoid contamination of specimens or reagents.
- In the event of specimens spilling, wear gloves and absorb the spill with paper towels. In the case of known or suspected *Cryptosporidium* or *Giardia*-containing samples, cover the spill area with paper towels and flood with 3% hydrogen peroxide. Allow a minimum of 20 minutes of contact time. Wipe the area dry.³ If *Cryptosporidium* or *Giardia*-containing samples are not suspected, thoroughly clean the contaminated area with a 1:10 dilution of freshly prepared household chlorine bleach. Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country. Allow a minimum of five minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution's standard procedures for a contamination or spill event. For equipment, follow the manufacturer's recommendations for decontamination of equipment.



Chemical Hazards, Storage and Handling

Chemical Hazards^{4,5}

- GHS UN Hazard Pictogram: 
- **Signal Word:** WARNING
- **GHS UN Hazard Statements**
 - Causes skin irritation
 - Causes serious eye irritation
- **Precautionary Statements**
 - Wash hands, forearms, and face thoroughly after handling.
 - Wear protective gloves, protective clothing, eye and face protection
 - IF ON SKIN: Wash with plenty of water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 - Specific treatment (see supplemental first aid instruction on Safety Data Sheet).
 - If skin irritation occurs: Get medical advice or attention.
 - If eye irritation persists: Get medical advice or attention.
 - Take off contaminated clothing and wash it before reuse.

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **Support** tab.

Storage and Handling

- Store the Xpert GI Panel cartridges at 2–28 °C until the expiration date provided on the label.
- If refrigerated, it is recommended to equilibrate the cartridge to room temperature (15-25 °C) before use
- Do not open a cartridge until you are ready to perform testing.
- Do not use cartridges that have passed the expiration date.
- Do not use a cartridge that has leaked.

Specimen Collection, Testing, and Results

Specimen Collection

Specimen Collection Transport and Storage

Specimens should be transferred into Cary Blair media following the Cary Blair manufacturer's instructions or institutional guidelines. Specimens should be tested with the Xpert GI Panel as soon as possible. Specimens can be transported and stored refrigerated (2–8 °C) up to four days until testing is performed on the GeneXpert or up to 24 hours at room temperature (15–25 °C).

Proper specimen collection, storage, and transport are critical to the performance of this test. Specimen stability under shipping and storage conditions other than those listed above have not been evaluated with the Xpert GI Panel test.

Procedure

Preparing the Cartridge

Operators should receive training on basic operation of the GeneXpert instrument and Xpert test(s) in accordance with their institution's guidelines.

i Important Start the test within 30 minutes of adding the sample to the cartridge.

1. Obtain the following items: Xpert cartridge, transfer swab (provided), and an appropriately collected and labeled test sample.
2. Remove a cartridge from the package (it is recommended to equilibrate the cartridge to room temperature [15–25 °C] before use).
3. Inspect the cartridge for damage. If damaged or has signs of leakage, do not use it.
4. Label the cartridge with specimen identification. Write on the side of the cartridge or affix an ID label. Do not put the label on the lid of the cartridge or over the existing 2D barcode on the cartridge.
5. Mix thoroughly until sample fully homogenized. Vortex can be used.
6. Open the cartridge by lifting the lid.
7. Remove the transfer swab from the wrapper.



8. Dip the transfer swab for approximately 5 seconds into the sample and place the inoculated swab into the sample chamber of the Xpert GI Panel cartridge.
9. Break the swab (at the break point) by snapping the shaft against the notch in the sample chamber opening (see [Figure 1](#)) leaving the swab tip in the sample chamber. There should not be any piece of the swab sticking out of the sample chamber.

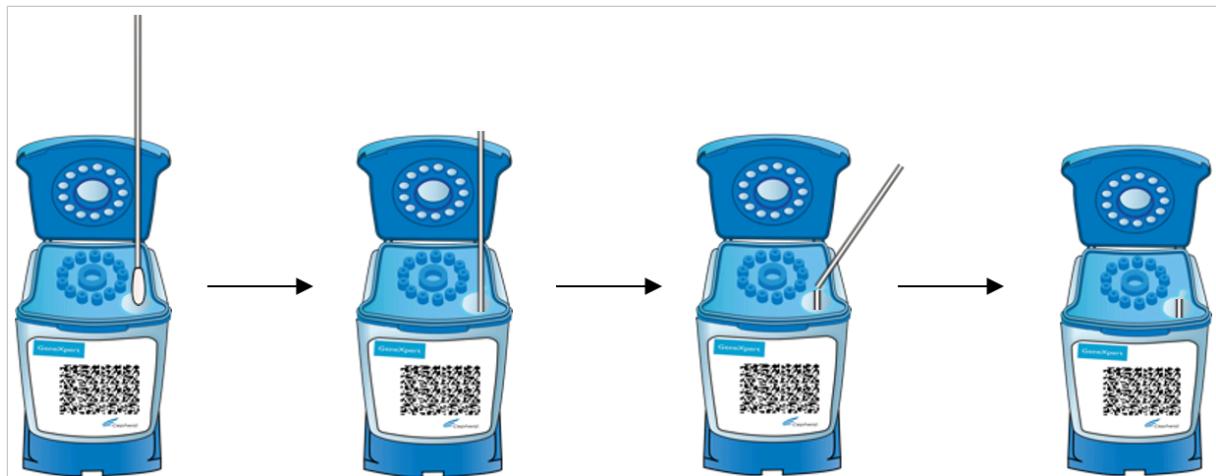


Figure 1 Xpert GI Panel Test Cartridge

10. Close the cartridge lid.

Starting the Test: GeneXpert System with Touchscreen

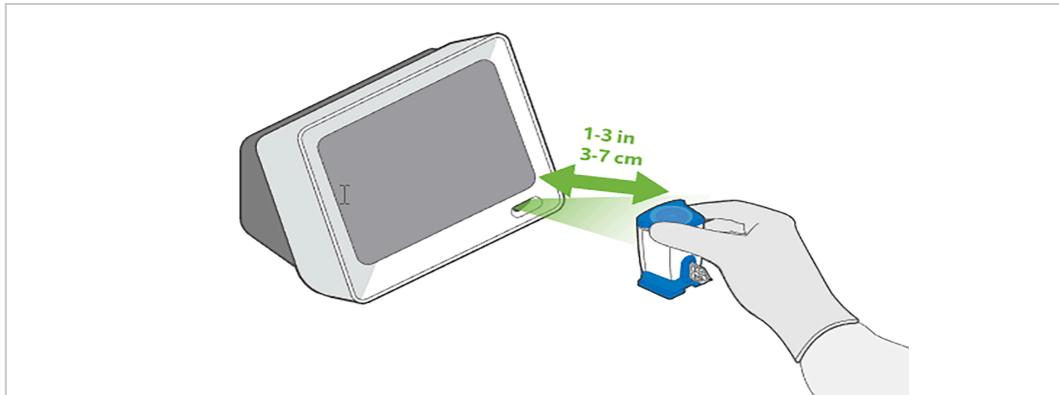


Important Before you start the test, make sure that:

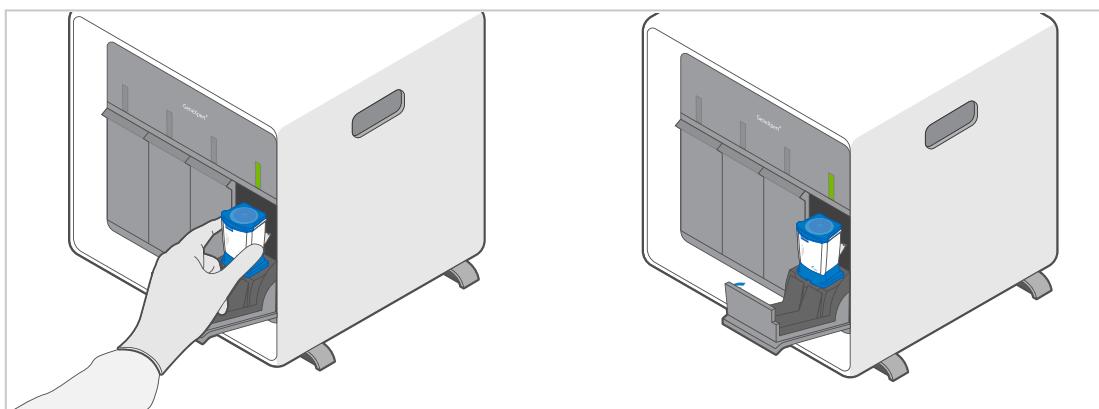
- The system is running the correct Cepheid OS software version shown in section - [Materials Required but Not Provided](#).
- The correct assay definition file is imported into the software.

Note The default workflow is shown. Your system administrator may alter the workflow.

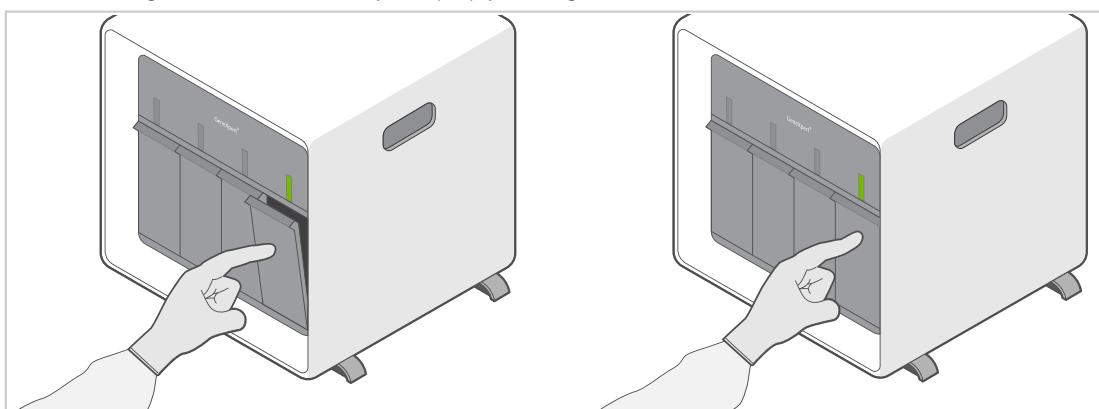
1. Turn on GeneXpert system with touchscreen.
2. Log on to system software using your username and password.
3. On the Modules tab, touch **Start Test**.
4. Follow onscreen prompts to create new test and enter patient and sample information.
5. Scan or manually input the cartridge serial number. If scanning, hold the cartridge about 1-3 inches (3-7 cm) away from the scanner. The scanner projects a green crosshair, which you center on the barcode. Scanning is complete when you hear an audible beep. Touch **Continue**.



6. Select the desired test and touch **Continue**.
7. Watch the cartridge preparation video, if needed.
8. On the **Confirm** screen, review all data and touch **Confirm**.
9. Open the module door under flashing green light and insert the cartridge.



10. Close cartridge module door completely by pressing until it latches. The test starts.



11. When the test completes, the **Results Summary** screen appears. Open the module door and remove cartridge.
12. Dispose of used cartridge in appropriate waste container according to your institution's standard practices.



Viewing Results: GeneXpert System with Touchscreen

The GeneXpert System with Touchscreen results screen will automatically interpret test results for you and clearly show them in the **View Results** window.

1. Tap **Results**.
2. Tap the test to be viewed in the Results screen.
3. Click **OK**.
4. To generate a PDF report file, touch **View Report**. More detailed instructions for viewing and uploading results are available in your system operator manual.

Quality Control

Each test includes a Sample Processing Control (SPC) (in the view result screen for the administrative level user), an Internal Control (IC), and a Probe Check Control (PCC).

- **Sample Processing Control (SPC)** — The SPC is included in each cartridge to ensure that the sample was processed correctly. The SPC verifies the lysis of hard to lyse pathogens (parasites and bacteria) if the pathogens are present and that sample processing is adequate. Additionally, this control ensures that the PCR reaction conditions (temperature and time) are appropriate for the amplification reaction, and that the PCR reagents are functional. The SPC also acts as a control for functionality of melt curve analysis. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria. The test result is **INVALID** if all targets are reported negative and the SPC does not meet the assigned acceptance criteria.
- **Internal Control (IC)** — The IC is an RNA control included in each cartridge to verify adequate processing of the sample. The IC verifies the release of RNA from the sample and that the sample processing is adequate. Additionally, this control detects specimen-associated inhibition of the reverse transcription and PCR reactions. The IC should be positive in a negative sample and can be negative or positive in a positive sample. The IC passes if it meets the validated acceptance criteria. The test result is **INVALID** if all targets are reported negative and the IC does not meet the assigned acceptance criteria.
- **Probe Check Control (PCC)** — Before the start of the PCR reaction, the GeneXpert Instrument Systems measure the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The Probe Check passes if it meets the assigned acceptance criteria.
- **External Controls** — External controls may be used in accordance with local, state, and federal accrediting organizations, as applicable.

Results

The results are interpreted automatically by the GeneXpert System and are shown in the **View Results** window.

Note On the GeneXpert System with Touchscreen, scrolling down may be needed to see the results for all the targets of the test.

- Positive targets are displayed in red text with a red box around them, negative targets are displayed in green text.



Campylobacter NEGATIVE
Salmonella NEGATIVE
STEC stx1 NEGATIVE
STEC stx2 NEGATIVE
Shigella EIEC NEGATIVE
V. cholerae NEGATIVE
V. parahaemolyticus NEGATIVE
Yersinia NEGATIVE
Cryptosporidium POSITIVE
Giardia NEGATIVE
Norovirus NEGATIVE

Figure 2 Example of Test Result with Single Positive target and negative result for other targets.
Cryptosporidium is Detected.

- Samples with coinfection may appear with positive results for multiple targets.

Campylobacter NEGATIVE
Salmonella NEGATIVE
STEC stx1 NEGATIVE
STEC stx2 POSITIVE
Shigella EIEC NEGATIVE
V. cholerae NEGATIVE
V. parahaemolyticus POSITIVE
Yersinia NEGATIVE
Cryptosporidium POSITIVE
Giardia NEGATIVE
Norovirus NEGATIVE

Figure 3 Example of Test Result with Positive Result for Multiple Pathogens (STEC stx2, V. parahaemolyticus, Cryptosporidium) and Negative for Other Pathogens.

- **Indeterminate samples** (Invalid, Error or No result) are lighted in gray color.

NO RESULT

Figure 4 Example of Test Result with NO RESULT outcome

Analyte names corresponding to the pathogens are listed in [Table 1](#). The results are interpreted as presented in [Table 2](#), [Table 3](#), [Table 4](#), and [Table 5](#). The following pathogens will be detected using melt curve analysis: *Campylobacter*, *Yersinia*, *STEC stx1*, *STEC stx2*, *V. cholerae*, and *V. parahaemolyticus*. Melt curve analysis is evaluated by GeneXpert Software to determine the presence of analyte. Melt peak temperature and melt peak height and valley of the curve is calculated automatically by the software. The melt curve is detected as positive if melt peak temperature falls within the valid melt peak temperature range specified for each analyte. The melt curve is called as negative if melt peak temperature does not fall within the valid melt peak temperature range.

The following pathogens will be detected using amplification curve analysis: *Salmonella*, *Shigella/EIEC*, *Giardia*, *Cryptosporidium*, and *Norovirus GI/GII*. The software automatically calculates the cycle threshold (Ct) and endpoint (EndPt) values.

The possible results are:



Table 2. Xpert GI Panel test with positive outcome for single pathogen

Result	Interpretation
Campylobacter POSITIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p>Campylobacter is detected. The Campylobacter melt peak temperature is within the valid range. The Campylobacter melt peak height is above the threshold setting. Except Campylobacter all pathogens listed in Table 1 are not detected. Probe Check: PASS; all probe check results pass. SPC – Not Applicable (NA); SPC is ignored because Campylobacter is detected. IC – NA; IC is ignored because Campylobacter is detected.</p>
Campylobacter NEGATIVE; Salmonella POSITIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p>Salmonella is detected. The Salmonella target has a Ct within the valid range and EndPt above the threshold setting. Except Salmonella all pathogens listed in Table 1 are not detected. Probe Check - PASS; all probe check results pass. SPC - NA; SPC is ignored because Salmonella is detected. IC – NA; IC is ignored because Salmonella is detected.</p>
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 POSITIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p>Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx1 is detected. The Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx1 melt curve is detected. The Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx1 melt peak temperature is within the valid range. The Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx1 Melt Peak height is above the threshold setting. Except Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx1 all pathogens listed in Table 1 are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx1 is detected. IC – NA; IC is ignored because Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx1 is detected.</p>



Result	Interpretation
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 POSITIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p>Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx2 is detected. The Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx2 melt curve is detected. The Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx2 melt peak temperature is within the valid range. The Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx2 Melt Peak height is above the threshold setting. Except Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx2 all pathogens listed in Table 1 are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx2 is detected. IC – NA; IC is ignored because Shiga toxin-producing <i>Escherichia coli</i> (STEC) stx2 is detected.</p>
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC POSITIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p><i>Shigella</i> or EIEC is detected. The <i>Shigella</i>/Enteroinvasive <i>Escherichia coli</i> (EIEC) target has a Ct within the valid range and EndPt above the threshold setting. Except <i>Shigella</i>/Enteroinvasive <i>Escherichia coli</i> (EIEC) all pathogens listed in Table 1 are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because <i>Shigella</i>/Enteroinvasive <i>Escherichia coli</i> (EIEC) is detected. IC – NA; IC is ignored because <i>Shigella</i>/Enteroinvasive <i>Escherichia coli</i> (EIEC) is detected.</p>
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae POSITIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p><i>V. cholerae</i> is detected. The <i>V. cholerae</i> melt curve is detected. The <i>V. cholerae</i> melt peak temperature is within the valid range. The <i>V. cholerae</i> Melt Peak height is above the threshold setting. Except <i>V. cholerae</i> all pathogens listed in Table 1 are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because <i>V. cholerae</i> is detected. IC – NA; IC is ignored because <i>V. cholerae</i> is detected.</p>



Result	Interpretation
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus POSITIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p><i>V. parahaemolyticus</i> detected. The <i>V. parahaemolyticus</i> melt curve is detected. The <i>V. parahaemolyticus</i> melt peak temperature is within the valid range. The <i>V. parahaemolyticus</i> Melt Peak height is above the threshold setting. Except <i>V. parahaemolyticus</i> all pathogens listed in Table 1 are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because <i>V. parahaemolyticus</i> is detected. IC - NA; IC is ignored because <i>V. parahaemolyticus</i> is detected.</p>
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia POSITIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p><i>Yersinia</i> is detected. The <i>Yersinia</i> melt curve is detected. The <i>Yersinia</i> melt peak temperature is within the valid range. The <i>Yersinia</i> Melt Peak height is above the threshold setting. Except <i>Yersinia</i> all pathogens listed in Table 1 are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because <i>Yersinia</i> is detected. IC - NA; IC is ignored because <i>Yersinia</i> is detected.</p>
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium POSITIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p><i>Cryptosporidium</i> is detected. The <i>Cryptosporidium</i> target has a Ct within the valid range and EndPt above the threshold setting. Except <i>Cryptosporidium</i> all pathogens listed in Table 1 are not detected. Probe Check - PASS; all probe check results pass. SPC - NA; SPC is ignored because <i>Cryptosporidium</i> is detected. IC - NA; IC is ignored because <i>Cryptosporidium</i> is detected.</p>



Result	Interpretation
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia POSITIVE; Norovirus NEGATIVE;	<p><i>Giardia</i> is detected.</p> <p>The <i>Giardia</i> target has a Ct within the valid range and EndPt above the threshold setting.</p> <p>Except <i>Giardia</i> all pathogens listed in Table 1 are not detected.</p> <p>Probe Check - PASS; all probe check results pass.</p> <p>SPC - NA; SPC is ignored because <i>Giardia</i> is detected.</p> <p>IC - NA; IC is ignored because <i>Giardia</i> is detected.</p>
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus POSITIVE;	<p>Norovirus G1 or GII is detected.</p> <p>The Norovirus target has a Ct within the valid range and EndPt above the threshold setting.</p> <p>Except Norovirus all pathogens listed in Table 1 are not detected.</p> <p>Probe Check - PASS; all probe check results pass.</p> <p>SPC - NA; SPC is ignored because Norovirus is detected.</p> <p>IC - NA; IC is ignored because Norovirus is detected.</p>

Table 3. Xpert GI Panel test with negative outcome for all pathogens

Result	Interpretation
Campylobacter NEGATIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC NEGATIVE; V. cholerae NEGATIVE; V. parahaemolyticus NEGATIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia NEGATIVE; Norovirus NEGATIVE;	<p>None of the pathogens listed in Table 1 are detected.</p> <p>SPC - PASS;</p> <p>SPC has a Ct within the valid range and EndPt above the minimum setting</p> <p>SPC melt curve is detected.</p> <p>SPC melt peak temperature is within the valid range.</p> <p>The SPC melt peak height is above the threshold setting.</p> <p>IC - PASS;</p> <p>IC has a Ct within the valid range and EndPt above the minimum setting.</p> <p>Probe Check - PASS; all probe check results pass.</p>

**Table 4. Xpert GI Panel test with positive outcome for two or more pathogens**

Result	Interpretation
Campylobacter POSITIVE;	Campylobacter, Shigella/Enteroinvasive <i>Escherichia coli</i> (EIEC), <i>Vibrio cholerae</i> , <i>Vibrio parahaemolyticus</i> , <i>Giardia</i> , and Norovirus GI/GII are detected.
Salmonella NEGATIVE;	The detected signal has a Ct within the valid range and EndPt above the minimum setting (applicable for the targets <i>Giardia</i> , <i>Shigella</i> /Enteroinvasive <i>Escherichia coli</i> (EIEC) and Norovirus).
STEC stx1 NEGATIVE;	The detected signal has a melt peak temperature within the valid range and melt peak height above the threshold setting (applicable for the targets <i>Campylobacter</i> , <i>Vibrio cholerae</i> and, <i>Vibrio parahaemolyticus</i>).
STEC stx2 NEGATIVE;	
Shigella EIEC POSITIVE;	Except <i>Campylobacter</i> , <i>Vibrio cholerae</i> , <i>Vibrio parahaemolyticus</i> , <i>Giardia</i> and Norovirus, all pathogens listed in Table 1 are not detected.
V. cholerae POSITIVE;	Probe Check – PASS; all probe check results pass.
V. parahaemolyticus POSITIVE;	SPC – NA; SPC is ignored because <i>Campylobacter</i> , <i>Shigella</i> /Enteroinvasive <i>Escherichia coli</i> (EIEC), <i>Vibrio cholerae</i> , <i>Vibrio parahaemolyticus</i> , <i>Giardia</i> and Norovirus are detected.
Yersinia NEGATIVE;	IC – NA; IC is ignored because <i>Campylobacter</i> , <i>Shigella</i> /Enteroinvasive <i>Escherichia coli</i> EIEC, <i>Vibrio cholerae</i> , <i>Vibrio parahaemolyticus</i> , <i>Giardia</i> and Norovirus are detected.
Cryptosporidium NEGATIVE;	
Giardia POSITIVE;	Note It is recommended that clinical specimens undergo repeat testing if nucleic acids from multiple analytes (3 or more) are detected in a single specimen. Repeat test according to the instructions in Retest Procedure .
Norovirus POSITIVE;	

Table 5. Xpert GI Panel test with Invalid, Error or No Result Outcome

Result	Interpretation
INVALID	Sample Processing Control (SPC) and/or Internal Control (IC) does not meet acceptance criteria and none of the target pathogens meet criteria for the test result POSITIVE. Repeat test according to Retest Procedure . Probe Check - PASS; all probe check results pass.
ERROR	None of the target pathogens meet criteria for the test result POSITIVE or NEGATIVE. Repeat test according to Retest Procedure . Probe Check: FAIL ^a ; all or one of the probe check results fail SPC and IC: NO RESULT
NO RESULT	Test result POSITIVE or NEGATIVE of the target pathogens cannot be determined. Repeat test according to Retest Procedure . A NO RESULT indicates that insufficient data were collected. For example, the operator stopped a test that was in progress. All target pathogens: NO RESULT Probe Check: NA

a. If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range, or by a system component failure.

Reasons to Repeat the Test

If any of the test results mentioned below occur, repeat the test according to the retest procedure using a new sample, new cartridge (do not re-use the cartridge), and new reagent.

- An **INVALID** result indicates that the control SPC and/or IC failed. The sample was not properly processed, PCR is inhibited or the sample was not properly collected.
- An **ERROR** result indicates that the test was aborted. Possible causes include: the reaction tube was filled improperly; a reagent probe integrity problem was detected; or the maximum pressure limits were exceeded.
- A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress, or a power failure occurred.
- If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid for assistance.



- Because the incidence of infection with multiple (3 or more) agents are low, it is recommended that specimens undergo repeat testing if nucleic acids from multiple analytes are detected in a single specimen. Repeat test according to the instructions in [Retest Procedure](#) section.

Retest Procedure

- If the result of a test is **INVALID, ERROR, NO RESULT**, or any other reason that requires retesting, use a new cartridge to retest the affected specimen (do not re-use the cartridge).
- Refer to [Specimen Collection Transport and Storage](#) for specimen collection if needed.
- Remove a new cartridge from the kit.
- See [Procedure](#), including [Preparing the Cartridge](#) and [Starting the Test: GeneXpert System with Touchscreen](#).

Limitations

Limitations

- All assay results should be used and interpreted in the context of a full clinical evaluation as an aid in the diagnosis of gastrointestinal infection.
- There is a risk of false positive values resulting from cross-contamination by target organisms, their nucleic acids, or the amplified product.
- There is a risk of false positive values resulting from non-specific signals in the assay.
- Analyte targets (virus, bacteria, or parasite nucleic acid sequences) may persist *in vivo*, independent of virus, bacteria, or parasite viability. Detection of analyte target(s) does not guarantee that the corresponding live organism(s) is present, or that the corresponding organism(s) is the causative agent for clinical symptoms.
- The detection of viral, bacterial, or parasitic sequences is dependent upon proper specimen collection, handling, transportation, storage, and preparation (including extraction). Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- Underlying polymorphisms in primer-binding regions can affect the targets being detected and subsequently the test results returned.
- Salmonella*: not all *Salmonella* serotypes were tested in validation studies.
- There is a risk of false negative values resulting from improperly collected, transported, or handled specimens.
- There is a risk of false negative values due to the presence of strain/species sequence variability in the targets of the assay, procedural errors, amplification inhibitors in specimens, or inadequate numbers of organisms for amplification.
- The performance of this test has not been established for monitoring treatment of infection with any of the targeted microorganisms.
- Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely when prevalence of disease is high. False positive test results are more likely when prevalence is low.
- The effect of interfering substances has only been evaluated for those listed in the labeling at its indicated amount or concentration. Interference by substances other than those described in the interfering substances section of the package insert can lead to erroneous results.
- There is a potential risk for non-determinate result or false negative results when over-filling the Cary Blair



medium vial above the max fill line with stool sample. The stool specimen should be collected and transferred to Cary Blair medium according to the Cary Blair manufacturer's instructions.

- Cross-reactivity with gastrointestinal tract organisms other than those listed in the instruction for use may lead to erroneous results.
- This test is a qualitative test and does not provide the quantitative value of detected organism present.
- The performance of the Xpert GI Panel test was validated using the procedures provided in this instructions for use only. Modifications to these procedures may alter the performance of the test.
- The Xpert GI Panel test detects *Salmonella enterica* and *Salmonella bongori* and does not differentiate between these two species of *Salmonella*. *Salmonella enterica* is further divided into serotypes or serovars and not all *Salmonella* serotypes and serovars were tested in validation studies. However, inclusivity testing and *in silico* analysis supports that the Xpert GI Panel test detects the *Salmonella enterica* subspecies *enterica*, *salamae*, *arizona*, *diarizone*, *houtenae* and *indica*, and a diversity of *Salmonella enterica* subspecies *enterica* serovars causing human gastrointestinal infections.
- The performance of this test has only been validated with human stool collected in Cary Blair transport medium, according to the media manufacturers' instructions. It has not been validated for use with other stool transport media, raw stool, rectal swabs, endoscopy stool aspirates, or vomitus.
- The Xpert GI Panel test detects *Campylobacter jejuni* (subspecies *jejuni* and *doylei*) and *Campylobacter coli* and does not differentiate between these two species of *Campylobacter*. Additional testing is required to differentiate between these species and to detect other *Campylobacter* species that may be present in stool specimens.
- The Xpert GI Panel test detects *Cryptosporidium parvum*, *C. hominis*, *C. meleagridis*, *C. canis*, *C. ubiquitum*, and *C. muris* and does not differentiate between these six species of *Cryptosporidium*. Additional testing is required to differentiate between these species and to detect other *Cryptosporidium* species that may be present in stool specimens. *Cryptosporidium* inclusivity testing and *in silico* analysis demonstrated that the Xpert GI Panel may have reduced sensitivity for detection of *C. muris*.
- The Xpert GI Panel test detects Norovirus GI and GII and does not differentiate between the two genogroups. Mutations or polymorphisms in primer or probe binding regions of Norovirus may affect detection of new or unknown Norovirus variants resulting in a false negative result.
- *Shigella dysenteriae* possess a shiga toxin gene (*stx*) that is identical to the *stx1* gene of STEC. The detection of both *Shigella*/Enteroinvasive *E. coli* (EIEC) and STEC *stx1* analyte in the same specimen may indicate the presence of *S. dysenteriae*. Rare instances of the detection of shiga-like toxin genes in other genera/species have been reported, e.g., *Aeromonas caviae*, *Acinetobacter haemolyticus*, *Shigella sonnei*, *Enterobacter cloacae*, *Citrobacter freundii*, and *Klebsiella pneumoniae*.
- This assay is not intended for use with Cary Blair media formulations that contain formalin, other chemical fixatives, or preservatives.

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 6](#).

The number and percentage of positive cases per analyte calculated for each age group are presented in [Table 6](#).

**Table 6. 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
<i>Campylobacter</i>	4.3% (67/1568)	5.9% (11/185)	17.2% (5/29)	4.6% (18/394)	3.9% (13/336)	3.2% (20/624)
<i>Salmonella</i>	3.3% (51/1568)	6.5% (12/185)	6.9% (2/29)	4.1% (16/394)	3.3% (11/336)	1.6% (10/624)
<i>V. parahaemolyticus</i>	0.0% (0/1505)	0.0% (0/179)	0.0% (0/29)	0.0% (0/377)	0.0% (0/321)	0.0% (0/599)
<i>V. cholerae</i>	0.1% (1/1568)	0.0% (0/185)	0.0% (0/29)	0.3% (1/394)	0.0% (0/336)	0.0% (0/624)
<i>Yersinia</i>	1.6% (25/1568)	2.2% (4/185)	0.0% (0/29)	1.0% (4/394)	1.5% (5/336)	1.9% (12/624)
<i>Shigella</i> 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 <i>stx1</i>	0.4% (6/1497)	0.6% (1/173)	0.0% (0/25)	0.3% (1/374)	0.6% (2/320)	0.3% (2/605)
STEC <i>stx2</i>	0.2% (3/1497)	0.0% (0/173)	0.0% (0/25)	0.0% (0/374)	0.3% (1/320)	0.3% (2/605)
<i>Cryptosporidium</i>	2.2% (34/1568)	5.4% (10/185)	0.0% (0/29)	3.8% (15/394)	2.1% (7/336)	0.3% (2/624)
<i>Giardia</i>	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 7](#). 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 7. Expected Values for Analytes in Multi-analyte Detections by Xpert GI Panel

Multi-analyte Combinations ^a	Number of Specimens (n/N)	Percent of Specimens (%)
<i>Cryptosporidium</i> and Norovirus	1/25	4.0%
<i>Cryptosporidium</i> and <i>Giardia</i>	1/25	4.0%
<i>Yersinia</i> and Norovirus	2/25	8.0%
<i>Shigella</i> EIEC and Norovirus	2/25	8.0%
<i>Shigella</i> EIEC and <i>Giardia</i>	1/25	4.0%
STEC <i>stx1</i> and <i>Cryptosporidium</i>	1/25	4.0%
STEC <i>stx1</i> and <i>Shigella</i> EIEC	1/25	4.0%
STEC <i>stx1</i> and STEC <i>stx2</i>	1/25	4.0%
<i>Salmonella</i> and Norovirus	2/25	8.0%
<i>Salmonella</i> , <i>Giardia</i> , and Norovirus	1/25	4.0%
<i>Salmonella</i> and <i>Yersinia</i>	1/25	4.0%
<i>Salmonella</i> , STEC <i>stx1</i> , and STEC <i>stx2</i>	1/25	4.0%
<i>Campylobacter</i> and Norovirus	2/25	8.0%
<i>Campylobacter</i> and <i>Cryptosporidium</i>	1/25	4.0%
<i>Campylobacter</i> and <i>Yersinia</i>	2/25	8.0%
<i>Campylobacter</i> and <i>Shigella</i> EIEC	3/25	12.0%



Multi-analyte Combinations ^a	Number of Specimens (n/N)	Percent of Specimens (%)
<i>Campylobacter, Shigella EIEC, and Norovirus</i>	1/25	4.0%
<i>Campylobacter and Salmonella</i>	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 Specific Performance Characteristics

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 8](#).

Table 8. Demographic Information of Eligible Prospective Specimens

Prospective Fresh Specimens (N=1592)	Number of Specimens (%)
Sex	
Female	907 (57.0%)
Male	685 (43.0%)
Age (years)	



Prospective Fresh Specimens (N=1592)		Number of Specimens (%)
<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 two 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 9](#). 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 9](#).

Table 9. 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
<i>Campylobacter</i>	604	62/66 ^a	93.9	85.4–97.6	533/538 ^a	99.1	97.8–99.6
<i>Salmonella</i>	1568	49/54 ^b	90.7	80.1–96.0	1512/1514	99.9	99.5–100.0
<i>V. parahaemolyticus</i>	1505	0/0	N/A	N/A	1505/1505	100.0	99.7–100.0
<i>V. cholerae</i>	1568	0/1 ^c	0	0.0–79.3	1566/1567 ^c	99.9	99.6–100.0
<i>Yersinia</i>	603	15/15	100.0	79.6–100.0	578/588 ^d	98.3	96.9–99.1
<i>Shigella</i> EIEC	1568	34/37 ^e	91.9	78.7–97.2	1527/1531 ^e	99.7	99.3–99.9
STEC <i>stx1</i>	1497	6/6	100.0	61.0–100.0	1491/1491	100.0	99.7–100.0
STEC <i>stx2</i>	1497	2/2	100.0	34.2–100.0	1494/1495	99.9	99.6–100.0
<i>Cryptosporidium</i>	1568	32/32	100.0	89.3–100.0	1534/1536 ^f	99.9	99.5–100.0



Analyte	Total	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP+FN)	%	95% CI	TN/(TN+FP)	%	95% CI
<i>Giardia</i>	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 test (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).

Table 10 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 10. Multi-analyte Combinations Detected by Xpert GI Panel

Analyte 1	Analyte 2	Analyte 3	Total	Total Specimens with Discrepant Results	Discrepant Analyte(s)
<i>Cryptosporidium</i>	Norovirus	N/A	1	1	Norovirus
<i>Cryptosporidium</i>	<i>Giardia</i>	N/A	1	0	N/A
<i>Yersinia</i>	Norovirus	N/A	2	2	Specimen 1: <i>Yersinia</i> , Norovirus; Specimen 2: <i>Yersinia</i> , Norovirus, <i>Shigella</i> EIEC ^a
<i>Shigella</i> EIEC	Norovirus	N/A	2	1	<i>Shigella</i> EIEC, Norovirus
<i>Shigella</i> EIEC	<i>Giardia</i>	N/A	1	1	<i>Shigella</i> EIEC
STEC stx1	<i>Cryptosporidium</i>	N/A	1	0	N/A
STEC stx1	<i>Shigella</i> EIEC	N/A	1	0	N/A
STEC stx1	STEC stx2	N/A	1	0	N/A
<i>Salmonella</i>	Norovirus	N/A	2	0	N/A
<i>Salmonella</i>	<i>Giardia</i>	Norovirus	1	1	Norovirus
<i>Salmonella</i>	<i>Yersinia</i>	N/A	1	0	N/A
<i>Salmonella</i>	STEC stx1	STEC stx2	1	0	N/A
<i>Campylobacter</i>	Norovirus	N/A	2	1	Norovirus
<i>Campylobacter</i>	<i>Cryptosporidium</i>	N/A	1	0	N/A
<i>Campylobacter</i>	<i>Yersinia</i>	N/A	2	0	N/A



Analyte 1	Analyte 2	Analyte 3	Total	Total Specimens with Discrepant Results	Discrepant Analyte(s)
<i>Campylobacter</i>	<i>Shigella</i> EIEC	N/A	3	1	<i>Campylobacter</i>
<i>Campylobacter</i>	<i>Shigella</i> EIEC	Norovirus	1	1	<i>Campylobacter</i> , Norovirus
<i>Campylobacter</i>	<i>Salmonella</i>	N/A	1	0	N/A
Total Multi-Analyte Detections		25	9		
Multi-Analyte Detections with 2 Analytes		22	7		N/A
Multi-Analyte Detections 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 11](#).

Table 11. Demographic Information of Eligible Pre-selected Archived Specimens

Pre-selected 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 12](#).

Table 12. Clinical Performance of Xpert GI Panel in Pre-selected Archived Specimens

Analyte	Total	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TN+FP)	%	95% CI	TN/(TN+FP)	%	95% CI
<i>Salmonella</i>	68	6/7 ^a	85.7	48.7–97.4	61/61	100.0	94.1–100.0
<i>Shigella</i> EIEC	68	15/15	100.0	79.6–100.0	52/53 ^b	98.1	90.1–99.7
<i>Cryptosporidium</i>	68	3/4 ^c	75.0	30.1–95.4	64/64	100.0	94.3–100.0
<i>Giardia</i>	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 13](#).

Table 13. Performance of Xpert GI Panel in Contrived Samples

Analyte	Total	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP+FN)	%	95% CI	TN/(TP+FN)	%	95% CI
<i>V. parahaemolyticus</i>	146	63/65 ^a	96.9	89.5–99.2	81/81	100.0	95.5–100.0
<i>V. cholerae</i>	146	65/65	100.0	94.4–100.0	81/81	100.0	95.5–100.0
<i>Yersinia</i>	126	45/45	100.0	92.1–100.0	81/81	100.0	95.5–100.0
<i>Shigella</i> EIEC	96	15/15	100.0	79.6–100.0	81/81	100.0	95.5–100.0
STEC stx1	146	65/65	100.0	94.4–100.0	81/81	100.0	95.5–100.0
STEC stx2	146	65/65	100.0	94.4–100.0	81/81	100.0	95.5–100.0



Analyte	Total	Positive Percent Agreement			Negative Percent Agreement		
		TP/(TP+FN)	%	95% CI	TN/(TP+FN)	%	95% CI
<i>Cryptosporidium</i>	113	32/32	100.0	89.3–100.0	81/81	100.0	95.5–100.0
<i>Giardia</i>	116	35/35	100.0	90.1–100.0	81/81	100.0	95.5–100.0

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 at 7x LoD that were not detected. It is possible that variability in test performance was due to variability of the clinical stool matrix composition.

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 value for each Xpert GI Panel target pathogen strain are presented in [Table 14](#).

Table 14. Limit of Detection (LoD) for Xpert GI Panel Analytes

Target Pathogen	Strain	Strain ID	Confirmed LoD
<i>Campylobacter</i>	<i>Campylobacter coli</i>	CCUG 11283T	46 CFU/mL
	<i>Campylobacter jejuni</i>	CCUG 41359	183 CFU/mL
<i>Shigella/EIEC</i>	<i>Shigella sonnei</i>	CCUG 68726T	82 CFU/mL
	<i>Enteroinvasive Escherichia coli (EIEC)</i>	CCUG 46406	204 CFU/mL
<i>Salmonella</i>	<i>Salmonella bongori</i>	CCUG 30042T	261 CFU/mL
	<i>Salmonella enterica</i>	NCTC 13171	1,242 CFU/mL
<i>STEC stx1/stx2</i>	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
<i>Vibrio cholerae</i>	<i>Vibrio cholerae</i>	NCTC 8457	136 CFU/mL
	<i>Vibrio cholerae</i>	CCUG 67718	459 CFU/mL
<i>Vibrio parahaemolyticus</i>	<i>Vibrio parahaemolyticus</i>	CCUG 14474T	127 CFU/mL
	<i>Vibrio parahaemolyticus</i>	CCUG 67711	489 CFU/mL
<i>Yersinia enterocolitica</i>	<i>Yersinia enterocolitica</i>	CCUG 52867T	348 CFU/mL
	<i>Yersinia enterocolitica</i>	CCUG 12369T	106 CFU/mL
<i>Cryptosporidium</i>	<i>Cryptosporidium hominis</i>	Waterborne Inc. TU502	72 oocysts/mL
	<i>Cryptosporidium parvum</i>	Waterborne Inc. P102C, Iowa	246 oocysts/mL



Target Pathogen	Strain	Strain ID	Confirmed LoD
<i>Giardia</i>	<i>Giardia lamblia</i>	Waterborne Inc. P101, H3	246 cysts/mL
	<i>Giardia intestinalis</i>	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 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 ≤ 3 x LoD using six replicates. Non-target bacteria were tested at 1E6 CFU/mL and non-target viruses and parasites/yeast were tested at ≥ 1 E4 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. [Table 15](#), [Table 16](#), and [Table 17](#) present the bacteria, viruses, parasites/yeast evaluated in the Xpert GI Panel analytical (exclusivity) and microbial interference study. [Table 18](#) presents the target pathogen strains evaluated for in-assay cross reactivity of the Xpert GI Panel test.

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

Bacteria		
Non-target Microorganism	Strain ID	Concentration Tested
<i>Abiotrophia defectiva</i>	CCUG 27639	1E6 CFU/mL
<i>Acinetobacter baumannii</i>	CCUG 19096T	1E6 CFU/mL
<i>Acinetobacter lwoffii</i>	ZeptoMetrix 0801909	1E6 CFU/mL
<i>Aeromonas caviae</i>	CCUG 25939	1E6 CFU/mL
<i>Aeromonas salmonicida</i> (<i>Aeromonas hydrophila</i>)	ATCC 7965	1E6 CFU/mL
<i>Aeromonas schubertii</i>	CCUG 27820	1E6 CFU/mL
<i>Aeromonas sobria</i>	CCUG 14830	1E6 CFU/mL
<i>Aeromonas veronii</i>	CCUG 27821T	1E6 CFU/mL
<i>Alcaligenes faecalis</i> subsp. <i>faecalis</i>	CCUG 1814T	1E6 CFU/mL
<i>Anaerococcus tetradius</i>	CCUG 46590T	1E6 CFU/mL
<i>Arcobacter butzleri</i>	CCUG 30485	1E6 CFU/mL
<i>Arcobacter cryaerophilus</i>	CCUG 17801	1E6 CFU/mL
<i>Bacillus cereus</i>	ZeptoMetrix 0801823	1E6 CFU/mL
<i>Bacteroides caccae</i>	ATCC 43185	1E6 CFU/mL



Bacteria		
Non-target Microorganism	Strain ID	Concentration Tested
<i>Bacteroides fragilis</i>	ZeptoMetrix 0801583	1E6 CFU/mL
<i>Bacteroides stercoris</i>	ATCC 43183	1E6 CFU/mL
<i>Bacteroides thetaiotaomicron</i>	CCUG 10774	1E6 CFU/mL
<i>Phocaeicola vulgatus (Bacteroides vulgatus)</i>	ATCC 8482	1E6 CFU/mL
<i>Bifidobacterium adolescentis</i>	CCUG 18363T	1E6 CFU/mL
<i>Bifidobacterium bifidum</i>	CCUG 45217	1E6 CFU/mL
<i>Bifidobacterium longum</i> subsp. <i>longum</i>	ATCC 15707	1E6 CFU/mL
<i>Brevundimonas diminuta</i>	CCUG 2031	1E6 CFU/mL
<i>Cedecea daviseae</i>	CCUG 12370	1E6 CFU/mL
<i>Chlamydia trachomatis</i>	ZeptoMetrix 0801775	1E6 CFU/mL
<i>Citrobacter amalonaticus</i>	CCUG 4860A	1E6 CFU/mL
<i>Citrobacter freundii</i>	ZeptoMetrix 0801563	1E6 CFU/mL
<i>Citrobacter koseri</i>	CCUG 4859	1E6 CFU/mL
<i>Citrobacter sedlakii</i>	CCUG 30794	1E6 CFU/mL
<i>Clostridium difficile</i>	ZeptoMetrix 0801619	1E6 CFU/mL
<i>Hathewaya histolytica (Clostridium histolyticum)</i>	ATCC 19401	1E6 CFU/mL
<i>Clostridium novyi</i>	ATCC 17861	1E6 CFU/mL
<i>Clostridium perfringens</i>	ATCC 13124	1E6 CFU/mL
<i>Thomasclavelia ramosa (Clostridium ramosum)</i>	CCUG 24038	1E6 CFU/mL
<i>Clostridium septicum</i>	ATCC 12464	1E6 CFU/mL
<i>Paeniclostridium sordellii (Clostridium sordellii)</i>	DSMZ 2141	1E6 CFU/mL
<i>Clostridium tetani</i>	ATCC 19406	1E6 CFU/mL
<i>Collinsella aerofaciens</i>	CCUG 28087	1E6 CFU/mL
<i>Corynebacterium genitalium</i>	CCUG 65575	1E6 CFU/mL
<i>Corynebacterium lipophiloflavum</i>	CCUG 37336	1E6 CFU/mL
<i>Desulfovibrio piger</i>	NA	<i>In silico</i> analysis
<i>Edwardsiella tarda</i>	CCUG 1638	1E6 CFU/mL
<i>Eggerthella lenta</i>	ATCC 43055	1E6 CFU/mL
<i>Klebsiella aerogenes (Enterobacter aerogenes)</i>	ZeptoMetrix 0801518	1E6 CFU/mL
<i>Enterobacter cancerogenus</i>	ATCC 35316	1E6 CFU/mL
<i>Enterobacter cloacae</i> subsp. <i>cloacae</i>	ZeptoMetrix 0801830	1E6 CFU/mL
<i>Enterococcus faecalis</i>	ZeptoMetrix 0801637	1E6 CFU/mL
<i>Enterococcus faecium</i>	ZeptoMetrix 0804210	1E6 CFU/mL
Enteropathogenic <i>E. coli</i> EAEC	ZeptoMetrix 0801919	1E6 CFU/mL
Enteropathogenic <i>E. coli</i> EPEC	ZeptoMetrix 0801938	1E6 CFU/mL
Enterotoxigenic <i>E. coli</i> ETEC	ZeptoMetrix 0801624	1E6 CFU/mL
<i>Escherichia fergusonii</i>	CCUG 18766	1E6 CFU/mL
<i>Escherichia hermannii</i>	CCUG 15714	1E6 CFU/mL
<i>Pseudescherichia vulneris (Escherichia vulneris)</i>	CCUG 15715	1E6 CFU/mL



Bacteria		
Non-target Microorganism	Strain ID	Concentration Tested
<i>Fusobacterium varium</i>	ATCC 8501	1E6 CFU/mL
<i>Gardnerella vaginalis</i>	ZeptoMetrix 0801894	1E6 CFU/mL
<i>Gemella morbillorum</i>	CCUG 18164	1E6 CFU/mL
<i>Haemophilus influenzae</i>	ZeptoMetrix 080167	1E6 CFU/mL
<i>Hafnia alvei</i>	CCUG 41547T	1E6 CFU/mL
<i>Helicobacter pylori</i>	ZeptoMetrix 0804383	1E6 CFU/mL
<i>Klebsiella oxytoca</i>	ZeptoMetrix 0801881	1E6 CFU/mL
<i>Klebsiella pneumoniae</i> subsp. <i>pneumoniae</i>	CCUG 225T	1E6 CFU/mL
<i>Lactobacillus acidophilus</i>	ATCC 314	1E6 CFU/mL
<i>Limosilactobacillus reuteri</i>	CCUG 33624	1E6 CFU/mL
<i>Lactococcus lactis</i> subsp. <i>lactis</i>	CCUG 32211	1E6 CFU/mL
<i>Leminorella grimontii</i>	CCUG 20909B	1E6 CFU/mL
<i>Listeria monocytogenes</i>	ZeptoMetrix 0801534	1E6 CFU/mL
<i>Megamonas hypermegale</i>	CCUG 5856	1E6 CFU/mL
<i>Megasphaera elsdenii</i>	ATCC 25940	1E6 CFU/mL
<i>Morganella morganii</i> subsp. <i>morganii</i>	ZeptoMetrix 0804010	1E6 CFU/mL
<i>Neisseria gonorrhoeae</i>	ZeptoMetrix 0801482	1E6 CFU/mL
<i>Parabacteroides merdae</i>	CCUG 38734	1E6 CFU/mL
<i>Peptoniphilus asaccharolyticus</i>	ATCC 14963	1E6 CFU/mL
<i>Peptostreptococcus anaerobius</i>	CCUG 7835	1E6 CFU/mL
<i>Photobacterium damselae</i> subsp. <i>damselae</i>	CCUG 13626	1E6 CFU/mL
<i>Plesiomonas shigelloides</i>	CCUG 410T	1E6 CFU/mL
<i>Porphyromonas asaccharolytica</i>	CCUG 7834T	1E6 CFU/mL
<i>Prevotella melaninogenica</i>	ATCC 25845	1E6 CFU/mL
<i>Proteus mirabilis</i>	ZeptoMetrix 0801544	1E6 CFU/mL
<i>Proteus penneri</i>	CCUG 15722	1E6 CFU/mL
<i>Proteus vulgaris</i>	ZeptoMetrix 0801898	1E6 CFU/mL
<i>Providencia alcalifaciens</i>	ZeptoMetrix 0801906	1E6 CFU/mL
<i>Pseudomonas aeruginosa</i>	CCUG 551T	1E6 CFU/mL
<i>Ruminococcus bromii</i>	ATCC 27255	1E6 CFU/mL
<i>Serratia fonticola</i>	CCUG 14186	1E6 CFU/mL
<i>Serratia liquefaciens</i>	CCUG 9285T	1E6 CFU/mL
<i>Serratia marcescens</i> subsp. <i>marcescens</i>	ZeptoMetrix 0801723	1E6 CFU/mL
<i>Shewanella algae</i>	CCUG 39064	1E6 CFU/mL
<i>Shimwellia blattae</i>	CCUG 14803BT	1E6 CFU/mL
<i>Staphylococcus aureus</i> subsp. <i>aureus</i>	ATCC 25923	1E6 CFU/mL
<i>Staphylococcus epidermidis</i>	ZeptoMetrix 0801651	1E6 CFU/mL
<i>Stenotrophomonas maltophilia</i>	ZeptoMetrix 0801569	1E6 CFU/mL
<i>Streptococcus agalactiae</i>	CCUG 4208	1E6 CFU/mL



Bacteria		
Non-target Microorganism	Strain ID	Concentration Tested
<i>Streptococcus intermedius</i>	ZeptoMetrix 0801895	1E6 CFU/mL
<i>Streptococcus pyogenes</i>	CCUG 4207	1E6 CFU/mL
<i>Streptococcus salivarius</i> subsp. <i>salivarius</i>	ZeptoMetrix 0801896	1E6 CFU/mL
<i>Streptococcus suis</i>	CCUG 7984	1E6 CFU/mL
<i>Trabulsiella guamensis</i>	ATCC 49492	1E6 CFU/mL
<i>Veillonella parvula</i>	ATCC 10790	1E6 CFU/mL
<i>Vibrio vulnificus</i>	CCUG 48492	1E6 CFU/mL
<i>Yersinia bercovieri</i>	CCUG 26329T	1E6 CFU/mL
<i>Yersinia frederiksenii</i>	CCUG 11293	1E6 CFU/mL
<i>Yersinia intermedia</i>	CCUG 11292T	1E6 CFU/mL
<i>Yersinia kristensenii</i>	CCUG 11294	1E6 CFU/mL
<i>Yersinia mollaretii</i>	CCUG 26331	1E6 CFU/mL
<i>Yersinia rohdei</i>	CCUG 38833	1E6 CFU/mL

Table 16. 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 1E5 TCID ₅₀ /mL ^b
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	<i>In silico</i> 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
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



Viruses		
Non-target Microorganism	Strain ID	Concentration Tested
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 17. 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
<i>Blastocystis hominis</i>	NA	<i>In silico</i> analysis
<i>Candida albicans</i>	ZeptoMetrix 0801504	1E6 CFU/mL
<i>Cyclospora cayetanensis</i>	ATCC PRA-3000SD	1E7 copies/mL ^a 1E6 copies/mL ^b
<i>Encephalitozoon cuniculi</i>	NA	<i>In silico</i> analysis
<i>Encephalitozoon hellum</i>	NA	<i>In silico</i> analysis
<i>Entamoeba dispar</i>	ATCC PRA-368	N/A ^c
<i>Entamoeba histolytica</i>	ATCC 30459	2E4 cells/mL ^a 1E4 cells/mL ^b
<i>Entamoeba invadens</i>	ATCC 30994	5E4 cells/mL
<i>Pentatrichomonas hominis</i>	ATCC 30000	1E6 cells/mL
<i>Trichomonas vaginalis</i>	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 18. Target Pathogen Strains Evaluated in the Xpert GI Panel In-assay Cross Reactivity Study

Target Pathogen	Strain ID	Concentration Tested
<i>Campylobacter coli</i>	CCUG 53138	1E6 CFU/mL
	ATCC 43478	1E6 CFU/mL
	CCUG 36766	1E6 CFU/mL
<i>Shigella boydii</i> (Subgroup C, serotype 8)	CCUG 37892	1E6 CFU/mL
<i>Shigella boydii</i> (Subgroup C, serotype 10)	CCUG 9564	1E6 CFU/mL
<i>Shigella flexneri</i> (Subgroup B, serotype 2a)	CCUG 56439T	1E6 CFU/mL



Target Pathogen	Strain ID	Concentration Tested
<i>Shigella flexneri</i> (Subgroup B, serotype 4a)	CCUG 37906	1E6 CFU/mL
Enteroinvasive <i>Escherichia coli</i> (EIEC)	CCUG 38094	1E6 CFU/mL
<i>Escherichia coli</i> (STEC), O111	NCTC 13794	1E6 CFU/mL
<i>Escherichia coli</i> (STEC), O113	D5586	1E6 CFU/mL
<i>Escherichia coli</i> (STEC), O104	NCTC 13796	1E6 CFU/mL
<i>Salmonella bongori</i>	CCUG 63587	1E6 CFU/mL
<i>Salmonella enterica</i> subsp. <i>indica</i>	CCUG 30038T	1E6 CFU/mL
<i>Salmonella enterica</i> subsp. <i>enterica</i> Paratyphi A	NCTC 5702	1E6 CFU/mL
<i>Vibrio cholerae</i> , O:139 (non-O:1)	CCUG 34707	1E6 CFU/mL
<i>Vibrio cholerae</i> , O:1	CCUG 9118T	1E6 CFU/mL
<i>Vibrio parahaemolyticus</i>	CCUG 43362	1E6 CFU/mL
	CCUG 19113	1E6 CFU/mL
	CCUG 15657T	1E6 CFU/mL
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
<i>Yersinia enterocolitica</i> , subsp. <i>enterocolitica</i> , biotype 1 (serotype O:8)	CCUG 33055	1E6 CFU/mL
<i>Yersinia enterocolitica</i> , subsp. <i>enterocolitica</i> , biotype 2 (serotype O:5,27)	NCTC 10463	1E6 CFU/mL
<i>Yersinia enterocolitica</i> , subsp. <i>enterocolitica</i> , biotype 4 (serotype O:3)	CCUG 34604	1E6 CFU/mL
<i>Cryptosporidium parvum</i>	Waterborne Inc. P102C Iowa	9.94E4 oocysts/mL
<i>Cryptosporidium hominis</i>	Waterborne Inc. TU502	1E6 oocysts/mL
<i>Giardia intestinalis</i>	ATCC 30888	1E6 cysts/mL
	ATCC 50114	1E6 cysts/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 ≤ 3 x LoD, diluted into clinical stool matrix, 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 ≤ 3 x 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. Table 19 to Table 29 present the evaluated strains, test levels and the results for detection.

Table 19. *Campylobacter* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
<i>Campylobacter coli</i>	CCUG 10960	549	3x LoD	Positive
	CCUG 53138	549	3x LoD	Positive



Specific Performance Characteristics

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
	ATCC 43478	549	3x LoD	Positive
	CCUG 36766	549	3x LoD	Positive
<i>Campylobacter jejuni</i>	CCUG 59141	549	3x LoD	Positive
	CCUG 10259	549	3x LoD	Positive
	Zeptometrix 0801650	549	3x LoD	Positive
<i>Campylobacter jejuni</i> subsp. <i>doylei</i>	CCUG 24567T	549	3x LoD	Positive
<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	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
<i>Campylobacter fetus</i>	CCUG 71557	24,000	131x LoD	Negative
<i>Campylobacter lari</i>	CCUG 15031	24,000	131x LoD	Negative
<i>Campylobacter upsaliensis</i>	CCUG 14913T	24,000	131x LoD	Negative
	CCUG 24191	24,000	131x LoD	Negative

Table 20. 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)	Multiples of LoD	Reported Results
<i>Cryptosporidium parvum</i>	IDT Synthetic DNA, L25642	3,690	3x LoD	Positive
<i>Cryptosporidium meleagridis</i>	IDT Synthetic DNA, EF179381	3,690	3x LoD	Positive
<i>Cryptosporidium canis</i>	IDT Synthetic DNA, AF112576	3,690	3x LoD	Positive
<i>Cryptosporidium ubiquitum</i>	IDT Synthetic DNA, QZWX01000067	3,690	3x LoD	Positive
<i>Cryptosporidium hominis</i>	IDT Synthetic DNA, JIBM01000066	3,690	3x LoD	Positive
<i>Cryptosporidium muris</i>	Waterborne Inc. P104, RN66	480,000	390x LoD	Negative ^a
	IDT Synthetic DNA, AB089284	100,000	81x LoD	Positive ^b

a. Two out of 5 replicates and 1 out of 2 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 21. STEC Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples 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



Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
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) 0.6x LoD (stx2)	Positive Positive
STEC stx1/stx2 (O111)	NCTC 13794	1,872	3x LoD (stx1) 0.6x LoD (stx2)	Positive Positive
STEC stx1/stx2 (O157)	Microbiologics 0617P (ATCC 35150)	1,872	3x LoD (stx1) 0.6x LoD (stx2)	Positive Positive

Table 22. Norovirus Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (cp/mL)	Multiples 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 LoD	
Norovirus GII.3[P12]	Clinical Specimen 435625, Precision for Medicine U.S.	894	3x LoD	Positive
		9	0.03x LoD	
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
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



Specific Performance Characteristics

Target Pathogen Strain	Strain ID	Test Concentration (cp/mL)	Multiples of LoD	Reported Results
	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 (GIX)	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 23. *Salmonella* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
<i>Salmonella bongori</i>	CCUG 63587	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>salamae</i>	CCUG 30039T	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>arizona</i> ae	CCUG 6322T	2,400	1.9x LoD	Positive
	CCUG 63588	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>diarizonae</i>	CCUG 63589	2,400	1.9x LoD	Positive
	CCUG 30040T	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>houtenae</i>	CCUG 30041T	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>indica</i>	CCUG 30038T	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Agona	CCUG 21287	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Anatum	CCUG 21243	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Bareilly	CCUG 12616	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Berta	CCUG 27106	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Blockley	CCUG 21263	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Branderup	CCUG 50923	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Derby	CCUG 21276	2,400	1.9x LoD	Positive



Specific Performance Characteristics

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
<i>Salmonella enterica</i> subsp. <i>enterica</i> Enteritidis	CCUG 34136T	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Hadar	CCUG 21271	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Heidelberg	CCUG 21289	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> 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
<i>Salmonella enterica</i> subsp. <i>enterica</i> Infantis	CCUG 12615	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Javiana	CCUG 21235	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Litchfield	NCTC 6028	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Mbandaka	CCUG 21272	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Mississippi	Clinical Specimen S027019, Public Health Agency of Sweden	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Montevideo	CCUG 21239	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Muenchen	CCUG 21254	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Newport	CCUG 21283	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Oranienburg	CCUG 12649	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Panama	CCUG 21275	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Paratyphi A	NCTC 5702	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Poona	CCUG 39842	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Reading	NCTC 5720	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Saintpaul	CCUG 21282	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Sandiego	NCTC 6024	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Schwarzengrund	CCUG 21280	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Senftenberg	CCUG 37886	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Stanley	CCUG 26623	2,400	1.9x LoD	Positive
<i>Salmonella enterica</i> subsp. <i>enterica</i> Thompson	CCUG 12652	2,400	1.9x LoD	Positive



Specific Performance Characteristics

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

Table 24. Shigella Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

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

a. *Shigella* strains carrying STEC stx1 gene.

**Table 25. Enteroinvasive *Escherichia coli* (EIEC) Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study**

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
Enteroinvasive <i>Escherichia coli</i> (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 confirmed the absence of the EIEC target gene ipaH in strain NCTC 9013, i.e., target gene loss confirmed.

Table 26. *Vibrio cholerae* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

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

Table 27. *Vibrio parahaemolyticus* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

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

Table 28. *Yersinia enterocolitica* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
<i>Yersinia enterocolitica</i> biotype 1 (O:8)	CCUG 33055	1,044	3x LoD	Positive
<i>Yersinia enterocolitica</i> biotype 2 (O:9)	CCUG 8239A	1,044	3x LoD	Positive
<i>Yersinia enterocolitica</i> biotype 2 (O:5, 27)	NCTC 10463	1,044	3x LoD	Positive
<i>Yersinia enterocolitica</i> biotype 4 (O:3)	CCUG 34604	1,044	3x LoD	Positive

Table 29. *Giardia* Strains Evaluated in the Xpert GI Panel Analytical Reactivity Study

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

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 30 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 30. 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



Type of Substance	Substance	Concentration Tested in Raw Stool
Method Specific Substances (Cary Blair medium)	Sodium phosphate	5% w/v
	Nonoxynol-9	50% v/v
	Stearic 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.

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., ≤ 3 x 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 31 presents the target pathogen combinations and the reported results.

Table 31. Target Pathogen Combinations Evaluated in the Xpert GI Panel Competitive Inhibition Study

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



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

Reproducibility and Precision

The reproducibility and precision of the Xpert GI Panel was established at 3 sites (2 external and 1 internal) using three contrived panels. Panel 1 and Panel 3 were both 3-member panels including 1 negative sample, 1 low positive ($\sim 1x$ LoD) sample, and 1 moderate positive ($\sim 3x$ LoD) sample that were tested fresh. Panel 2 was a 5-member panel including 1 negative sample, 2 low positive ($\sim 1x$ LoD) samples, and 2 moderate positive ($\sim 3x$ LoD) samples that were tested frozen. The negative samples consisted of pooled negative clinical stool matrix. The positive samples were contrived by diluting target pathogen into pooled negative clinical stool matrix. Panel 1 and Panel 2 testing was conducted over 6 days using 3 lots of Xpert GI Panel cartridges at 3 participating sites, each with 2 operators to yield a total of 144 observations per panel member (3 Sites \times 2 Operators \times 3 Lots \times 2 days/Lot \times 2 Runs \times 2 replicates) using a GeneXpert Dx System, a GeneXpert Infinity System, or a GeneXpert System with Touchscreen. Panel 3 testing was conducted over 3 days using 3 lots of Xpert GI Panel cartridges at 3 participating sites, each with 2 operators to yield a total of 108 observations per panel member (3 Sites \times 2 Operators \times 3 Lots \times 1 day/Lot \times 2 Runs \times 3 replicates) using a GeneXpert Dx System, a GeneXpert Infinity System, or a GeneXpert System with Touchscreen. Panel 3 testing was conducted over 3 days in order to test low and moderate *V. parahaemolyticus* positives within the 4-day window of specimen stability (2–8°C).

The percent agreement of the correct results compared to the expected results analyzed by each of the 2 operators and each site is shown in [Table 32](#). 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.



Table 32. Reproducibility and Precision Results - % Agreement

Panel	Sample	Site 1			Site 2			Site 3			% Total Agreement [95% CI]
		OP 1	OP 2	Site	OP 1	OP 2	Site	OP 1	OP 2	Site	
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 1	<i>Campylobacter</i> 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	<i>Campylobacter</i> 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 <i>stx2</i> 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	STEC <i>stx2</i> 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 2	<i>Salmonella</i> 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	<i>Salmonella</i> 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 ^a	24/24	47/47	24/24	24/24	48/48	
Panel 2	<i>Yersinia</i> 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	<i>Yersinia</i> 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 ^a	24/24	47/47	24/24	24/24	48/48	
Panel 2	<i>Cryptosporidium</i> 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	<i>Cryptosporidium</i> 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 ^a	24/24	47/47	24/24	24/24	48/48	
Panel 2	<i>Giardia</i> 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	<i>Giardia</i> 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	<i>Shigella</i> 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	<i>Shigella</i> 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 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			
Panel 3	<i>V. parahaemolyticus</i> 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	<i>V. parahaemolyticus</i> 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 ^b	18/18	36/36	18/18	18/18	36/36			

a. One sample was non-determinate on both initial and retest and was excluded from the analyses.

b. One moderate positive sample (02-03-12-A) tested positive for *V. parahaemolyticus* and *V. cholerae*. This sample was considered concordant for *V. parahaemolyticus*.

The evaluation of reproducibility and within-laboratory precision of the analyte internal continuous 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 33.

Table 33. Reproducibility and Precision Results: Nested ANOVA by Coefficient of Variation

Sample	Response	N	Mean Response	Site		Operator		Lot		Day		Run		Within-Run		Total	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
<i>Campylobacter</i> 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
<i>Campylobacter</i> 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 <i>stx2</i> 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 <i>stx2</i> 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
<i>Salmonella</i> 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
<i>Salmonella</i> 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
<i>Yersinia</i> 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
<i>Yersinia</i> 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
<i>Cryptosporidium</i> 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
<i>Cryptosporidium</i> 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



Specific Performance Characteristics

Sample	Response	N	Mean Response	Site		Operator		Lot		Day		Run		Within-Run		Total	
				SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
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
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. <i>parahaemolyticus</i> Low Pos	MP	108	15.5	1.3	8.4	0	0	0.9 ^c	5.8 ^c	N/A ^c	N/A ^c	0.8	5.1	2	12.9	2.7	17.2
	MV	108	-13.5	1.1	8.1	0	0	0.8 ^c	5.7 ^c	N/A ^c	N/A ^c	0.8	6.2	1.8	13.5	2.4	17.9
V. <i>parahaemolyticus</i> Mod Pos	MP	108	16.2	1.1	6.7	0	0	0.8 ^c	5.1 ^c	N/A ^c	N/A ^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 ^c	5.6 ^c	N/A ^c	N/A ^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; N/A, not available, SD, standard deviation

- One sample excluded due to a non-determinate result.
- One sample excluded due to negative *Yersinia* result with missing melt peak and melt valley values.
- 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.

① Appendix

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Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag Number

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Table of Symbols

Symbol	Meaning
REF	Catalog number
IVD	<i>In vitro</i> diagnostic medical device
Rx only	For prescription use only
	Do not reuse
LOT	Batch code
	Consult instructions for use
	Caution
	Manufacturer
	Country of manufacture
	Contains sufficient for n tests
CONTROL	Control
	Use-by date
	Temperature limitation
	Biological risks
	Irritant (skin and eye)

Revision History

Description of Changes: 303-4456 Rev A

Purpose: Initial release



