Test Training
Xpert® GI Panel

For use with:
GeneXpert® Dx System
GeneXpert® System with Touchscreen
GeneXpert® Infinity System

Catalog Number : GXGI-CE-10

For CE-IVD Only

CE-marked in accordance with IVDR (Regulation (EU) 2017/746)

CE 2797 IVD In Vitro Diagnostic Medical Device

303-7273 Rev. A April 2026

Training Objectives

At the end of the training, users will be able to:

- Properly store and handle the Xpert® GI Panel cartridge kit and specimen collection
- Follow proper laboratory safety precautions
- Collect and transport appropriate specimen
- Prepare a cartridge and run the Xpert® GI Panel
- Explain the Xpert® GI Panel control strategy
- Interpret the patient results report

Training Agenda

1 Overview

2 Kit Handling

3 Specimen Collection, Transport and Storage

4 Cartridge Preparation

5 Quality Controls

6 Results Interpretation

7 Troubleshooting

AGENDA

Overview

The Cepheid Solution

AGENDA

- Qualitative detection of **DNA** and **RNA** targets from multiple bacteria, parasites and/or virus directly from stool in Cary Blair transport media
- On-board internal controls for each specimen
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)
  - Internal Control (IC)
- Results in approximately 74 minutes
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

Intended Use

AGENDA

- 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).

Intended Use (Continued)

AGENDA

- 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

Cepheid

Intended Use (Continued)

AGENDA

- 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.

Intended User/Environment

The Xpert® GI Panel is intended to be performed by healthcare professionals trained on the use of the test. This test is for use in a laboratory environment.

Cepheid

Xpert® GI Panel Requirements

AGENDA

GeneXpert® Software	• GeneXpert® Dx software **v6.6** or higher • Cepheid OS software **v2.3** or higher • Xpertise software **v7.2** or higher • GeneXpert® system equipped with 10-color modules
Test Kits	• GXGI-CE-10
Specimen Collection	• Stool in Cary Blair media
Materials Required but Not Provided	• Cary Blair media
Other Materials	• Personal Protective Equipment (PPE) • 1:10 dilution bleach • 70% ethanol or denatured ethanol • Printer if needed

Cepheid

AGENDA

Kit Handling

Good Laboratory Practice Review

AGENDA

Personal Protective Equipment (PPE)

- Wear clean lab coats, safety glasses, and gloves
- Change gloves between processing specimens

Lab Bench Area

- Clean work surfaces routinely with:
  - ✓ 1:10 dilution of household bleach*
  - ✓ 70% ethanol solution
- After cleaning, ensure work surfaces are dry and gloves are changed

Specimen and Kit Storage

- Store specimens away from kit to prevent contamination

Equipment

- Follow the manufacturer's requirements for instrument maintenance
- Setup specimens away from the instrument
- Use filtered pipette tips when recommended

*Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration

Cepheid

Xpert® GI Panel Kit Components

AGENDA

Catalog Number	GXGI-CE-10
Cartridges Per Kit	10
Disposable Transfer Swabs	10
CD	CD (*not pictured*) contains the following: • Assay Definition File (ADF) • Instructions to import ADF into GeneXpert® software • Instructions for use
Storage	2-28° C

Cartridges contain chemically hazardous substances. Please see Instructions for Use and Safety Data Sheet for more detailed information.

Xpert® GI Panel Storage and Handling

AGENDA

- 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.

Warnings and Precautions

AGENDA

- Do not use a cartridge that:
  - appears wet, has leaked or if the lid seal appears to have been broken
  - appears damaged
  - has been dropped after removing it from packaging
  - has been dropped or shaken after adding the specimen to it
  - has a damaged reaction tube
  - has been used; each cartridge is single-use to process one test
  - has expired
- Do not reuse transfer pipettes
- Specimens must be collected and tested before the expiration date of the Cary Blair Medium.
- 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.

Cepheid

Warnings and Precautions (Continued)

AGENDA

- 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]
- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see Specimen Collection, Transport, and Storage Section). Specimen stability under shipping conditions other than those recommended has not been evaluated.
- 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.

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

Cepheid

AGENDA

Specimen Collection, Transport and Storage

Specimen Collection

AGENDA

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.

Specimen Transport and Storage

AGENDA

Specimen Type	Transport and Storage
Cary Blair medium	15-25° C for up to 24 hours
	2-8° C up to 4 days

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.

AGENDA

Cartridge Preparation

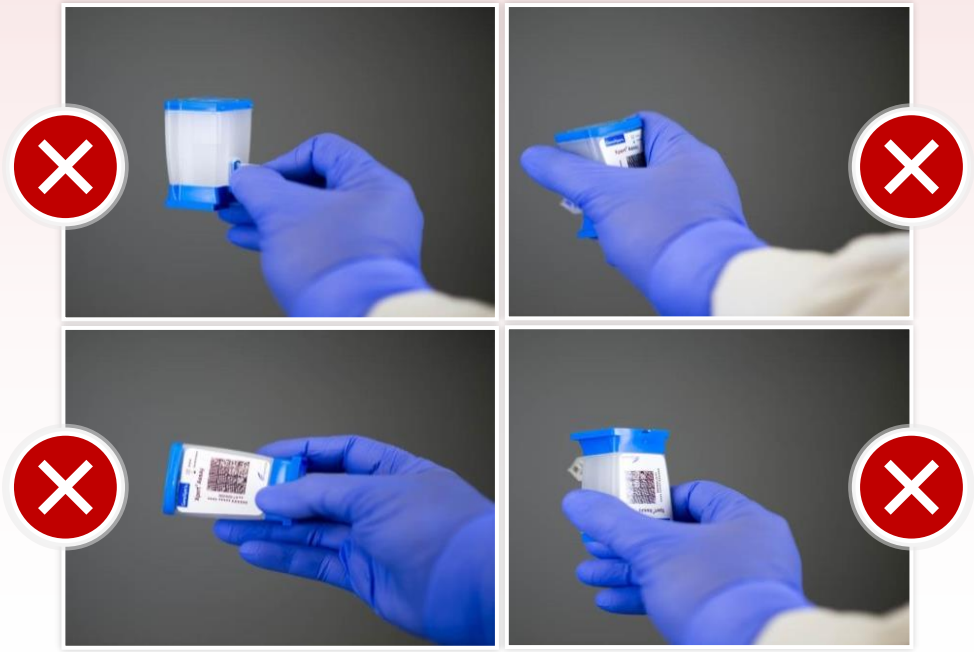
Proper Cartridge Handling Techniques

AGENDA

Correct

- Do not touch the reaction tube
- Keep the cartridge upright after seal has been broken
- Do not tilt when scanning the cartridge

Incorrect



Xpert® GI Panel Cartridge Preparation

AGENDA

Xpert® GI Panel Cartridge Preparation

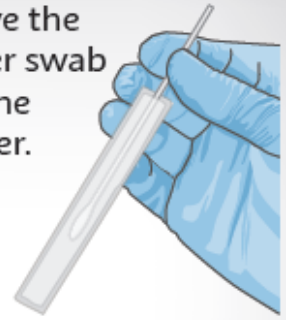
Refer to the Instructions for Use for detailed instructions, precautions, and warnings.

1. Remove a cartridge from the package (it is recommended to equilibrate the cartridge to room temperature[15-25°C] before use).

2. Mix specimen thoroughly until fully homogenized. Vortex can be used.

3. Open the cartridge by lifting the lid.

4. Remove the transfer swab from the wrapper.



5. 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.

6. Break the swab (at the break point) by snapping the shaft against the notch in the sample chamber opening leaving the swab tip in the sample chamber.

NOTE: *There should not be any piece of the swab sticking out of the sample chamber.*

7. Close the cartridge lid.

CE 2797 IVD

In Vitro Diagnostic Medical Device. CE-marked in accordance with IVDR (Regulation (EU) 2017/746). May not be available in all countries.

303-7272 Rev. A April 2026

Cepheid. A better way.

Which GeneXpert® System Do You Have?

AGENDA

1 GeneXpert Dx

2 GeneXpert System with Touchscreen

3 GeneXpert Infinity

For complete details on how to run a test, refer to the Instructions for Use and the system Operator Manual.

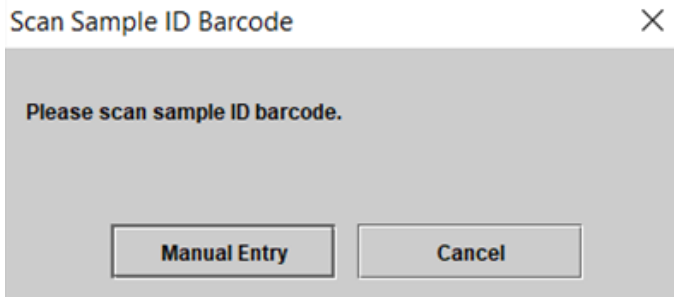
Run a Test on GeneXpert® Dx

AGENDA

1 Start a test.

Start the test within 30 minutes after adding the specimen to the cartridge.

2 Scan barcode for Patient and/or Sample ID.



3 Scan the cartridge.

To Scan do not click on Manual Entry or Cancel.

Run a Test on GeneXpert® Dx (*Continued*)

AGENDA

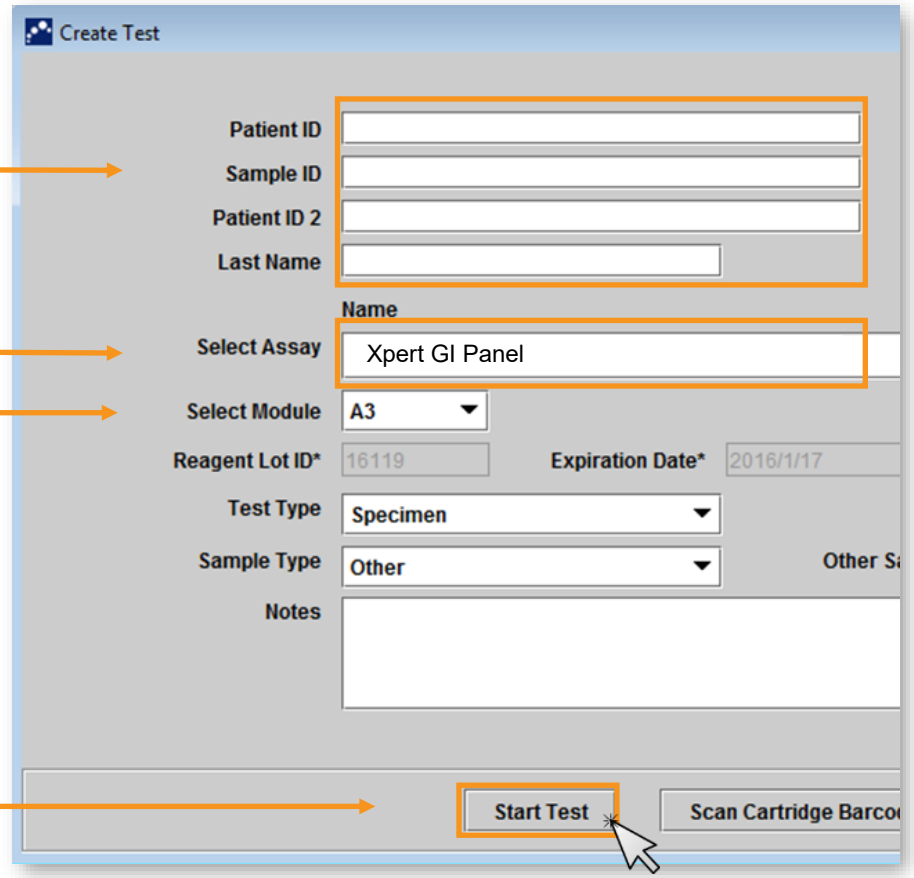
4 Complete the fields as required.

5 Xpert® GI Panel test is selected automatically.

6 The module is selected automatically.

7 Click on Start Test.

8 A green light will flash on the module.
Load the cartridge into module and close the door.



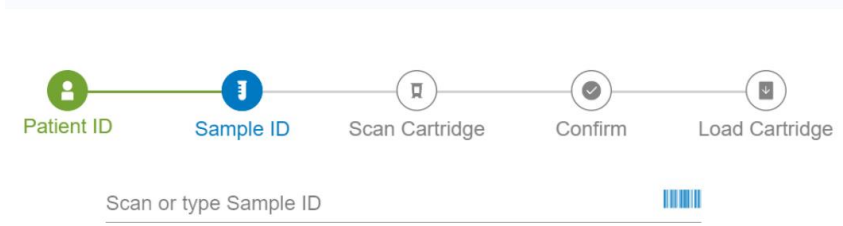
Run a Test on GeneXpert® System with Touchscreen

AGENDA

1 Start a test.

Start the test within 30 minutes after adding the specimen to the cartridge.

2 Scan barcode for Patient and/or Sample ID.



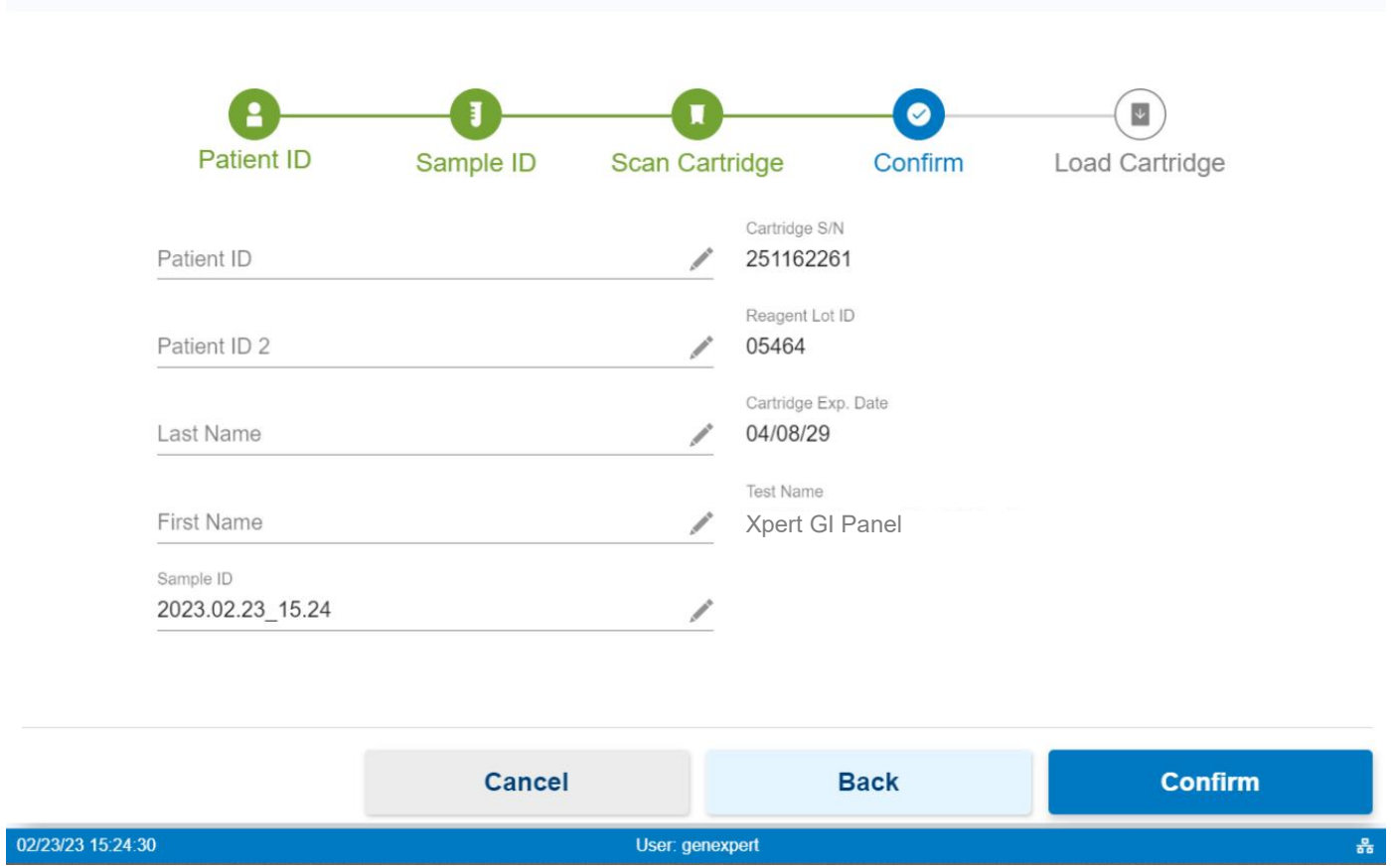
3 Scan the cartridge.

Run a Test on GeneXpert® System with Touchscreen (*Continued*)

AGENDA

4 Click Confirm.

5 A green light will flash on the module. Load the cartridge into module and close the door.



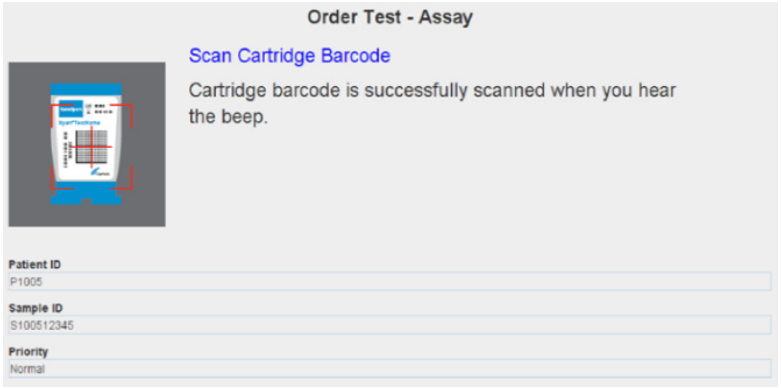
Run a Test on GeneXpert® Infinity

AGENDA

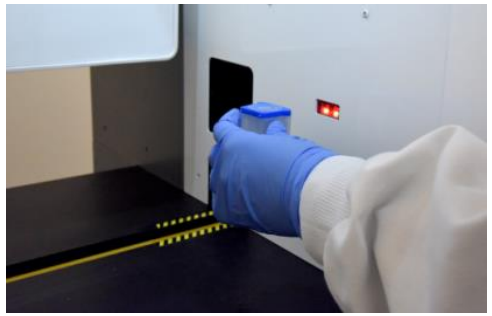
1 Start a test.

Place the cartridge on the conveyor within 30 minutes of adding the specimen.

2 Scan barcode for Patient and/or Sample ID.



3 Scan the cartridge.



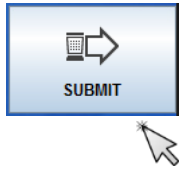
Run a Test on GeneXpert® Infinity (*Continued*)

AGENDA

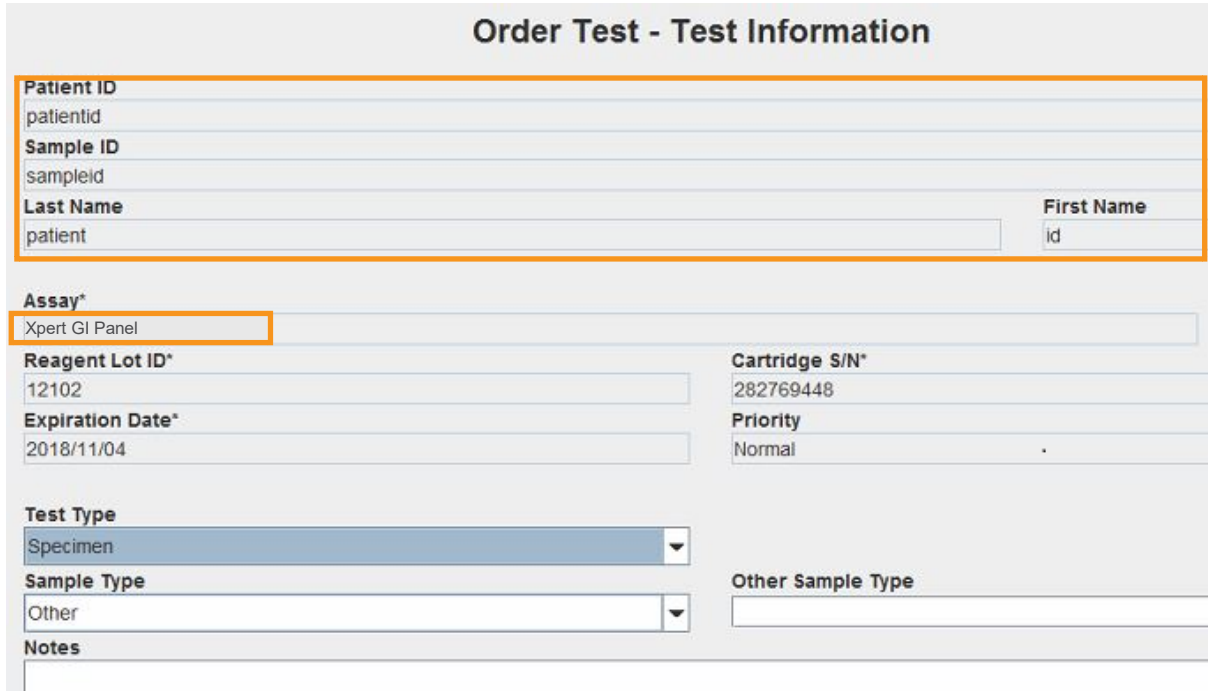
4 Complete the fields as required.

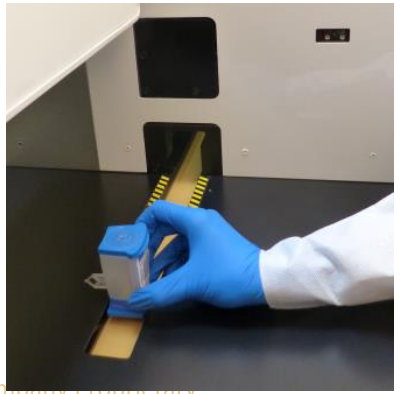
5 Xpert® GI Panel test is selected automatically.

6 Click SUBMIT.



7 Place the cartridge on the conveyor belt.





Waste Disposal Warnings and Precautions

AGENDA

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents and require use of 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 disposal.

Please Note: Used cartridges may contain potentially infectious materials, as well as highly amplified PCR target(s). Do not open or attempt to alter any part of the cartridge for disposal.

If country 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.

Cepheid

AGENDA

Quality Controls

Xpert® GI Panel Control Strategy

AGENDA

Xpert® GI Panel Quality Controls

- Each Xpert® cartridge is a self-contained test device
- Cepheid designed specific molecular methods to include internal controls that enable the system to detect specific failure modes within each cartridge:
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)
  - Internal Control (IC)

Refer to 301-4868 GeneXpert® Quality Control Features for all Cepheid Xpert® tests.

Internal Quality Controls

AGENDA

Probe Check Controls (PCC)

Before the PCR step, fluorescence signal is measured on all probes and compared with default factory settings to monitor:

- Bead rehydration
- Probe integrity
- Reaction tube filling
- Dye stability

Sample Processing Controls (SPC)

The SPC is present to control for adequate processing of the specimen and to monitor for the presence of potential inhibitor(s) in the PCR reaction.

- Verifies the lysis of hard to lyse pathogens (parasites and bacteria)
- Verifies adequate extraction and amplification of the specimen
- Detects PCR inhibition
- Ensures appropriate PCR conditions for amplification (temperature and time)
- Verifies that PCR reagents are functional
- Acts as a control for functionality of melt curve analysis
- Must be positive in a negative specimen to be a valid test
- Can be positive or negative in a positive specimen

Cepheid

Internal Quality Controls (*Continued*)

AGENDA

Internal Control (IC)

The IC is an RNA control included in each cartridge to verify release of RNA from the sample.

- Verifies the sample processing is adequate.
- Detects specimen-associated inhibition of the reverse transcription and PCR reactions.
- Must be positive in a negative sample Can be negative or positive in a positive sample.

Commercially Available External Controls

AGENDA

Microbiologics® Gastrointestinal Control Panel (Inactivated Swab)

Contents	Part Number	Total Vials/Boxes
Positive Control	8248	6 individually packaged lyophilized positive control swabs
Negative Control	8248	6 individually packaged lyophilized negative control swabs

NOTE: To minimize degradation of the control material, return unopened QC to the manufacturer's recommended storage conditions immediately after use.

Cepheid

Commercially Available External Controls (*Continued*)

AGENDA

The external quality control materials provided by the specified vendor's IFU are an optional source. All external controls must be used in accordance with local, state, and/or federal regulations or accreditation requirements, as applicable.

AGENDA

Results Interpretation

Xpert® GI Panel Targets and Results

AGENDA

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

The results are interpreted automatically by the GeneXpert® system software and shown in the **View Results** window. The test provides test results based on the detection of respective gene targets according to the algorithms in the ADF.

Cepheid

Which GeneXpert® System Do You Have?

AGENDA

1 GeneXpert Dx

2 GeneXpert System with Touchscreen

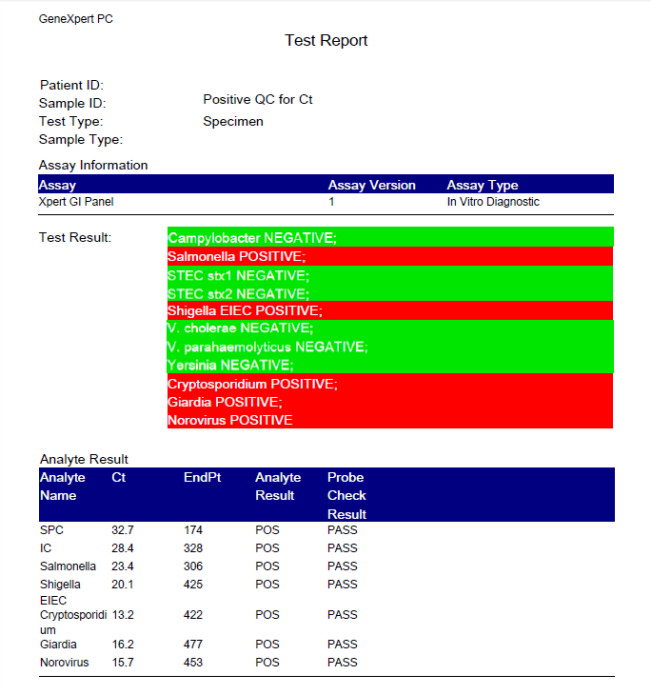
3 GeneXpert Infinity

For complete details on how to run a test, refer to the Instructions for Use and the system Operator Manual.

GeneXpert® Dx GI Panel POSITIVE

AGENDA

Example Report



GeneXpert PC

Test Report

Patient ID:
Sample ID: Positive QC for Ct
Test Type: Specimen
Sample Type:

Assay Information

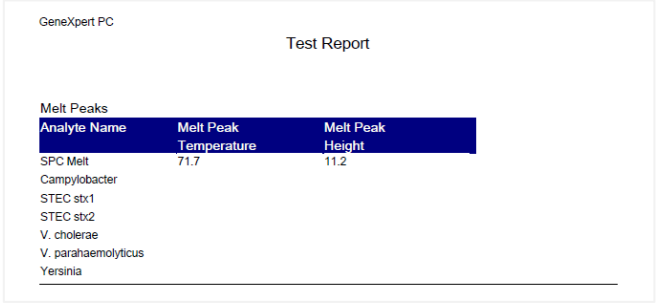
Assay	Assay Version	Assay Type
Xpert GI Panel	1	In Vitro Diagnostic

Test Result:

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	32.7	174	POS	PASS
IC	28.4	328	POS	PASS
Salmonella	23.4	306	POS	PASS
Shigella EIEC	20.1	425	POS	PASS
Cryptosporidium	13.2	422	POS	PASS
Giardia	16.2	477	POS	PASS
Norovirus	15.7	453	POS	PASS



GeneXpert PC

Test Report

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	71.7	11.2
Campylobacter		
STEC stx1		
STEC stx2		
V. cholerae		
V. parahaemolyticus		
Yersinia		

- The *Salmonella*, *Shigella EIEC*, *Cryptosporidium*, *Giardia*, and/or Norovirus signal has a Ct within the valid cycle range.
- Except Target(s) detected, all other pathogens are not detected.
- Probe Check: PASS; all probe check results pass.
- SPC – Not Applicable (NA); SPC is ignored because Target(s) are detected.
- IC – NA; IC is ignored because Target(s) are detected.

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. **This does not apply when running Quality Control.**

Cepheid

GeneXpert® Dx GI Panel POSITIVE

AGENDA

Example Report

GeneXpert PC

Test Report

Patient ID:
Sample ID: Positive QC for Melts
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert GI Panel	1	In Vitro Diagnostic

Test Result:

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	30.4	194	POS	PASS
IC	28.8	330	POS	PASS
Salmonella	0.0	1	NEG	PASS
Shigella EIEC	0.0	-1	NEG	PASS
Cryptosporidium	0.0	8	NEG	PASS
Giardia	0.0	1	NEG	PASS
Norovirus	0.0	1	NEG	PASS

GeneXpert PC

Test Report

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	71.7	11.2
Campylobacter	60.6	28.2
STEC stx1	74.9	49.5
STEC stx2	76.9	20.5
V. cholerae	61.1	20.6
V. parahaemolyticus	66.2	20.9
Yersinia	61.8	21.5

- The *Campylobacter*, STEC stx1, STEC stx2, *V. cholerae*, *V. parahaemolyticus*, and/or *Yersinia* signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range.
- Except Target(s) detected, all other pathogens are not detected.
- Probe Check: PASS; all probe check results pass.
- SPC – Not Applicable (NA); SPC is ignored because Target(s) detected.
- IC – NA; IC is ignored because Target(s) detected.

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. **This does not apply when running Quality Control.**

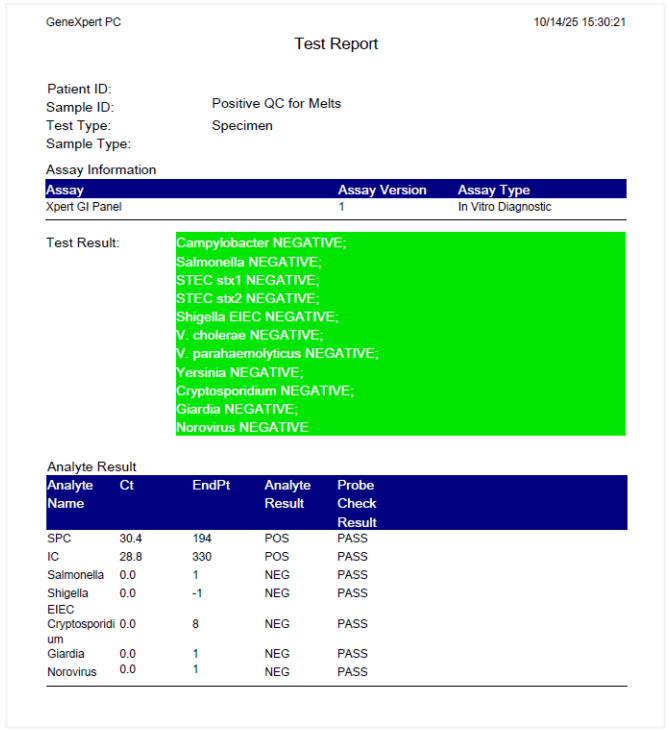
Melt Peak data is not included on the test report when run on the GeneXpert® Dx software. If needed, the Melt Peaks data can be added to the Dx test report by reprinting it and selecting the Melt Peaks box. The Melt Peaks can also be accessed in the Melt Peaks tab in the GeneXpert® Dx software.

Cepheid

GeneXpert® Dx GI Panel NEGATIVE

AGENDA

Example Report



GeneXpert PC 10/14/25 15:30:21

Test Report

Patient ID:
Sample ID: Positive QC for Melts
Test Type: Specimen
Sample Type:

Assay Information

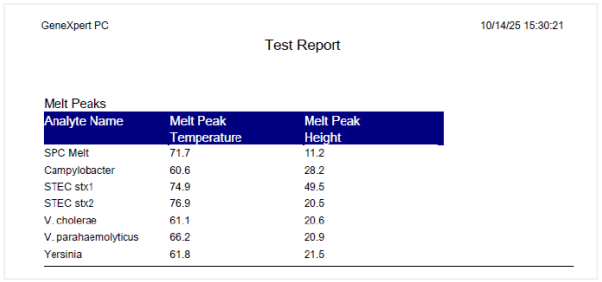
Assay	Assay Version	Assay Type
Xpert GI Panel	1	In Vitro Diagnostic

Test Result:

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SPC	30.4	194	POS	PASS
IC	28.8	330	POS	PASS
Salmonella	0.0	1	NEG	PASS
Shigella	0.0	-1	NEG	PASS
EIEC				
Cryptosporidium	0.0	8	NEG	PASS
Giardia	0.0	1	NEG	PASS
Norovirus	0.0	1	NEG	PASS



GeneXpert PC 10/14/25 15:30:21

Test Report

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	71.7	11.2
Campylobacter	60.6	28.2
STEC stx1	74.9	49.5
STEC stx2	76.9	20.5
V. cholerae	61.1	20.6
V. parahaemolyticus	66.2	20.9
Yersinia	61.8	21.5

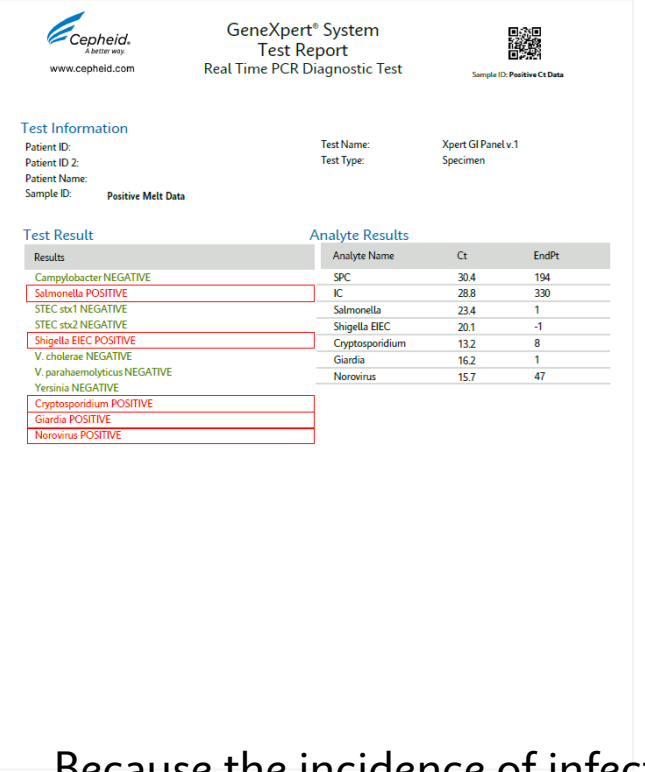
- None of the pathogens listed are detected.
- SPC - PASS
  - The SPC signal has a Ct within the valid cycle range AND
  - The SPC signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range.
- IC – PASS
  - The IC signal has a Ct within the valid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

Cepheid

GeneXpert® System with Touchscreen
GI Panel POSITIVE

AGENDA

Example Report



Cepheid
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: Positive Ct Data

Test Information

Patient ID:
Patient ID 2:
Patient Name:
Sample ID: Positive Melt Data

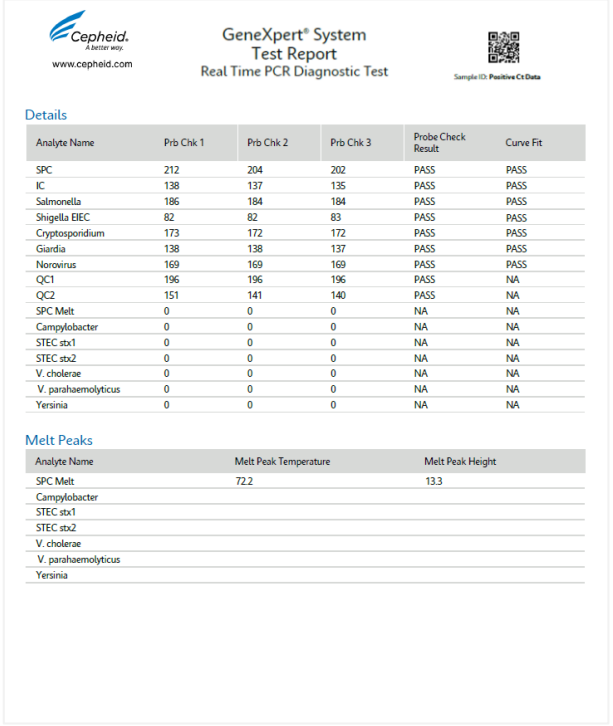
Test Name: Xpert GI Panel v.1
Test Type: Specimen

Test Result

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

Analyte Results

Analyte Name	Ct	EndPt
SPC	30.4	194
IC	28.8	330
Salmonella	23.4	1
Shigella EIEC	20.1	-1
Cryptosporidium	13.2	8
Giardia	16.2	1
Norovirus	15.7	47



Cepheid
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: Positive Ct Data

Details

Analyte Name	Prb Chk 1	Prb Chk 2	Prb Chk 3	Probe Check Result	Curve Fit
SPC	212	204	202	PASS	PASS
IC	138	137	135	PASS	PASS
Salmonella	186	184	184	PASS	PASS
Shigella EIEC	82	82	83	PASS	PASS
Cryptosporidium	173	172	172	PASS	PASS
Giardia	138	138	137	PASS	PASS
Norovirus	169	169	169	PASS	PASS
QC1	196	196	196	PASS	NA
QC2	151	141	140	PASS	NA
SPC Melt	0	0	0	NA	NA
Campylobacter	0	0	0	NA	NA
STEC stx1	0	0	0	NA	NA
STEC stx2	0	0	0	NA	NA
V. cholerae	0	0	0	NA	NA
V. parahaemolyticus	0	0	0	NA	NA
Yersinia	0	0	0	NA	NA

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	72.2	13.3
Campylobacter		
STEC stx1		
STEC stx2		
V. cholerae		
V. parahaemolyticus		
Yersinia		

- The *Salmonella*, *Shigella EIEC*, *Cryptosporidium*, *Giardia*, and/or Norovirus signal has a Ct within the valid cycle range.
- Except Target(s) detected, all other pathogens are not detected.
- Probe Check: PASS; all probe check results pass.
- SPC – Not Applicable (NA); SPC is ignored because Target(s) are detected.
- IC – NA; IC is ignored because Target(s) are detected.

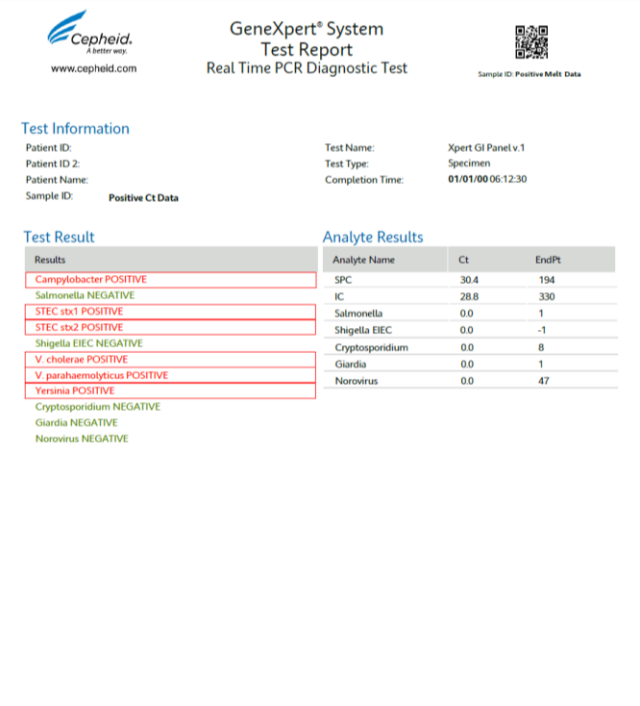
Because the incidence of infection with multiple (3 or more) agents are low, it is recommended that specimens undergo repeat testing if nucleic acids from multiple analytes are detected in a single specimen. **This does not apply when running Quality Control.**

Cepheid

GeneXpert® System with Touchscreen
GI Panel POSITIVE

AGENDA

Example Report



Cepheid
A better way.
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: Positive Melt Data

Test Information

Patient ID:
Patient ID 2:
Patient Name:
Sample ID: Positive Ct Data

Test Name: Xpert GI Panel v.1
Test Type: Specimen
Completion Time: 01/01/00 06:12:30

Test Result

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

Analyte Results

Analyte Name	Ct	EndPt
SPC	30.4	194
IC	28.8	330
Salmonella	0.0	1
Shigella EIEC	0.0	-1
Cryptosporidium	0.0	8
Giardia	0.0	1
Norovirus	0.0	47

Cepheid
A better way.
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: Positive Melt Data

Details

Analyte Name	Prb Chk 1	Prb Chk 2	Prb Chk 3	Probe Check Result	Curve Fit
SPC	193	181	177	PASS	PASS
IC	183	183	181	PASS	PASS
Salmonella	203	201	200	PASS	PASS
Shigella EIEC	83	82	83	PASS	PASS
Cryptosporidium	170	165	163	PASS	PASS
Giardia	114	113	112	PASS	PASS
Norovirus	144	143	141	PASS	PASS
QC1	189	189	188	PASS	NA
QC2	142	128	126	PASS	NA
SPC Melt	0	0	0	NA	NA
Campylobacter	0	0	0	NA	NA
STEC stx1	0	0	0	NA	NA
STEC stx2	0	0	0	NA	NA
V. cholerae	0	0	0	NA	NA
V. parahaemolyticus	0	0	0	NA	NA
Yersinia	0	0	0	NA	NA

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	71.7	11.2
Campylobacter	60.6	28.2
STEC stx1	74.9	49.5
STEC stx2	76.9	20.5
V. cholerae	61.1	20.6
V. parahaemolyticus	66.2	20.9
Yersinia	61.8	21.5

- The *Campylobacter*, STEC stx1, STEC stx2, *V. cholerae*, *V. parahaemolyticus*, and/or *Yersinia* signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range.
- Except Target(s) detected, all other pathogens are not detected.
- Probe Check: PASS; all probe check results pass.
- SPC – Not Applicable (NA); SPC is ignored because Target(s) detected.
- IC – NA; IC is ignored because Target(s) detected.

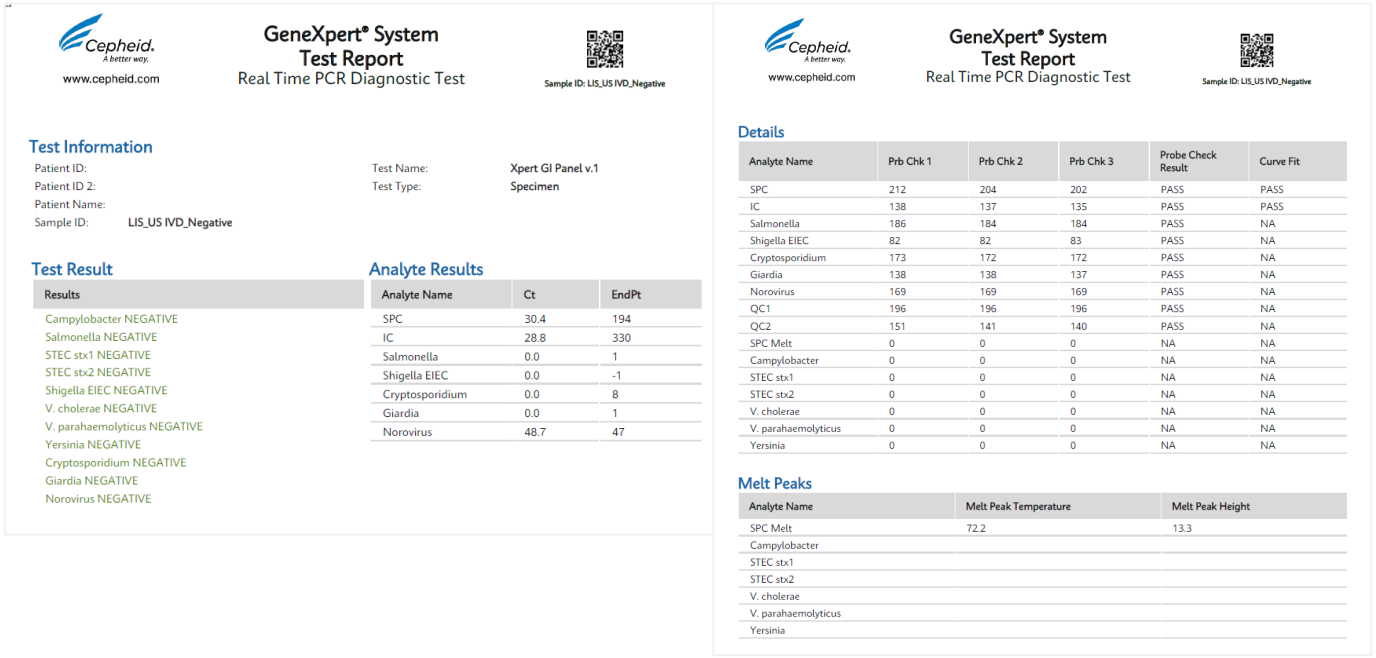
Because the incidence of infection with multiple (3 or more) agents are low, it is recommended that specimens undergo repeat testing if nucleic acids from multiple analytes are detected in a single specimen. **This does not apply when running Quality Control.**

Cepheid

GeneXpert® System with Touchscreen GI Panel NEGATIVE

AGENDA

Example Report



Cepheid. A better way. www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: LIS_US IVD_Negative

Test Information

Patient ID:
Patient ID 2:
Patient Name:
Sample ID: LIS_US IVD_Negative

Test Name: Xpert GI Panel v.1
Test Type: Specimen

Test Result

Results
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

Analyte Results

Analyte Name	Ct	EndPt
SPC	30.4	194
IC	28.8	330
Salmonella	0.0	1
Shigella EIEC	0.0	-1
Cryptosporidium	0.0	8
Giardia	0.0	1
Norovirus	48.7	47

Cepheid. A better way. www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: LIS_US IVD_Negative

Details

Analyte Name	Prb Chk 1	Prb Chk 2	Prb Chk 3	Probe Check Result	Curve Fit
SPC	212	204	202	PASS	PASS
IC	138	137	135	PASS	PASS
Salmonella	186	184	184	PASS	NA
Shigella EIEC	82	82	83	PASS	NA
Cryptosporidium	173	172	172	PASS	NA
Giardia	138	138	137	PASS	NA
Norovirus	169	169	169	PASS	NA
QC1	196	196	196	PASS	NA
QC2	151	141	140	PASS	NA
SPC Melt	0	0	0	NA	NA
Campylobacter	0	0	0	NA	NA
STEC stx1	0	0	0	NA	NA
STEC stx2	0	0	0	NA	NA
V. cholerae	0	0	0	NA	NA
V. parahaemolyticus	0	0	0	NA	NA
Yersinia	0	0	0	NA	NA

Melt Peaks

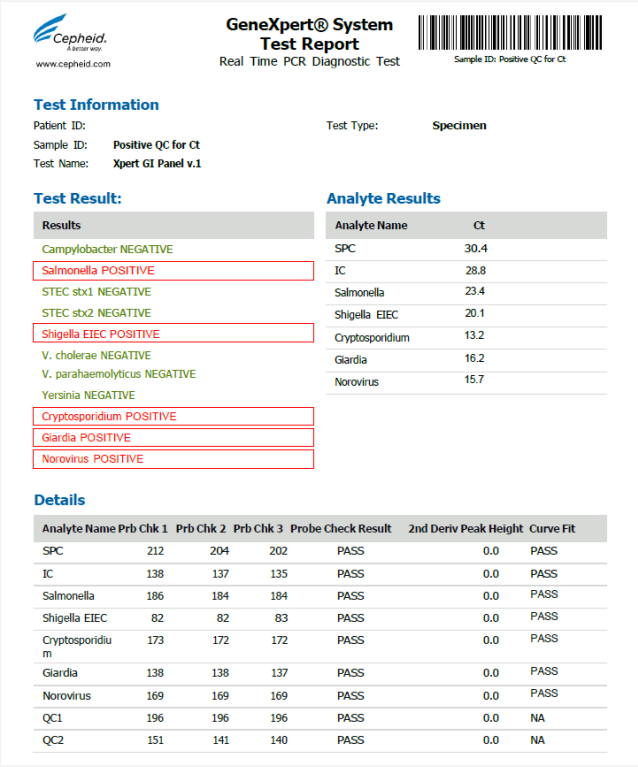
Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	72.2	13.3
Campylobacter		
STEC stx1		
STEC stx2		
V. cholerae		
V. parahaemolyticus		
Yersinia		

- None of the pathogens listed 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.

GeneXpert® Infinity GI Panel POSITIVE

AGENDA

Example Report



Cepheid
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: Positive QC for Ct

Test Information

Patient ID:
Sample ID: **Positive QC for Ct**
Test Name: **Xpert GI Panel v.1**
Test Type: **Specimen**

Test Result:

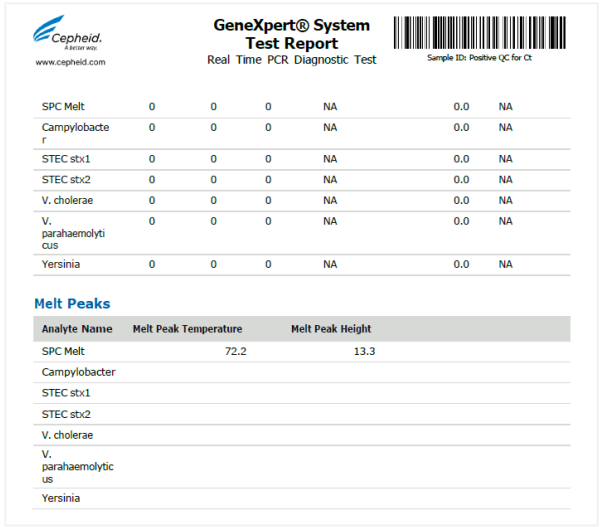
Results
Campylobacter NEGATIVE
Salmonella POSITIVE
STEC stx1 NEGATIVE
STEC stx2 NEGATIVE
Shigella EIEC POSITIVE
V. cholerae NEGATIVE
V. parahaemolyticus NEGATIVE
Yersinia NEGATIVE
Cryptosporidium POSITIVE
Giardia POSITIVE
Norovirus POSITIVE

Analyte Results

Analyte Name	Ct
SPC	30.4
IC	28.8
Salmonella	23.4
Shigella EIEC	20.1
Cryptosporidium	13.2
Giardia	16.2
Norovirus	15.7

Details

Analyte Name	Prb Chk 1	Prb Chk 2	Prb Chk 3	Probe Check Result	2nd Deriv Peak Height	Curve Fit
SPC	212	204	202	PASS	0.0	PASS
IC	138	137	135	PASS	0.0	PASS
Salmonella	186	184	184	PASS	0.0	PASS
Shigella EIEC	82	82	83	PASS	0.0	PASS
Cryptosporidium	173	172	172	PASS	0.0	PASS
Giardia	138	138	137	PASS	0.0	PASS
Norovirus	169	169	169	PASS	0.0	PASS
QC1	196	196	196	PASS	0.0	NA
QC2	151	141	140	PASS	0.0	NA



Cepheid
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: Positive QC for Ct

SPC Melt	0	0	0	NA	0.0	NA
Campylobacter	0	0	0	NA	0.0	NA
STEC stx1	0	0	0	NA	0.0	NA
STEC stx2	0	0	0	NA	0.0	NA
V. cholerae	0	0	0	NA	0.0	NA
V. parahaemolyticus	0	0	0	NA	0.0	NA
Yersinia	0	0	0	NA	0.0	NA

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	72.2	13.3
Campylobacter		
STEC stx1		
STEC stx2		
V. cholerae		
V. parahaemolyticus		
Yersinia		

- The *Salmonella*, *Shigella EIEC*, *Cryptosporidium*, *Giardia*, and/or Norovirus signal has a Ct within the valid cycle range.
- Except Target(s) detected, all other pathogens are not detected.
- Probe Check: PASS; all probe check results pass.
- SPC – Not Applicable (NA); SPC is ignored because Target(s) are detected.
- IC – NA; IC is ignored because Target(s) are detected.

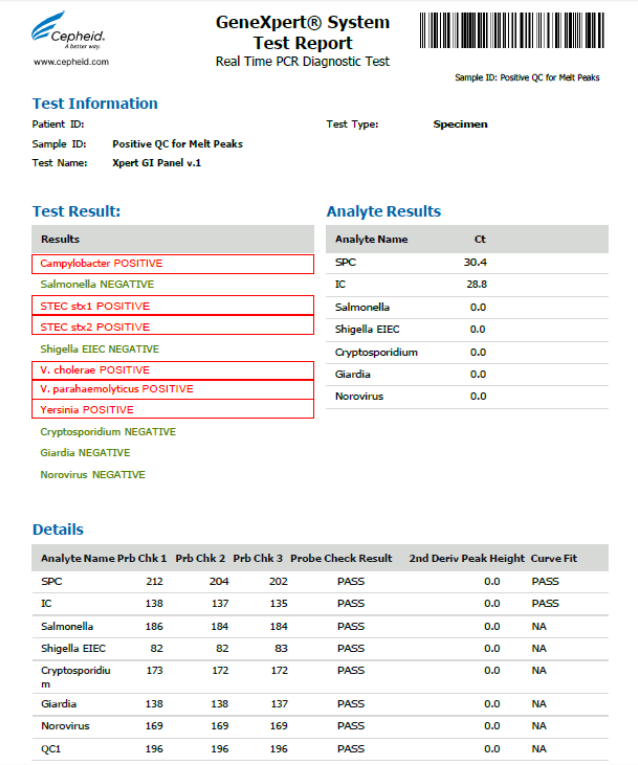
Because the incidence of infection with multiple (3 or more) agents are low, it is recommended that specimens undergo repeat testing if nucleic acids from multiple analytes are detected in a single specimen. **This does not apply when running Quality Control.**

Cepheid

GeneXpert® Infinity GI Panel POSITIVE

AGENDA

Example Report



Cepheid
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: Positive QC for Melt Peaks

Test Information

Patient ID:
Sample ID: Positive QC for Melt Peaks
Test Name: Xpert GI Panel v.1
Test Type: Specimen

Test Result:

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

Analyte Results

Analyte Name	Ct
SPC	30.4
IC	28.8
Salmonella	0.0
Shigella EIEC	0.0
Cryptosporidium	0.0
Giardia	0.0
Norovirus	0.0

Details

Analyte Name	Prb Chk 1	Prb Chk 2	Prb Chk 3	Probe Check Result	2nd Deriv Peak Height	Curve Fit
SPC	212	204	202	PASS	0.0	PASS
IC	138	137	135	PASS	0.0	PASS
Salmonella	186	184	184	PASS	0.0	NA
Shigella EIEC	82	82	83	PASS	0.0	NA
Cryptosporidium	173	172	172	PASS	0.0	NA
Giardia	138	138	137	PASS	0.0	NA
Norovirus	169	169	169	PASS	0.0	NA
QC1	196	196	196	PASS	0.0	NA
QC2	151	141	140	PASS	0.0	NA
SPC Melt	0	0	0	NA	0.0	NA
Campylobacter	0	0	0	NA	0.0	NA
STEC stx1	0	0	0	NA	0.0	NA
STEC stx2	0	0	0	NA	0.0	NA
V. cholerae	0	0	0	NA	0.0	NA
V. parahaemolyticus	0	0	0	NA	0.0	NA
Yersinia	0	0	0	NA	0.0	NA

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	71.7	11.2
Campylobacter	60.6	28.2
STEC stx1	74.9	49.5
STEC stx2	76.9	20.5
V. cholerae	61.1	20.6
V. parahaemolyticus	66.2	20.9
Yersinia	61.8	21.5

- The *Campylobacter*, STEC stx1, STEC stx2, *V. cholerae*, *V. parahaemolyticus*, and/or *Yersinia* signal has a melt peak above the target specific threshold setting and within the melt temperature (Tm) valid range.
- Except Target(s) detected, all other pathogens are not detected.
- Probe Check: PASS; all probe check results pass.
- SPC – Not Applicable (NA); SPC is ignored because Target(s) detected.
- IC – NA; IC is ignored because Target(s) detected.

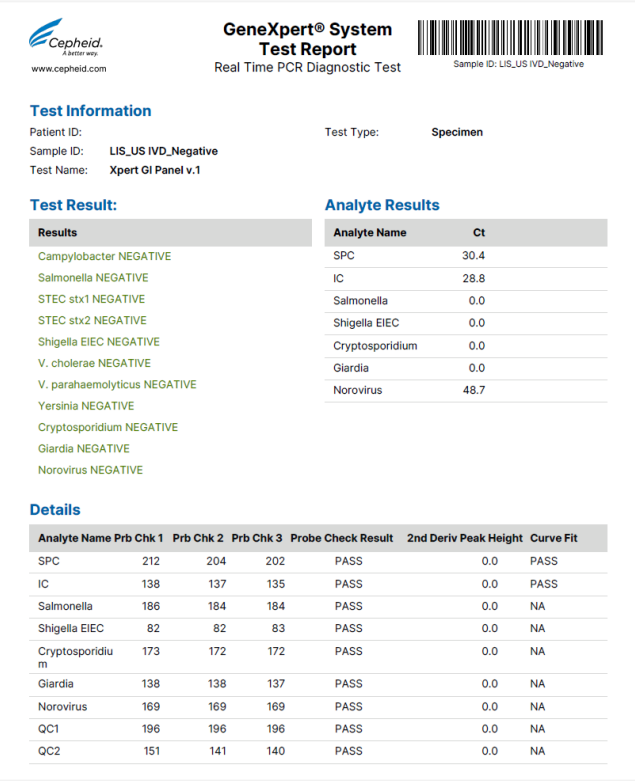
Because the incidence of infection with multiple (3 or more) agents are low, it is recommended that specimens undergo repeat testing if nucleic acids from multiple analytes are detected in a single specimen. **This does not apply when running Quality Control.**

Cepheid

GeneXpert® Infinity GI Panel NEGATIVE

AGENDA

Example Report



Cepheid. A better way.
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: LIS_US IVD_Negative

Test Information

Patient ID:
Sample ID: LIS_US IVD_Negative
Test Name: Xpert GI Panel v.1
Test Type: Specimen

Test Result:

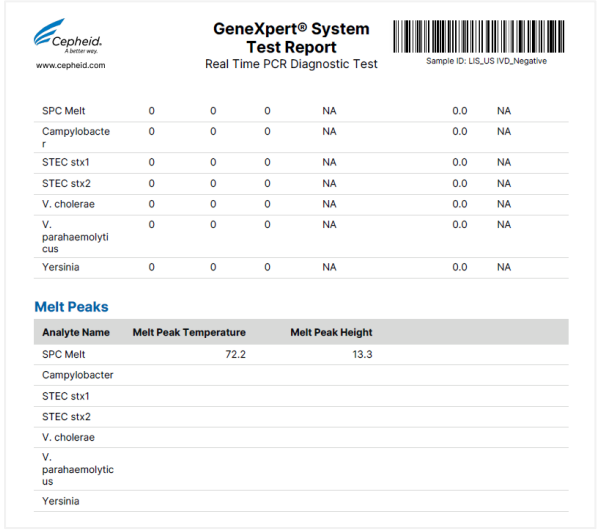
Results
Campylobacter NEGATIVE
Salmonella NEGATIVE
STEC stx1 NEGATIVE
STEC stx2 NEGATIVE
Shigella EIEC NEGATIVE
V. cholerae NEGATIVE
V. parahaemolyticus NEGATIVE
Yersinia NEGATIVE
Cryptosporidium NEGATIVE
Giardia NEGATIVE
Norovirus NEGATIVE

Analyte Results

Analyte Name	Ct
SPC	30.4
IC	28.8
Salmonella	0.0
Shigella EIEC	0.0
Cryptosporidium	0.0
Giardia	0.0
Norovirus	48.7

Details

Analyte Name	Prb Chk 1	Prb Chk 2	Prb Chk 3	Probe Check Result	2nd Deriv Peak Height	Curve Fit
SPC	212	204	202	PASS	0.0	PASS
IC	138	137	135	PASS	0.0	PASS
Salmonella	186	184	184	PASS	0.0	NA
Shigella EIEC	82	82	83	PASS	0.0	NA
Cryptosporidium	173	172	172	PASS	0.0	NA
Giardia	138	138	137	PASS	0.0	NA
Norovirus	169	169	169	PASS	0.0	NA
QC1	196	196	196	PASS	0.0	NA
QC2	151	141	140	PASS	0.0	NA



Cepheid. A better way.
www.cepheid.com

GeneXpert® System
Test Report
Real Time PCR Diagnostic Test

Sample ID: LIS_US IVD_Negative

SPC Melt	0	0	0	NA	0.0	NA
Campylobacter	0	0	0	NA	0.0	NA
STEC stx1	0	0	0	NA	0.0	NA
STEC stx2	0	0	0	NA	0.0	NA
V. cholerae	0	0	0	NA	0.0	NA
V. parahaemolyticus	0	0	0	NA	0.0	NA
Yersinia	0	0	0	NA	0.0	NA

Melt Peaks

Analyte Name	Melt Peak Temperature	Melt Peak Height
SPC Melt	72.2	13.3
Campylobacter		
STEC stx1		
STEC stx2		
V. cholerae		
V. parahaemolyticus		
Yersinia		

- None of the pathogens listed 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.

AGENDA

Troubleshooting

Reasons to Repeat the Test

AGENDA

INVALID	ERROR	NO RESULT
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.	None of the target pathogens meet criteria for the test result POSITIVE or NEGATIVE. Repeat test according to the Retest Procedure.	Test result POSITIVE or NEGATIVE of the target pathogens cannot be determined. Repeat test according to the Retest Procedure.
Repeat test according to the Retest Procedure.	SPC and IC: NO RESULT	Targets – NO RESULT
Probe Check: PASS; All probe check results pass	Probe Check: FAIL; All or one of the probe check results failed. If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range, or by a system component failure.	Probe Check: NA (not applicable)

Cepheid

Retest Procedure

AGENDA

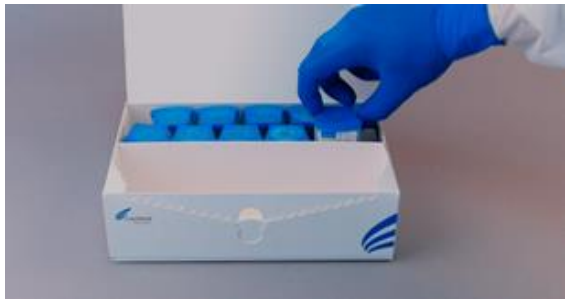
1

Discard used cartridge. Follow your institution's safety guidelines for disposal of cartridges.

2

If the result is INVALID, ERROR, NO RESULT or the result indicates infection with multiple pathogens, (3 or more) use a new cartridge to retest the specimen.

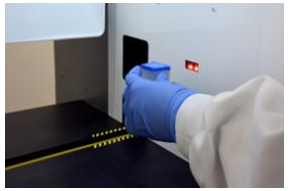
3



Obtain a new cartridge.

Process the specimen per the Instructions For Use.

4



Run the test on the system.

Technical Assistance

AGENDA

- Before contacting Cepheid Technical Support, collect the following information:
  - Product name
  - Lot number
  - Serial number of the System
  - Software version and, if applicable, computer service tag number
  - Error messages (if any)

- Log your case online using the following link *https://my.cepheid.com/contact/technical-support*

Cepheid
A better way.

Thank You

www.Cepheid.com

End Show

danaher