GeneXpert
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Xpert® GI Panel

REF GXGI-10

Instructions for Use

For Use with GeneXpert® Dx System or GeneXpert Infinity System

IVD

Cepheid

In Vitro Diagnostic Medical Device

303-4454, Rev. A
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Trademark, Patents, and Copyright Statements

See Section 26, Revision History for a description of changes.

Xpert® GI Panel

For *in Vitro* Diagnostic Use Only.

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1 Proprietary Name

Xpert® GI Panel

2 Common or Usual Name

Xpert GI Panel

3 Intended Use

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

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

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

4 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.

5 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, computer, and preloaded software for running tests and viewing the results. Each test requires the use of a single-use disposable GeneXpert cartridge that contains target-specific reagents and carries out the reverse transcription and PCR processes. Because the cartridges are self-contained, the risk of cross-contamination between samples is minimized. For a full description of the systems, refer to the appropriate *GeneXpert Dx System Operator Manual* or *GeneXpert Infinity System 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 and valley 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	*Campylobacter* (*C. jejuni/C. coli*)	Campylobacter	Melt curve analysis
	Shiga toxin-producing *Escherichia coli* (STEC) *stx1/stx2*	STEC stx1	Melt curve analysis
		STEC stx2	Melt curve analysis
	Salmonella	Salmonella	Amplification analysis

Pathogen Detected		Reported Analyte Name	Detection Method
	Shigella/Enteroinvasive *Escherichia coli*	Shigella EIEC	Amplification analysis
	Yersinia enterocolitica	Yersinia	Melt curve analysis
	Vibrio parahaemolyticus	V. parahaemolyticus	Melt curve analysis
	Vibrio cholerae	V. cholerae	Melt curve analysis
Parasites	*Giardia* (also known as *G, duodenalis*, *G. lamblia* and *G. intestinalis*)	Giardia	Amplification analysis
	Cryptosporidium	Cryptosporidium	Amplification analysis
Virus	Norovirus GI/GII	Norovirus	Amplification analysis

6 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.

7 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.

8 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.

9 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 Prevention[1] 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 Section 11). 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.

10 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.

11 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.

12 Procedure

12.1 Preparing the Cartridge

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

Obtain the following items: Xpert cartridge, transfer swab (provided), and an appropriately collected and labelled test sample.

1. Remove a cartridge from the package (it is recommended to equilibrate the cartridge to room temperature [15–25 °C] before use).
2. Inspect the cartridge for damage. If damaged or has signs of leakage, do not use it.
3. 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.
4. Mix specimen thoroughly until fully homogenized. Vortex can be used.
5. Open the cartridge lid by lifting the lid.
6. Remove the transfer swab from the wrapper.
7. 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.

8. 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.

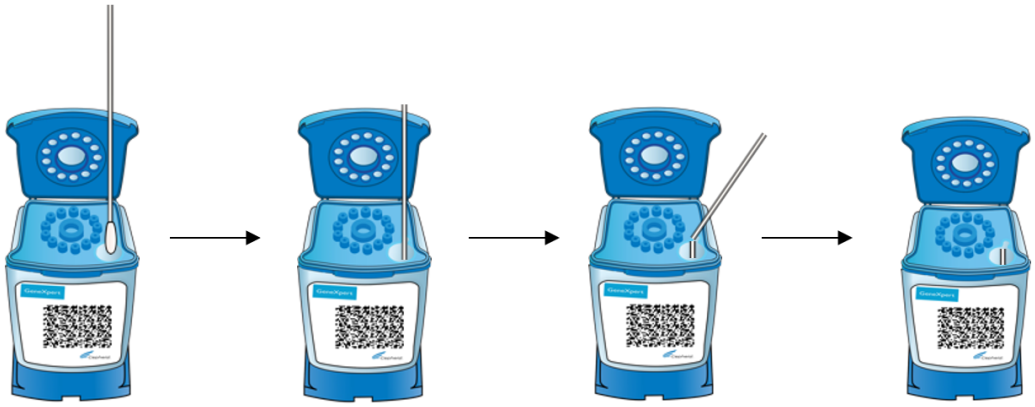

Figure 1. Xpert GI Panel Test Cartridge (Top View)

9. Close the cartridge lid.

13 Running the Test

- For the GeneXpert Dx System, see Section 13.1.
- For the GeneXpert Infinity System, see Section 13.2.

13.1 GeneXpert Dx System

13.1.1 Starting the Test

Important

Before you start the test, make sure that:

- The system is running the GeneXpert Dx software version shown in section - Materials Required but Not Provided.
- The correct assay definition file is imported into the software.

This section lists the basic steps for running the test. For detailed instructions, see the *GeneXpert Dx System Operator Manual*.

Note The steps you follow can be different if the system administrator changed the default workflow of the system.

1. Turn on the GeneXpert Dx System, then turn on the computer and log on. The GeneXpert software will launch automatically. If it does not, double-click the GeneXpert Dx software shortcut icon on the Windows® desktop.
2. Log on using your username and password.
3. In the **GeneXpert System** window, click **Create Test**.
   The **Create Test** window displays. The **Scan Patient ID barcode** dialog box displays.
4. Scan or type in the Patient ID. If typing the Patient ID, make sure the Patient ID is typed correctly.
   The Patient ID is associated with the test results and displays in the **View Results** window and all the reports. The **Scan Sample ID barcode** dialog box displays.
5. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly.
   The Sample ID is associated with the test results and displays in the **View Results** window and all the reports. The **Scan Cartridge Barcode** dialog box displays.
6. Scan the barcode on the cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.

Note If the barcode on the cartridge does not scan, then repeat the test with a new cartridge. If you have scanned the cartridge barcode in the software and the assay definition file is not available, a screen displays indicating the assay definition file is not loaded on the system. If this screen displays, contact Cepheid Technical Support.

7. Click **Start Test**. In the dialog box that displays, type your password, if required.
8. Open the instrument module door with the blinking green light and load the cartridge.
9. Close the door. The test starts and the green light stops blinking.

   When the test is finished, the light turns off.
10. Wait until the system releases the door lock before opening the module door, then remove the cartridge.
11. Dispose of the used cartridges in the appropriate specimen waste containers according to your institution's standard practices.

Note Do not open or attempt to alter any part of the used cartridge for disposal. Do not turn off or unplug the instrument while a test is in progress. Turning off or unplugging the instrument or computer will stop the test.

13.1.2 Viewing and Printing Results

This section lists the basic steps for viewing and printing results. For more detailed instructions on how to view and print the results, see the *GeneXpert Dx System Operator Manual*.

1. Click the **View Results** icon to view results.
2. Upon completion of the test, click the **Report** button of the **View Results** window to view and/or generate a PDF report file.

13.2 GeneXpert Infinity System

13.2.1 Starting the Test

Before you start the test, make sure that:

Important
- The system is running the Xpertise software version shown in section - Materials Required but Not Provided.
- The correct assay definition file is imported into the software.

This section lists the basic steps for running the test. For detailed instructions, see the *GeneXpert Infinity System Operator Manual*.

Note The steps you follow can be different if the system administrator changed the default workflow of the system.

1. Power up the instrument. The Xpertise software will launch automatically. If it does not, double-click the Xpertise software shortcut icon on the Windows® desktop.
2. Log on to the computer, then log on to the GeneXpert Xpertise software using your user name and password.
3. In the **Xpertise Software Home** workspace, click **Orders** and in the **Orders** workspace, click **Order Test**. The **Order Test - Patient ID** workspace displays.
4. Scan or type in the Patient ID. If typing the Patient ID, make sure the Patient ID is typed correctly. The Patient ID is associated with the test results and displays in the **View Results** window and all the reports.
5. Enter any additional information required by your institution, and click the **CONTINUE** button. The **Order Test - Sample ID** workspace displays.
6. Scan or type in the Sample ID. If typing the Sample ID, make sure the Sample ID is typed correctly. The Sample ID is associated with the test results and displays in the **View Results** window and all the reports.
7. Click the **CONTINUE** button. The **Order Test - Assay** workspace displays.
8. Scan the barcode on the cartridge. Using the barcode information, the software automatically fills the boxes for the following fields: Select Assay, Reagent Lot ID, Cartridge SN, and Expiration Date.

Note If the barcode on the cartridge does not scan, then repeat the test with a new cartridge. If you have scanned the cartridge barcode in the software and the assay definition file is not available, a screen displays indicating the assay definition file is not loaded on the system. If this screen displays, contact Cepheid Technical Support.

   After the cartridge is scanned, the **Order Test - Test Information** workspace displays.
9. Verify that the information is correct, and click **Submit**. In the dialog box that displays, type your password, if required.

10. Place the cartridge on the conveyor belt.

Note Do not turn off or unplug the system while a test is in progress. Turning off or unplugging the GeneXpert instrument or computer will stop the test.

The cartridge automatically loads, the test runs, and the used cartridge are placed into the waste container.

13.2.2 Viewing and Printing Results

This section lists the basic steps for viewing and printing results. For more detailed instructions on how to view and print the results, see the *GeneXpert Infinity System Operator Manual*.

1. In the **Xpertise Software Home** workspace, click the **RESULTS** icon. The Results menu displays.
2. In the Results menu, select the **VIEW RESULTS** button. The **View Results** workspace displays showing the test results.
3. Click the **REPORT** button to view and/or generate a PDF report file.

14 Quality Control

Each test includes a Sample Processing Control (SPC), 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 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 System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. The PCC passes if it meets the assigned acceptance criteria.
- **External Controls** — Following good laboratory practice, external controls, not provided in the kit, should be used in accordance with the requirements of local and state accrediting organizations, as applicable.

15 Interpretation of Results

The results are interpreted automatically by the GeneXpert System and are shown in the **View Results** window (Figure 2, Figure 3, Figure 4, and Figure 5).

- **Positive targets** are **highlighted in red color**, **Negative targets** are **highlighted in green color**.

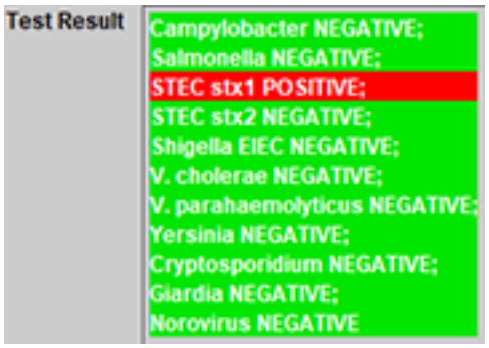

Figure 2. Xpert GI Panel: An Example of test result with Single Positive analyte (highlighted in Red color: STEC stx1 POSITIVE) and negative result for other pathogens (highlighted in Green color). STEC stx1is detected.

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

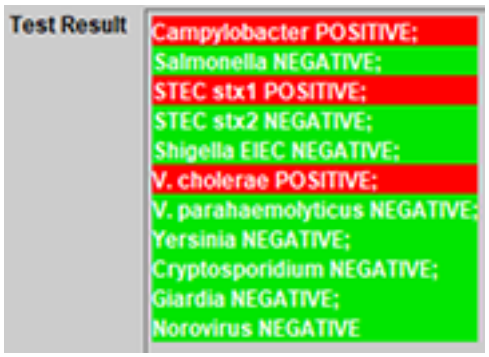

Figure 3. Xpert GI Panel: An Example of Test Result with Positive Result for multiple pathogens (*Campylobacter, STEC stx1* and *V. cholerae* - highlighted in Red color) and negative for other pathogens (highlighted in green color).

- **Non-determinate** samples (Invalid, Error or No result) are **highlighted in gray color**.

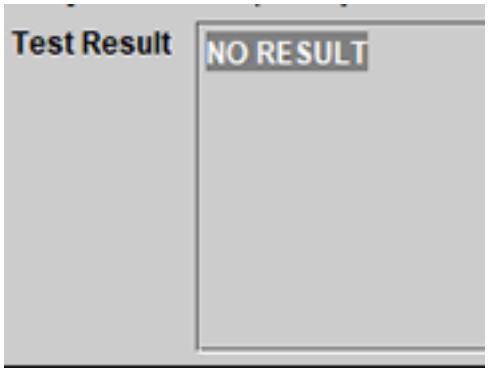

Figure 4. Example of Test Result with No Result outcome (highlighted in Grey color).

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 4. 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.

Table 2. Test Results Interpretation for 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;	***Campylobacter* is detected.** The *Campylobacter* signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. 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.
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;	***Salmonella* is detected.** The *Salmonella* signal has a Ct within the valid cycle range. 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.
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;	**Shiga toxin-producing *Escherichia coli* (STEC) stx1 is detected.** The Shiga toxin-producing *Escherichia coli* (STEC) stx1 signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. Except Shiga toxin-producing *Escherichia coli* (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 *Escherichia coli* (STEC) *stx1* is detected. IC – NA; IC is ignored because Shiga toxin-producing *Escherichia coli* (STEC) *stx1* is detected.
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;	**Shiga toxin-producing *Escherichia coli* (STEC) stx2 is detected.** The Shiga toxin-producing *Escherichia coli* (STEC) stx2 signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. Except Shiga toxin-producing *Escherichia coli* (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 *Escherichia coli* (STEC) *stx2* is detected. IC – NA; IC is ignored because Shiga toxin-producing *Escherichia coli* (STEC) *stx2* is detected.

Result	Interpretation
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;	***Shigella* or EIEC is detected.** The *Shigella*/Enteroinvasive *Escherichia coli* (EIEC) signal has a Ct within the valid cycle range. Except *Shigella*/Enteroinvasive *Escherichia coli* (EIEC)all pathogens listed in **Table 1** are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because *Shigella*/Enteroinvasive *Escherichia coli* (EIEC) is detected. IC – NA; IC is ignored because *Shigella*/Enteroinvasive *Escherichia coli* (EIEC) is detected.
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;	***V. cholerae* is detected.** The *V. cholerae* signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. Except *V. cholerae* all pathogens listed in **Table 1** are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because *V. cholerae* is detected. IC – NA; IC is ignored because *V. cholerae* is detected.
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;	***V. parahaemolyticus* is detected.** The *V. parahaemolyticus* signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. Except *V. parahaemolyticus*all pathogens listed in **Table 1** are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because *V. parahaemolyticus* is detected. IC – NA; IC is ignored because *V. parahaemolyticus* is detected.
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;	***Yersinia* is detected.** The *Yersinia* signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. Except *Yersinia* all pathogens listed in **Table 1** are not detected. Probe Check: PASS; all probe check results pass. SPC - NA; SPC is ignored because *Yersinia* is detected. IC – NA; IC is ignored because *Yersinia* is detected.
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;	***Cryptosporidium* is detected.** The *Cryptosporidium* signal has a Ct within the valid cycle range. Except *Cryptosporidium* all pathogens listed in **Table 1** are not detected. Probe Check - PASS; all probe check results pass. SPC - NA; SPC is ignored because *Cryptosporidium* is detected. IC – NA; IC is ignored because *Cryptosporidium* is detected.

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;	***Giardia* is detected.** The *Giardia*signal has a Ct within the valid cycle range. Except *Giardia* all pathogens listed in **Table 1** are not detected. Probe Check - PASS; all probe check results pass. SPC - NA; SPC is ignored because *Giardia* is detected. IC – NA; IC is ignored because *Giardia* is detected.
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;	**Norovirus GI or GII is detected.** The Norovirus signal has a Ct within the valid cycle range. Except Norovirus all pathogens listed in **Table 1** are not detected. Probe Check - PASS; all probe check results pass. SPC - NA; SPC is ignored because Norovirus is detected. IC – NA; IC is ignored because Norovirus is detected.

Table 3. Test Results Interpretation for 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;	None of the pathogens listed in **Table 1** are detected. SPC - PASS; ● The SPC signal has a Ct within the valid cycle range AND ● The SPC signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. IC – PASS; ● The IC signal has a Ct within the valid cycle range. Probe Check - PASS; all probe check results pass.

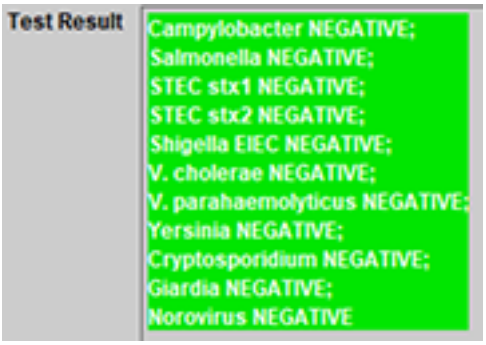

Figure 5. Xpert GI Panel: An Example of Test Result with Negative outcome for all pathogens (highlighted in Green color). None of the pathogens were detected.

Table 4. Test Results Interpretation for Xpert GI Panel test with Positive Outcome for Two or More Pathogens

Result	Interpretation
Campylobacter POSITIVE; Salmonella NEGATIVE; STEC stx1 NEGATIVE; STEC stx2 NEGATIVE; Shigella EIEC POSITIVE; V. cholerae POSITIVE; V. parahaemolyticus POSITIVE; Yersinia NEGATIVE; Cryptosporidium NEGATIVE; Giardia POSITIVE; Norovirus POSITIVE;	***Campylobacter, Shigella*/Enteroinvasive *Escherichia coli* (EIEC), *Vibrio cholerae, Vibrio parahaemolyticus, Giardia*, and Norovirus GI/GIIare detected.** The detected signal has a Ct within the valid cycle range. (applicable for *Giardia*, *Shigella*/Enteroinvasive *Escherichia coli* (EIEC)andNorovirus). The detected signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range. (applicable for *Campylobacter, Vibrio cholerae* and *Vibrio parahaemolyticus*). Except *Campylobacter*, *Vibrio cholerae, Vibrio parahaemolyticus, Giardia* and Norovirus,all pathogens listed in **Table 1** are not detected. Probe Check – PASS; all probe check results pass. SPC – NA; SPC is ignored because *Campylobacter*, *Shigella*/Enteroinvasive *Escherichia coli* (EIEC), *Vibrio cholerae, Vibrio parahaemolyticus,Giardia* and Norovirusare detected. IC – NA; IC is ignored because *Campylobacter*, *Shigella*/Enteroinvasive *Escherichia coli* EIEC, *Vibrio cholerae, Vibrio parahaemolyticus*, *Giardia* andNorovirus are detected. **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 Section 16.2.

Table 5. Test Results Interpretation for 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 Section 16.2. 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 Section 16.2. 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 Section 16.2. 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.

16 Retests

16.1 Reasons to Repeat the Test

If any of the test results mentioned below occur, repeat the test according to the instructions in Retest Procedure Section.

- An **INVALID** result indicates that the control SPC and/or the control IC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.
- An **ERROR** result could be due to, but not limited to, Probe Check Control failed, 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 Section 16.2 Retest Procedure.

16.2 Retest Procedure

If the result is non-determinate (INVALID, ERROR, NO RESULT) or the result indicate infection with multiple pathogens, use a new cartridge to retest the affected specimen (do not re-use the cartridge).

- Refer to Section 11 for specimen collection if needed.
- Remove a new cartridge from the kit.
- See Procedure, including Section 12.1 and Section 13.

17 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 instruction for use 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 Analytical Specificity (Exclusivity) and Microbial Interference of 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 andnot 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*, *arizonae*, *diarizonae*, *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 (*subspecie*s 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*.
- The Xpert GI Panel is not intended for use with Cary Blair media formulations that contain formalin, other chemical fixatives, or preservatives.

18 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
Campylobacter	4.3% (67/1568)	5.9% (11/185)	17.2% (5/29)	4.6% (18/394)	3.9% (13/336)	3.2% (20/624)
Salmonella	3.3% (51/1568)	6.5% (12/185)	6.9% (2/29)	4.1% (16/394)	3.3% (11/336)	1.6% (10/624)
V. parahaemolyticus	0.0% (0/1505)	0.0% (0/179)	0.0% (0/29)	0.0% (0/377)	0.0% (0/321)	0.0% (0/599)
V. cholerae	0.1% (1/1568)	0.0% (0/185)	0.0% (0/29)	0.3% (1/394)	0.0% (0/336)	0.0% (0/624)
Yersinia	1.6% (25/1568)	2.2% (4/185)	0.0% (0/29)	1.0% (4/394)	1.5% (5/336)	1.9% (12/624)
Shigella EIEC	2.4% (38/1568)	3.2% (6/185)	0.0% (0/29)	4.3% (17/394)	2.4% (8/336)	1.1% (7/624)

Analyte	Overall[a]	< 18 years	18–21 years	22–49 years	50–64 years	≥ 65 years
STEC *stx1*	0.4% (6/1497)	0.6% (1/173)	0.0% (0/25)	0.3% (1/374)	0.6% (2/320)	0.3% (2/605)
STEC *stx2*	0.2% (3/1497)	0.0% (0/173)	0.0% (0/25)	0.0% (0/374)	0.3% (1/320)	0.3% (2/605)
Cryptosporidium	2.2% (34/1568)	5.4% (10/185)	0.0% (0/29)	3.8% (15/394)	2.1% (7/336)	0.3% (2/624)
Giardia	1.5% (24/1568)	1.6% (3/185)	0.0% (0/29)	3.8% (15/394)	0.9% (3/336)	0.5% (3/624)
Norovirus	4.7% (72/1521)	7.2% (13/181)	0.0% (0/29)	5.0% (19/381)	3.4% (11/327)	4.8% (29/603)

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

Expected Values for Analytes in Multi-analyte Detections

The prevalence of multi-analyte combinations detected by the Xpert GI Panel is presented in Table 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 (%)
Cryptosporidium and Norovirus	1/25	4.0%
Cryptosporidium and *Giardia*	1/25	4.0%
Yersinia and Norovirus	2/25	8.0%
Shigella EIEC and Norovirus	2/25	8.0%
Shigella EIEC and *Giardia*	1/25	4.0%
STEC *stx1* and *Cryptosporidium*	1/25	4.0%
STEC *stx1* and *Shigella* EIEC	1/25	4.0%
STEC *stx1* and STEC *stx2*	1/25	4.0%
Salmonella and Norovirus	2/25	8.0%
Salmonella, *Giardia*, and Norovirus	1/25	4.0%
Salmonella and *Yersinia*	1/25	4.0%
Salmonella, STEC *stx1*, and STEC *stx2*	1/25	4.0%
Campylobacter and Norovirus	2/25	8.0%
Campylobacter and *Cryptosporidium*	1/25	4.0%
Campylobacter and *Yersinia*	2/25	8.0%
Campylobacter and *Shigella* EIEC	3/25	12.0%

Multi-analyte Combinations[a]	Number of Specimens (n/N)	Percent of Specimens (%)
Campylobacter, *Shigella* EIEC, and Norovirus	1/25	4.0%
Campylobacter and *Salmonella*	1/25	4.0%

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

19 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)	
<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%)

Prospective Fresh Specimens (N=1592)	Number of Specimens (%)
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
Campylobacter	604	62/66[a]	93.9	85.4–97.6	533/538[a]	99.1	97.8–99.6
Salmonella	1568	49/54[b]	90.7	80.1–96.0	1512/1514	99.9	99.5–100.0
V. parahaemolyticus	1505	0/0	N/A	N/A	1505/1505	100.0	99.7–100.0
V. cholerae	1568	0/1[c]	0	0.0–79.3	1566/1567[c]	99.9	99.6–100.0
Yersinia	603	15/15	100.0	79.6–100.0	578/588[d]	98.3	96.9–99.1
Shigella EIEC	1568	34/37[e]	91.9	78.7–97.2	1527/1531[e]	99.7	99.3–99.9
STEC *stx1*	1497	6/6	100.0	61.0–100.0	1491/1491	100.0	99.7–100.0
STEC *stx2*	1497	2/2	100.0	34.2–100.0	1494/1495	99.9	99.6–100.0
Cryptosporidium	1568	32/32	100.0	89.3–100.0	1534/1536[f]	99.9	99.5–100.0
Giardia	1568	20/21[g]	95.2	77.3–99.2	1543/1547[g]	99.7	99.3–99.9
Norovirus GI/GII	1521	46/47	97.9	88.9–99.6	1448/1474	98.2	97.4–98.8

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

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

[b] Of 5 specimens with FN *Salmonella* results, 3 were also negative and 2 were not evaluable by the discrepant 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)
Cryptosporidium	Norovirus	N/A	1	1	Norovirus
Cryptosporidium	*Giardia*	N/A	1	0	N/A
Yersinia	Norovirus	N/A	2	2	Specimen 1: *Yersinia,* Norovirus; Specimen 2: *Yersinia,* Norovirus, *Shigella* EIEC[a]
Shigella EIEC	Norovirus	N/A	2	1	*Shigella* EIEC, Norovirus
Shigella EIEC	*Giardia*	N/A	1	1	*Shigella* EIEC
STEC *stx1*	*Cryptosporidium*	N/A	1	0	N/A
STEC *stx1*	*Shigella* EIEC	N/A	1	0	N/A
STEC *stx1*	STEC *stx2*	N/A	1	0	N/A
Salmonella	Norovirus	N/A	2	0	N/A
Salmonella	*Giardia*	Norovirus	1	1	Norovirus
Salmonella	*Yersinia*	N/A	1	0	N/A
Salmonella	STEC *stx1*	STEC *stx2*	1	0	N/A
Campylobacter	Norovirus	N/A	2	1	Norovirus
Campylobacter	*Cryptosporidium*	N/A	1	0	N/A
Campylobacter	*Yersinia*	N/A	2	0	N/A
Campylobacter	*Shigella* EIEC	N/A	3	1	*Campylobacter*
Campylobacter	*Shigella* EIEC	Norovirus	1	1	*Campylobacter,* Norovirus
Campylobacter	*Salmonella*	N/A	1	0	N/A
Total Multi-Analyte Detections			25	9	N/A
Multi-Analyte Detections with 2 Analytes			22	7	

Analyte 1	Analyte 2	Analyte 3	Total	Total Specimens with Discrepant Results	Discrepant Analyte(s)
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
Salmonella	68	6/7[a]	85.7	48.7–97.4	61/61	100.0	94.1–100.0
Shigella EIEC	68	15/15	100.0	79.6–100.0	52/53[b]	98.1	90.1–99.7
Cryptosporidium	68	3/4[c]	75.0	30.1–95.4	64/64	100.0	94.3–100.0
Giardia	68	13/13	100.0	77.2–100.0	55/55	100.0	93.5–100.0
Norovirus GI/GII	35	17/17	100.0	81.6–100.0	18/18	100.0	82.4–100.0
Abbreviations: CI, confidence interval; FN, false negative; FP, false positive; N/A, not available; NAAT, Nucleic Acid Amplification Test; TN, true negative; TP, true positive							

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

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

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

Contrived Samples

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

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

The performance of the Xpert GI Panel in contrived samples was calculated relative to the expected result and presented in Table 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
V. parahaemolyticus	146	63/65[a]	96.9	89.5–99.2	81/81	100.0	95.5–100.0
V. cholerae	146	65/65	100.0	94.4–100.0	81/81	100.0	95.5–100.0
Yersinia	126	45/45	100.0	92.1–100.0	81/81	100.0	95.5–100.0
Shigella 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
Cryptosporidium	113	32/32	100.0	89.3–100.0	81/81	100.0	95.5–100.0
Giardia	116	35/35	100.0	90.1–100.0	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
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.

20 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
Campylobacter	*Campylobacter coli*	CCUG 11283T	46 CFU/mL
	Campylobacter jejuni	CCUG 41359	183 CFU/mL
Shigella/EIEC	*Shigella sonnei*	CCUG 68726T	82 CFU/mL
	Enteroinvasive *Escherichia coli* (EIEC)	CCUG 46406	204 CFU/mL
Salmonella	*Salmonella bongori*	CCUG 30042T	261 CFU/mL
	Salmonella enterica	NCTC 13171	1,242 CFU/mL
STEC stx1/stx2	STEC stx1	Statens Serum Institut MHI813	624 CFU/mL
	STEC stx2	Statens Serum Institut 31	3,010 CFU/mL
	STEC stx1_2	Statens Serum Institut EDL933	565 (stx1) CFU/mL 683 (stx2) CFU/mL
Vibrio cholerae	*Vibrio cholerae*	NCTC 8457	136 CFU/mL
	Vibrio cholerae	CCUG 67718	459 CFU/mL
Vibrio parahaemolyticus	*Vibrio parahaemolyticus*	CCUG 14474T	127 CFU/mL
	Vibrio parahaemolyticus	CCUG 67711	489 CFU/mL
Yersinia enterocolitica	*Yersinia enterocolitica*	CCUG 52867T	348 CFU/mL
	Yersinia enterocolitica	CCUG 12369T	106 CFU/mL
Cryptosporidium	*Cryptosporidium hominis*	Waterborne Inc. TU502	72 oocysts/mL

Target Pathogen	Strain	Strain ID	Confirmed LoD
	Cryptosporidium parvum	Waterborne Inc. P102C, Iowa	246 oocysts/mL
Giardia	*Giardia lamblia*	Waterborne Inc. P101, H3	246 cysts/mL
	Giardia intestinalis	ATCC 30957	0.36 cysts/mL
Norovirus	Norovirus GI	Clinical sample GI.3[P3]	298 cp/mL
	Norovirus GII	Clinical sample GII.4 Sydney	27 cp/mL

Analytical Specificity (Exclusivity) and Microbial Interference

Studies were performed to evaluate the analytical specificity (exclusivity), microbial interference and the in-assay cross reactivity of the Xpert GI Panel test. A total of 136 non-target microorganisms commonly found in stool and rectal flora were either tested with the Xpert GI Panel test (131 microorganisms) or assessed using *in silico* analysis directed against the Xpert GI Panel probe and primer sequences (five microorganisms). The non-target microorganisms evaluated using the Xpert GI Panel test were diluted into clinical stool matrix at high concentrations and tested in absence of target pathogens using three replicates, and in presence of target pathogens diluted to ≤ 3x LoD using six replicates. Non-target bacteria were tested at 1E6 CFU/mL and non-target viruses and parasites/yeast were tested at ≥ 1E4 units/mL.

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

No cross-reactivity or microbial interference were observed for any of the tested non-target microorganisms using the Xpert GI Panel test. The risk for cross reactivity or interference with the Xpert GI Panel test was assessed low using *in silico* analysis for five of the non-target microorganisms. No in-assay cross reactivity was observed for any of the Xpert GI Panel target pathogens tested at high concentrations. 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**
Abiotrophia defectiva	CCUG 27639	1E6 CFU/mL
Acinetobacter baumannii	CCUG 19096T	1E6 CFU/mL
Acinetobacter lwoffii	ZeptoMetrix 0801909	1E6 CFU/mL
Aeromonas caviae	CCUG 25939	1E6 CFU/mL
Aeromonas salmonicida (Aeromonas hydrophila)	ATCC 7965	1E6 CFU/mL
Aeromonas schubertii	CCUG 27820	1E6 CFU/mL
Aeromonas sobria	CCUG 14830	1E6 CFU/mL
Aeromonas veronii	CCUG 27821T	1E6 CFU/mL
Alcaligenes faecalis subsp. *faecalis*	CCUG 1814T	1E6 CFU/mL
Anaerococcus tetradius	CCUG 46590T	1E6 CFU/mL
Arcobacter butzleri	CCUG 30485	1E6 CFU/mL

Bacteria		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Arcobacter cryaerophilus	CCUG 17801	1E6 CFU/mL
Bacillus cereus	ZeptoMetrix 0801823	1E6 CFU/mL
Bacteroides caccae	ATCC 43185	1E6 CFU/mL
Bacteroides fragilis	ZeptoMetrix 0801583	1E6 CFU/mL
Bacteroides stercoris	ATCC 43183	1E6 CFU/mL
Bacteroides thetaiotaomicron	CCUG 10774	1E6 CFU/mL
Phocaeicola vulgatus (Bacteroides vulgatus)	ATCC 8482	1E6 CFU/mL
Bifidobacterium adolescentis	CCUG 18363T	1E6 CFU/mL
Bifidobacterium bifidum	CCUG 45217	1E6 CFU/mL
Bifidobacterium longum subsp. *longum*	ATCC 15707	1E6 CFU/mL
Brevundimonas diminuta	CCUG 2031	1E6 CFU/mL
Cedecea davisae	CCUG 12370	1E6 CFU/mL
Chlamydia trachomatis	ZeptoMetrix 0801775	1E6 CFU/mL
Citrobacter amalonaticus	CCUG 4860A	1E6 CFU/mL
Citrobacter freundii	ZeptoMetrix 0801563	1E6 CFU/mL
Citrobacter koseri	CCUG 4859	1E6 CFU/mL
Citrobacter sedlakii	CCUG 30794	1E6 CFU/mL
Clostridium difficile	ZeptoMetrix 0801619	1E6 CFU/mL
Hathewaya histolytica (Clostridium histolyticum)	ATCC 19401	1E6 CFU/mL
Clostridium novyi	ATCC 17861	1E6 CFU/mL
Clostridium perfringens	ATCC 13124	1E6 CFU/mL
Thomasclavelia ramosa (Clostridium ramosum)	CCUG 24038	1E6 CFU/mL
Clostridium septicum	ATCC 12464	1E6 CFU/mL
Paeniclostridium sordellii (Clostridium sordellii)	DSMZ 2141	1E6 CFU/mL
Clostridium tetani	ATCC 19406	1E6 CFU/mL
Collinsella aerofaciens	CCUG 28087	1E6 CFU/mL
Corynebacterium genitalium	CCUG 65575	1E6 CFU/mL
Corynebacterium lipophiloflavum	CCUG 37336	1E6 CFU/mL
Desulfovibrio piger	NA	*In silico* analysis
Edwardsiella tarda	CCUG 1638	1E6 CFU/mL
Eggerthella lenta	ATCC 43055	1E6 CFU/mL
Klebsiella aerogenes (Enterobacter aerogenes)	ZeptoMetrix 0801518	1E6 CFU/mL

Bacteria		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Enterobacter cancerogenus	ATCC 35316	1E6 CFU/mL
Enterobacter cloacae subsp. *cloacae*	ZeptoMetrix 0801830	1E6 CFU/mL
Enterococcus faecalis	ZeptoMetrix 0801637	1E6 CFU/mL
Enterococcus faecium	ZeptoMetrix 0804210	1E6 CFU/mL
Enteroaggregative *E. coli* EAEC	ZeptoMetrix 0801919	1E6 CFU/mL
Enteropathogenic *E. coli* EPEC	ZeptoMetrix 0801938	1E6 CFU/mL
Enterotoxigenic *E. coli* ETEC	ZeptoMetrix 0801624	1E6 CFU/mL
Escherichia fergusonii	CCUG 18766	1E6 CFU/mL
Escherichia hermannii	CCUG 15714	1E6 CFU/mL
Pseudescherichia vulneris (Escherichia vulneris)	CCUG 15715	1E6 CFU/mL
Fusobacterium varium	ATCC 8501	1E6 CFU/mL
Gardnerella vaginalis	ZeptoMetrix 0801894	1E6 CFU/mL
Gemella morbillorum	CCUG 18164	1E6 CFU/mL
Haemophilus influenzae	ZeptoMetrix 080167	1E6 CFU/mL
Hafnia alvei	CCUG 41547T	1E6 CFU/mL
Helicobacter pylori	ZeptoMetrix 0804383	1E6 CFU/mL
Klebsiella oxytoca	ZeptoMetrix 0801881	1E6 CFU/mL
Klebsiella pneumoniae subsp. *pneumoniae*	CCUG 225T	1E6 CFU/mL
Lactobacillus acidophilus	ATCC 314	1E6 CFU/mL
Limosilactobacillus reuteri	CCUG 33624	1E6 CFU/mL
Lactococcus lactis subsp. lactis	CCUG 32211	1E6 CFU/mL
Leminorella grimontii	CCUG 20909B	1E6 CFU/mL
Listeria monocytogenes	ZeptoMetrix 0801534	1E6 CFU/mL
Megamonas hypermegale	CCUG 5856	1E6 CFU/mL
Megasphaera elsdenii	ATCC 25940	1E6 CFU/mL
Morganella morganii subsp. *morganii*	ZeptoMetrix 0804010	1E6 CFU/mL
Neisseria gonorrhoeae	ZeptoMetrix 0801482	1E6 CFU/mL
Parabacteroides merdae	CCUG 38734	1E6 CFU/mL
Peptoniphilus asaccharolyticus	ATCC 14963	1E6 CFU/mL
Peptostreptococcus anaerobius	CCUG 7835	1E6 CFU/mL
Photobacterium damselae subsp. *damselae*	CCUG 13626	1E6 CFU/mL
Plesiomonas shigelloides	CCUG 410T	1E6 CFU/mL
Porphyromonas asaccharolytica	CCUG 7834T	1E6 CFU/mL

Bacteria		
Non-target Microorganism	**Strain ID**	**Concentration Tested**
Prevotella melaninogenica	ATCC 25845	1E6 CFU/mL
Proteus mirabilis	ZeptoMetrix 0801544	1E6 CFU/mL
Proteus penneri	CCUG 15722	1E6 CFU/mL
Proteus vulgaris	ZeptoMetrix 0801898	1E6 CFU/mL
Providencia alcalifaciens	ZeptoMetrix 0801906	1E6 CFU/mL
Pseudomonas aeruginosa	CCUG 551T	1E6 CFU/mL
Ruminococcus bromii	ATCC 27255	1E6 CFU/mL
Serratia fonticola	CCUG 14186	1E6 CFU/mL
Serratia liquefaciens	CCUG 9285T	1E6 CFU/mL
Serratia marcescens subsp. *marcescens*	ZeptoMetrix 0801723	1E6 CFU/mL
Shewanella algae	CCUG 39064	1E6 CFU/mL
Shimwellia blattae	CCUG 14803BT	1E6 CFU/mL
Staphylococcus aureus subsp. *aureus*	ATCC 25923	1E6 CFU/mL
Staphylococcus epidermidis	ZeptoMetrix 0801651	1E6 CFU/mL
Stenotrophomonas maltophilia	ZeptoMetrix 0801569	1E6 CFU/mL
Streptococcus agalactiae	CCUG 4208	1E6 CFU/mL
Streptococcus intermedius	ZeptoMetrix 0801895	1E6 CFU/mL
Streptococcus pyogenes	CCUG 4207	1E6 CFU/mL
Streptococcus salivarius subsp. *salivarius*	ZeptoMetrix 0801896	1E6 CFU/mL
Streptococcus suis	CCUG 7984	1E6 CFU/mL
Trabulsiella guamensis	ATCC 49492	1E6 CFU/mL
Veillonella parvula	ATCC 10790	1E6 CFU/mL
Vibrio vulnificus	CCUG 48492	1E6 CFU/mL
Yersinia bercovieri	CCUG 26329T	1E6 CFU/mL
Yersinia frederiksenii	CCUG 11293	1E6 CFU/mL
Yersinia intermedia	CCUG 11292T	1E6 CFU/mL
Yersinia kristensenii	CCUG 11294	1E6 CFU/mL
Yersinia mollaretii	CCUG 26331	1E6 CFU/mL
Yersinia rohdei	CCUG 38833	1E6 CFU/mL

Table 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	*In silico* analysis
Adenovirus Type 31	ZeptoMetrix 0810073CF	1E5 $TCID_{50}$/mL
Adenovirus Type 40	ZeptoMetrix 0810084CF	1E5 $TCID_{50}$/mL
Adenovirus Type 41	ZeptoMetrix 0810085CF	1E5 $TCID_{50}$/mL
Astrovirus	ATCC VR-1936	1E6 $TCID_{50}$/mL
Parvovirus	ZeptoMetrix 0810064C	1E6 IU/mL
Cytomegalovirus	ATCC VR-538	5E5 $TCID_{50}$/mL
Enterovirus	ATCC VR-836	5E5 $TCID_{50}$/mL
Hepatitis A virus	ATCC VR-1541	5E5 $TCID_{50}$/mL
Herpes Simplex Virus Type 2	ZeptoMetrix 0810006CF	5E5 $TCID_{50}$/mL
Human coxsackievirus	ZeptoMetrix 0810074CF	5E5 $TCID_{50}$/mL
Rhinovirus	ZeptoMetrix 0810012CFN	2E4 $TCID_{50}$/mL[a] 1E5 $TCID_{50}$/mL[b]
Rotavirus	ATCC VR-2551	1E6 $TCID_{50}$/mL
Sapovirus	ATCC VR-3237SD	1E7 genome copies/mL[a] 1E6 genome copies/mL[b]

[a] Concentration of the non-target microorganism tested with *Salmonella enterica, Giardia lamblia, Vibrio cholerae* and negative sample.

[b] Concentration of the non-target microorganism tested with *Campylobacter jejuni,* STEC stx1 and stx2, EIEC*, Yersinia enterocolitica, Vibrio parahaemolyticus, Cryptosporidium parvum* and Norovirus GI and GII.

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

[a] Concentration of the non-target microorganism tested with *Salmonella enterica, Giardia lamblia, Vibrio cholerae* and negative sample.

[b] Concentration of the non-target microorganism tested with *Campylobacter jejuni,* STEC stx1 and stx2, EIEC*, Yersinia enterocolitica, Vibrio parahaemolyticus, Cryptosporidium parvum* and Norovirus GI and GII.

[c] For *Entamoeba dispar*, ATCC PRA-368, no titer or cell count was available according to vendor ATCC. According to the Certificate of Analysis, the microorganism was released based on visual observation methods.

Table 18. Target Pathogen Strains Evaluated in the Xpert GI Panel In-assay Cross Reactivity Study

Target Pathogen	Strain ID	Concentration Tested
Campylobacter coli	CCUG 53138	1E6 CFU/mL
	ATCC 43478	1E6 CFU/mL
	CCUG 36766	1E6 CFU/mL
Shigella boydii (Subgroup C, serotype 8)	CCUG 37892	1E6 CFU/mL
Shigella boydii (Subgroup C, serotype 10)	CCUG 9564	1E6 CFU/mL
Shigella flexneri (Subgroup B, serotype 2a)	CCUG 56439T	1E6 CFU/mL
Shigella flexneri (Subgroup B, serotype 4a)	CCUG 37906	1E6 CFU/mL
Enteroinvasive *Escherichia coli* (EIEC)	CCUG 38094	1E6 CFU/mL
Escherichia coli (STEC), O111	NCTC 13794	1E6 CFU/mL
Escherichia coli (STEC), O113	D5586	1E6 CFU/mL
Escherichia coli (STEC), O104	NCTC 13796	1E6 CFU/mL

Target Pathogen	Strain ID	Concentration Tested
Salmonella bongori	CCUG 63587	1E6 CFU/mL
Salmonella enterica subsp. *indica*	CCUG 30038T	1E6 CFU/mL
Salmonella enterica subsp. enterica Paratyphi A	NCTC 5702	1E6 CFU/mL
Vibrio cholerae, O:139 (non-O:1)	CCUG 34707	1E6 CFU/mL
Vibrio cholerae, O:1	CCUG 9118T	1E6 CFU/mL
Vibrio parahaemolyticus	CCUG 43362	1E6 CFU/mL
	CCUG 19113	1E6 CFU/mL
	CCUG 15657T	1E6 CFU/mL
Norovirus GI.3 [P3]	Clinical Specimen, 460878, Precision for Medicine U.S.	1E6 cp/mL
Norovirus GII.7	Clinical Specimen, 461526, Precision for Medicine U.S.	1E6 cp/mL
Yersinia enterocolitica, subsp. *enterocolitica*, biotype 1 (serotype O:8)	CCUG 33055	1E6 CFU/mL
Yersinia enterocolitica, subsp. *enterocolitica*, biotype 2 (serotype O:5,27)	NCTC 10463	1E6 CFU/mL
Yersinia enterocolitica, subsp. *enterocolitica*, biotype 4 (serotype O:3)	CCUG 34604	1E6 CFU/mL
Cryptosporidium parvum	Waterborne Inc. P102C Iowa	9.94E4 oocysts/mL
Cryptosporidium hominis	Waterborne Inc. TU502	1E6 oocysts/mL
Giardia intestinalis	ATCC 30888	1E6 cysts/mL
	ATCC 50114	1E6 cysts/mL

Analytical Reactivity (Inclusivity)

Studies were performed to evaluate the analytical reactivity (inclusivity) of the Xpert GI Panel test. For each Xpert GI Panel target pathogen, multiple clinically relevant strains, representative of genotypic differences from various geographical regions, were evaluated using the Xpert GI Panel test. All strains were tested at ≤3x LoD, 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 ≤3x LoD, the strain was subsequently tested at a higher concentration. A strain was considered detected when all replicates at a test level were reported positive. 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
Campylobacter coli	CCUG 10960	549	3x LoD	Positive
	CCUG 53138	549	3x LoD	Positive
	ATCC 43478	549	3x LoD	Positive

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

Table 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
Cryptosporidium parvum	IDT Synthetic DNA, L25642	3,690	3x LoD	Positive
Cryptosporidium meleagridis	IDT Synthetic DNA, EF179381	3,690	3x LoD	Positive
Cryptosporidium canis	IDT Synthetic DNA, AF112576	3,690	3x LoD	Positive
Cryptosporidium ubiquitum	IDT Synthetic DNA, QZWX01000067	3,690	3x LoD	Positive
Cryptosporidium hominis	IDT Synthetic DNA, JIBM01000066	3,690	3x LoD	Positive
Cryptosporidium muris	Waterborne Inc. P104, RN66	480,000	390x LoD	Negative[a]
	IDT Synthetic DNA, AB089284	100,000	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
STEC stx2 (O121)	Statens Serum Institute D6088	9,030	3x LoD	Positive
STEC stx2 (O145)	NCTC 13797	9,030	3x LoD	Positive
STEC stx2 (O113)	Statens Serum Institute D5586	9,030	3x LoD	Positive
STEC stx2 (O104)	NCTC 13796	9,030	3x LoD	Positive
STEC stx1/stx2 (O26)	NCTC 13733	1,872	3x LoD (stx1)	Positive
			0.6x LoD (stx2)	Positive
STEC stx1/stx2 (O111)	NCTC 13794	1,872	3x LoD (stx1)	Positive
			0.6x LoD (stx2)	Positive
STEC stx1/stx2 (O157)	Microbiologics 0617P (ATCC 35150)	1,872	3x LoD (stx1)	Positive
			0.6x LoD (stx2)	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

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

Target Pathogen Strain	Strain ID	Test Concentration (cp/mL)	Multiples of LoD	Reported Results
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
Salmonella bongori	CCUG 63587	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *salamae*	CCUG 30039T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *arizonae*	CCUG 6322T	2,400	1.9x LoD	Positive
	CCUG 63588	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *diarizonae*	CCUG 63589	2,400	1.9x LoD	Positive
	CCUG 30040T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *houtenae*	CCUG 30041T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *indica*	CCUG 30038T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Agona	CCUG 21287	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Anatum	CCUG 21243	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Bareilly	CCUG 12616	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Berta	CCUG 27106	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Blockley	CCUG 21263	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Branderup	CCUG 50923	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Derby	CCUG 21276	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Enteritidis	CCUG 34136T	2,400	1.9x LoD	Positive

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
Salmonella enterica subsp. *enterica* Hadar	CCUG 21271	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Heidelberg	CCUG 21289	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* serotype Typhimurium 4,5,12: i: 1,2	CCUG 18375	2,400	1.9x LoD	Positive
	ATCC 14028	2,400	1.9x LoD	Positive
	CCUG 42060T	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Infantis	CCUG 12615	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Javiana	CCUG 21235	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Litchfield	NCTC 6028	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Mbandaka	CCUG 21272	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Mississippi	Clinical Specimen S027019, Public Health Agency of Sweden	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Montevideo	CCUG 21239	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Muenchen	CCUG 21254	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Newport	CCUG 21283	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Oranienburg	CCUG 12649	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Panama	CCUG 21275	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Paratyphi A	NCTC 5702	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Poona	CCUG 39842	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Reading	NCTC 5720	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Saintpaul	CCUG 21282	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Sandiego	NCTC 6024	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Schwarzengrund	CCUG 21280	2,400	1.9x LoD	Positive

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
Salmonella enterica subsp. *enterica* Senftenberg	CCUG 37886	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Stanley	CCUG 26623	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Thompson	CCUG 12652	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Typhi	Clinical Specimen 22-00912, Public Health Agency of Sweden	2,400	1.9x LoD	Positive
Salmonella enterica subsp. *enterica* Typhimurium	CCUG 35118	2,400	1.9x LoD	Positive

Table 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
Shigella boydii (Subgroup C, serotype 8)	CCUG 37892	612	3x LoD	Positive
Shigella boydii (Subgroup C, serotype 10)	CCUG 9564	612	3x LoD	Positive
Shigella boydii (Subgroup C, serotype 11)	ATCC 12031	612	3x LoD	Positive
Shigella dysenteriae (Subgroup A, serotype 1)	NCTC 4837[a]	204	1x LoD	Positive
	NCTC 8217[a]	612	3x LoD	Positive
	NCTC 8571[a]	612	3x LoD	Positive
Shigella dysenteriae (Subgroup A, serotype 8)	NCTC 9345	612	3x LoD	Positive
Shigella dysenteriae (Subgroup A, serotype 9)	NCTC 9348	612	3x LoD	Positive
Shigella flexneri (Subgroup B, serotype 2a)	CCUG 56439T	1,224	6x LoD	Positive
Shigella flexneri (Subgroup B, serotype 3)	CCUG 21251	612	3x LoD	Positive
Shigella flexneri (Subgroup B, serotype 4a)	CCUG 37906	612	3x LoD	Positive
Shigella flexneri (Subgroup B, serotype 6)	CCUG 39080	612	3x LoD	Positive
	ATCC 15391	612	3x LoD	Positive
Shigella sonnei (Subgroup D)	CCUG 9567	612	3x LoD	Positive

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
Shigella dysenteriae (Subgroup A, serotype 9)	ATCC 49547	*In silico* analysis	NA	100% match with primer and probe sequences

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

Table 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 *Escherichia coli* (EIEC)	CCUG 38092	204	1x LoD	Positive
	CCUG 38094	612	3x LoD	Positive
	NCTC 9013	70,000	343x LoD	Negative [a]

[a] Secondary PCR assay 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
Vibrio cholerae O:139	CCUG 34707	1,200	2.6x LoD	Positive
Vibrio cholerae O:1	CCUG 9118T	1,200	2.6x LoD	Positive

Table 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
Vibrio parahaemolyticus	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
Yersinia enterocolitica biotype 1 (O:8)	CCUG 33055	1,044	3x LoD	Positive
Yersinia enterocolitica biotype 2 (O:9)	CCUG 8239A	1,044	3x LoD	Positive
Yersinia enterocolitica biotype 2 (O:5, 27)	NCTC 10463	1,044	3x LoD	Positive

Target Pathogen Strain	Strain ID	Test Concentration (CFU/mL)	Multiples of LoD	Reported Results
Yersinia enterocolitica 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
Giardia intestinalis	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

Type of Substance	Substance	Concentration Tested in Raw Stool
	Ciprofloxacin	5% w/v
	Doxycycline	1% w/v
	Fluvastatin	1% w/v
	Glycerin	50% v/v
	Nystatin	50% w/v
	Metronidazole	60.8 mg/mL
	Vancomycin	12.5 mg/mL
	Naproxen sodium	10% w/v
	Bisacodyl	5% w/v
	Bismuth subsalicylate	1% w/v
	Calcium carbonate	5% w/v
	Docusate sodium	50% w/v
	Hydrocortisone	50% w/v
	Loperamide hydrochloride	5% w/v
	Magnesium hydroxide	10% w/v
	Phenylephrine hydrochloride	30% w/v
	Sodium phosphate	5% w/v
	Nonoxynol-9	50% v/v
	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., ≤3x LoD in presence of one or more additional target pathogen(s) at a high concentration in negative clinical stool matrix. The high test concentrations were 1E6 CFU/mL for bacterial pathogens, 1E5 cysts/mL for *Giardia lamblia*, and 1E5 cp/mL for Norovirus GI. All target pathogen combinations were diluted in clinical stool matrix and tested with six replicates. The study results showed no competitive inhibition for common gastrointestinal co-infections with the Xpert GI Panel test. Table 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 (≤3x LoD)	Reported Result for Low Titer Target Pathogen
STEC stx1 (1E6 CFU/mL) STEC stx2 (1E6 CFU/mL)	*Campylobacter jejuni*	549 CFU/mL	Positive
	Salmonella enterica	1,863 CFU/mL	Positive
Yersinia enterocolitica (1E6 CFU/mL)	*Campylobacter jejuni*	549 CFU/mL	Positive
	Salmonella enterica	1,863 CFU/mL	Positive
Norovirus GI (1E5 cp/mL)	*Campylobacter jejuni*	549 CFU/mL	Positive
	Salmonella enterica	1,863 CFU/mL	Positive
Campylobacter jejuni (1E6 CFU/mL) *Salmonella enterica* (1E6 CFU/mL)	STEC stx1	1,872 CFU/mL	Positive
	STEC stx2	9,030 CFU/mL	Positive
Yersinia enterocolitica (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
Campylobacter jejuni (1E6 CFU/mL) *Salmonella enterica* (1E6 CFU/mL)	*Yersinia enterocolitica*	1,044 CFU/mL	Positive
STEC stx1 (1E6 CFU/mL) STEC stx2 (1E6 CFU/mL)	*Yersinia enterocolitica*	1,044 CFU/mL	Positive
Campylobacter jejuni (1E6 CFU/mL) *Salmonella enterica* (1E6 CFU/mL)	Norovirus GI	894 cp/mL	Positive
Giardia lamblia (1E5 cysts/mL) *Yersinia enterocolitica* (1E6 CFU/mL)	Norovirus GI	894 cp/mL	Positive
STEC stx1 (1E6 CFU/mL) STEC stx2 (1E6 CFU/mL)	Norovirus GI	894 cp/mL	Positive
Norovirus GI (1E5 cp/mL)	*Giardia lamblia*	738 cysts/ml	Positive
	Yersinia enterocolitica	1,044 CFU/mL	Positive

21 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 (~1x LoD) sample, and 1 moderate positive (~3x LoD) sample that were tested fresh. Panel 2 was a 5-member panel including 1

negative sample, 2 low positive (~1x LoD) samples, and 2 moderate positive (~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 # 2 Operators # 3 Lots # 2 days/Lot # 2 Runs x 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 # 2 Operators # 3 Lots x 1 day/Lot # 2 Runs # 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	OP2	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)
		24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 1	*Campylobacter*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Low Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 1	*Campylobacter*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Mod Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 1	STEC *stx2*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Low Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 1	STEC *stx2*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Mod Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 2	Negative	100%	96%	98%	100%	96%	98%	100%	100%	100%	98.6% (142/144)
		24/24	23/24	47/48	24/24	23/24	47/48	24/24	24/24	48/48	[95.1–99.6]
Panel 2	*Salmonella*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Low Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 2	*Salmonella*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (143/143)
	Mod Pos	24/24	24/24	48/48	23/23[a]	24/24	47/47	24/24	24/24	48/48	[97.4–100.0]
Panel 2	*Yersinia*	100%	100%	100%	100%	96%	98%	100%	100%	100%	99.3% (143/144)
	Low Pos	24/24	24/24	48/48	24/24	23/24	47/48	24/24	24/24	48/48	[96.2–99.9]
Panel 2	*Yersinia*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (143/143)
	Mod Pos	24/24	24/24	48/48	23/23[a]	24/24	47/47	24/24	24/24	48/48	[97.4–100.0]
Panel 2	*Cryptosporidium*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Low Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 2	*Cryptosporidium*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (143/143)
	Mod Pos	24/24	24/24	48/48	23/23[a]	24/24	47/47	24/24	24/24	48/48	[97.4–100.0]
Panel 2	*Giardia*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Low Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]

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 2	*Giardia*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Mod Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 2	*Shigella* EIEC	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Low Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 2	*Shigella* EIEC	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Mod Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 2	Norovirus	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Low Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 2	Norovirus	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (144/144)
	Mod Pos	24/24	24/24	48/48	24/24	24/24	48/48	24/24	24/24	48/48	[97.4–100.0]
Panel 3	Negative	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (108/108)
		18/18	18/18	36/36	18/18	18/18	36/36	18/18	18/18	36/36	[96.6–100.0]
Panel 3	*V. parahaemolyticus*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (108/108)
	Low Pos	18/18	18/18	36/36	18/18	18/18	36/36	18/18	18/18	36/36	[96.6–100.0]
Panel 3	*V. parahaemolyticus*	100%	100%	100%	100%	100%	100%	100%	100%	100%	100% (108/108)
	Mod Pos	18/18	18/18	36/36	18/18[b]	18/18	36/36	18/18	18/18	36/36	[96.6–100.0]

[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 (%)
Campylobacter	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
Low Pos	MV	144	-13	0.4	3.3	0.0	0.0	0.9	7.2	0.6	4.3	0.0	0.0	1.5	11.6	1.9	14.7
Campylobacter	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
Mod Pos	MV	144	-13.7	0.6	4.3	0.0	0.0	0.5	3.8	0.5	3.5	0.0	0.0	1.3	9.5	1.6	11.6
STEC *stx2*	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
Low Pos	MV	144	-12.1	0.7	6.0	0.0	0.0	0.7	5.7	0.3	2.2	0.0	0.0	1.7	13.9	2.0	16.3
STEC *stx2*	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
Mod Pos	MV	144	-13.4	1.0	7.4	0.0	0.0	0.4	2.9	0.7	5.3	0.5	3.9	1.8	13.5	2.3	17.0
Salmonella Low Pos	Ct	144	34.6	0.4	1.0	0.2	0.4	0.0	0.0	0.3	0.8	0.0	0.0	0.7	1.9	0.8	2.3

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 (%)
Salmonella Mod Pos	Ct	143[a]	33.7	0.2	0.7	0.2	0.5	0.3	0.8	0.0	0.0	0.2	0.7	0.6	1.8	0.8	2.2
Yersinia Low Pos	MP	143[b]	14.2	0.4	2.8	0.0	0.0	0.0	0.0	0.0	0.0	0.7	5.0	1.4	10.0	1.6	11.5
	MV	143	-11.7	0.4	3.6	0.0	0.0	0.0	0.0	0.0	0.0	0.6	4.8	1.2	9.9	1.4	11.6
Yersinia Mod Pos	MP	143[a]	14.7	0.6	3.7	0.0	0.0	0.5	3.2	0.0	0.0	0.0	0.0	1.8	12.0	1.9	12.9
	MV	143[a]	-12.3	0.5	4.0	0.0	0.0	0.4	3.0	0.0	0.0	0.2	1.4	1.4	11.1	1.5	12.2
Cryptosporidium Low Pos	Ct	144	23.3	0.6	2.6	0.0	0.0	0.0	0.0	0.5	2.1	0.0	0.0	1.6	6.8	1.8	7.5
Cryptosporidium Mod Pos	Ct	143[a]	22.3	0.5	2.0	0.0	0.0	0.0	0.0	0.4	1.6	0.5	2.2	1.0	4.4	1.2	5.5
Giardia Low Pos	Ct	144	27.4	1.3	4.6	0.0	0.0	1.2	4.4	0.7	2.4	1.2	4.3	1.6	5.7	2.7	9.9
Giardia Mod Pos	Ct	144	26.6	1.2	4.5	0.0	0.0	1.4	5.4	0.4	1.6	1.1	4.2	1.3	4.9	2.6	9.7
Shigella EIEC Low Pos	Ct	144	32.8	0.4	1.1	0.1	0.3	0.2	0.5	0.1	0.4	0.0	0.0	0.8	2.3	0.9	2.7
Shigella EIEC Mod Pos	Ct	144	31.9	0.1	0.4	0.2	0.6	0.0	0.0	0.0	0.1	0.0	0.0	0.7	2.3	0.8	2.5
Norovirus Low Pos	Ct	144	33.2	0.3	0.9	0.0	0.0	0.2	0.6	0.3	0.8	0.3	0.8	0.6	2.0	0.8	2.5
Norovirus Mod Pos	Ct	144	32	0.3	0.9	0.0	0.1	0.1	0.4	0.1	0.4	0.1	0.3	0.6	1.8	0.7	2.1
V. parahaemolyticus Low Pos	MP	108	15.5	1.3	8.4	0	0	0.9[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. parahaemolyticus 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

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

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

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

22 References

1. Centers for Disease Control and Prevention. Biosafety in microbiological and biomedical laboratories. (refer to latest edition).
2. CLSI Publication M29. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. (refer to latest edition).
3. https://www.cdc.gov/parasites/crypto/resources/childcare_outbreak.pdf
4. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on the classification labeling and packaging of substances and mixtures amending and repealing, List of Precautionary Statements, Directives 67/548/EEC and 1999/45/EC (amending Regulation (EC) No 1907/2007).
5. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z.

23 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

Contact information for all Cepheid Technical Support offices is available on our website:www.cepheid.com/en/support/contact-us

24 Cepheid Headquarters Location

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25 Table of Symbols

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

26 Revision History

Description of Changes: 303-4454 Rev A

Purpose: Initial release