

QIAstat-Dx[®] Gastrointestinal Panel 2 Instructions for Use (Handbook)



Version 1

IVD

For In Vitro Diagnostic Use

For use with QIAstat-Dx Analyzer 1.0

REF

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Intended Use

The QIAstat-Dx® Gastrointestinal Panel 2 is a multiplexed nucleic acid test intended for use with QIAstat-Dx Analyzer 1.0 and for the simultaneous qualitative detection and identification of nucleic acids from multiple viruses, bacteria, and parasites directly from stool samples in Cary–Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following viruses, bacteria (including several diarrheagenic *E. coli*/*Shigella* pathotypes), and parasites are identified with the QIAstat-Dx Gastrointestinal Panel 2:

- Adenovirus F40/F41
- Astrovirus
- Norovirus (GI/GII)
- Rotavirus A
- Sapovirus (GI, GII, GIV, GV)
- *Campylobacter* (*C. jejuni*, *C. coli*, and *C. upsaliensis*)
- *Clostridium difficile* (toxin A/B)
- Enteraggregative *Escherichia coli* (EAEC)
- *Shigella*/Enteroinvasive *Escherichia coli* (EIEC)
- Enteropathogenic *Escherichia coli* (EPEC)
- Enterotoxigenic *Escherichia coli* (ETEC) *lt/st*
- *Plesiomonas shigelloides*
- *Salmonella* spp.
- Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2** (including specific identification of *E. coli* O157 serogroup within STEC)
- *Vibrio vulnificus*
- *Vibrio parahaemolyticus*
- *Vibrio cholerae*
- *Yersinia enterocolitica*
- *Cryptosporidium*
- *Cyclospora cayetanensis*
- *Entamoeba histolytica*
- *Giardia lamblia*

* Shiga-like toxin-producing *E. coli* (STEC) genes (*stx1* and *stx2*) are differentiated by QIAstat-Dx Gastrointestinal Panel 2.

Concomitant culture is necessary for organism recovery and further typing of bacterial agents.

The QIAstat-Dx Gastrointestinal Panel 2 is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and

epidemiological data. Confirmed positive results do not rule out co-infection with organisms not detected by the QIAstat-Dx Gastrointestinal Panel 2. The organisms detected may not be the sole or definitive cause of the disease.

QIAstat-Dx Gastrointestinal Panel 2 is not intended to monitor or guide treatment for *C. difficile* infections.

Negative QIAstat-Dx Gastrointestinal Panel 2 results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this assay test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

The QIAstat-Dx Gastrointestinal Panel 2 also aids in the detection and identification of acute gastroenteritis in the context of outbreaks. The QIAstat-Dx Gastrointestinal Panel 2 is intended for professional use only and is not intended for self-testing. The QIAstat-Dx Gastrointestinal Panel 2 is intended for in vitro diagnostic use.

Intended User

This kit is intended for professional use.

The product is to be used only by personnel specifically instructed and trained in molecular biology techniques and familiar with this technology.

Summary and Explanation

QIAstat-Dx Gastrointestinal Panel 2 Cartridge description

The QIAstat-Dx Gastrointestinal Panel 2 (Figure 1) is a disposable plastic device that allows performance of fully automated molecular assays for the detection of gastrointestinal pathogens. The main features of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge include compatibility with a liquid sample type, hermetical containment of the pre-loaded reagents necessary for testing, and true walk-away operation. All sample preparation and assay testing steps are performed within the cartridge.

All reagents required for the complete execution of a test run are pre-loaded and self-contained in the QIAstat-Dx Gastrointestinal Panel 2 Cartridge. The user does not need to come in contact with and/or manipulate any reagents. The QIAstat-Dx Analyzer 1.0 houses air filters for both incoming and outgoing air, further safeguarding the environment. After testing, the cartridge stays hermetically closed at all times, greatly enhancing its safe disposal.

Within the cartridge, multiple steps are automatically performed in sequence using pneumatic pressure to transfer samples and fluids via the transfer chamber to their intended destinations.

After the sample is manually loaded, the diagnostic tests with the QIAstat-Dx Gastrointestinal Panel 2 are performed on the QIAstat-Dx Analyzer 1.0. All of the sample preparation and analysis steps are performed automatically by the QIAstat-Dx Analyzer 1.0.

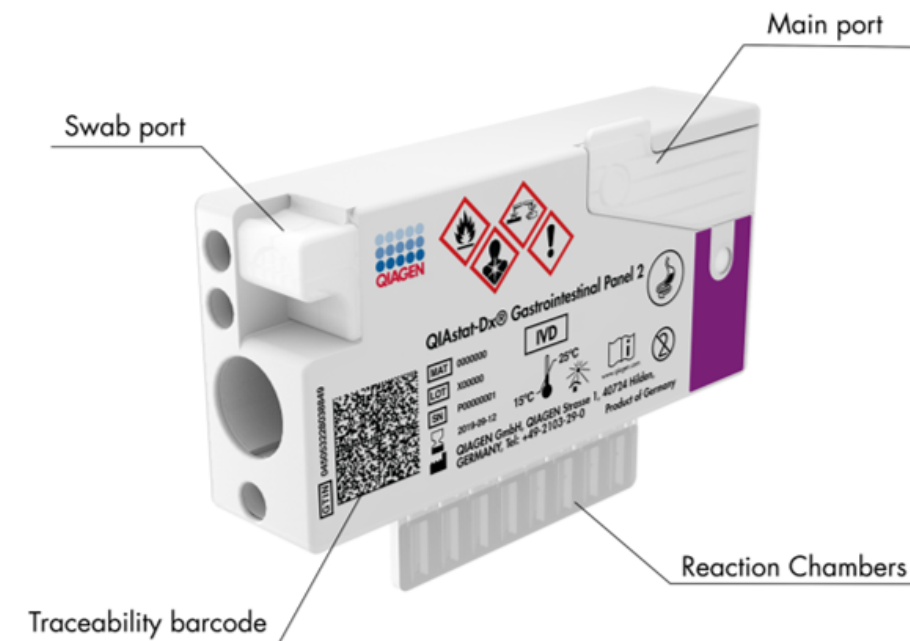


Figure 1. Layout of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge and its features.

Pathogen Information

Acute gastrointestinal infections can be caused by a variety of pathogens, including parasites, bacteria and viruses, and generally present with nearly indistinguishable clinical signs and symptoms. The rapid and accurate determination of the presence or absence of potential causative agent(s) helps make timely decisions regarding treatment, hospital admission, infection control, and return of the patient to work and family. It may also greatly support improved antimicrobial stewardship and other important public health initiatives.

The QIAstat-Dx Gastrointestinal Panel 2 Cartridge allows detection and differentiation of 22 parasitic, viral, and bacterial pathogens that cause gastrointestinal symptoms, which includes specific identification of *E. coli* O157 serogroup within STEC, resulting in 23 targets in total. Testing requires a small sample volume and minimal hands-on time, and the results are available in approximately 78 minutes.

Pathogens that can be detected and identified with the QIAstat-Dx Gastrointestinal Panel 2 are listed in Table 1.

Sample collection and cartridge loading

The collection of samples and their subsequent loading into the QIAstat-Dx Gastrointestinal Panel 2 Cartridge should be performed by personnel trained in safe handling of biological samples.

The following steps are performed:

1. Fresh unpreserved stool specimen is collected and resuspended into Cary-Blair transport medium as soon as possible after collection following the manufacturer's instructions. Attention should be given not to exceed the maximum fill line of the Cary-Blair container.

2. The sample information is manually written on or a sample label is affixed to the top of a QIAstat-Dx Gastrointestinal Panel 2 Cartridge.

Table 1. Pathogens detected by the QIAstat-Dx Gastrointestinal Panel 2

Pathogen	Classification (genome type)
Adenovirus F40/F41	Adenovirus (DNA)
Astrovirus	Astrovirus (RNA)
Norovirus GI/GII	Calicivirus (RNA)
Rotavirus A	Reovirus (RNA)
Sapovirus (GI, GII, GIV, GV)	Calicivirus (RNA)
<i>Campylobacter</i> (<i>C. jejuni</i> , <i>C. upsaliensis</i> , <i>C. coli</i>)	Bacterium (DNA)
<i>Clostridium difficile</i> (toxin A/B)	Bacterium (DNA)
Enteroaggregative <i>E. coli</i> (EAEC)	Bacterium (DNA)
Enteroinvasive <i>E. coli</i> (EIEC)/ <i>Shigella</i>	Bacterium (DNA)
Enteropathogenic <i>E. coli</i> (EPEC)	Bacterium (DNA)
Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	Bacterium (DNA)
<i>Plesiomonas shigelloides</i>	Bacterium (DNA)
<i>Salmonella</i> spp.	Bacterium (DNA)
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> (including specific identification of <i>E. coli</i> O157 serogroup within STEC)	Bacterium (DNA)
<i>Vibrio vulnificus</i>	Bacterium (DNA)
<i>Vibrio parahaemolyticus</i>	Bacterium (DNA)
<i>Vibrio cholerae</i>	Bacterium (DNA)

Table 1. Pathogens detected by the QIAstat-Dx Gastrointestinal Panel 2 (continued)

Pathogen	Classification (genome type)
<i>Yersinia enterocolitica</i>	Bacterium (DNA)
<i>Cryptosporidium</i>	Parasite (DNA)
<i>Cyclospora cayetanensis</i>	Parasite (DNA)
<i>Entamoeba histolytica</i>	Parasite (DNA)
<i>Giardia lamblia</i>	Parasite (DNA)

3. Liquid sample (stool resuspended in Cary-Blair transport medium) is loaded manually into the QIAstat-Dx Gastrointestinal Panel 2 Cartridge.

Note: Cary-Blair preserved stool specimens should present a homogenous suspension (easily vortexed).

Note: The user must perform a visual check of the sample inspection window to confirm that the liquid sample has been loaded.

4. The sample bar code (if available) and the QIAstat-Dx Gastrointestinal Panel 2 Cartridge bar code are scanned by the QIAstat-Dx Analyzer 1.0. If sample bar code is not available, the sample ID is manually written using the virtual keyboard of the touchscreen.
5. The QIAstat-Dx Gastrointestinal Panel 2 Cartridge is introduced into the QIAstat-Dx Analyzer 1.0.
6. The test is started on the QIAstat-Dx Analyzer 1.0.

The extraction, amplification, and detection of nucleic acids in the sample are performed automatically by the QIAstat-Dx Analyzer 1.0.

1. The liquid sample is homogenized, and cells are lysed in the lysis chamber of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge, which includes a rotor that turns at high speed and silica beads that provide effective cell disruption.

2. Nucleic acids are purified from the lysed sample via binding to a silica membrane in the purification chamber of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge in the presence of chaotropic salts and alcohol.
3. The purified nucleic acids are eluted from the membrane in the purification chamber and are mixed with the lyophilized PCR chemistry in the dried-chemistry chamber of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge.
4. The mixture of sample and PCR reagents is dispensed into the QIAstat-Dx Gastrointestinal Panel 2 Cartridge PCR chambers, which contain air-dried assay-specific primers and probes.
5. The QIAstat-Dx Analyzer 1.0 creates the optimal temperature profiles to carry out effective multiplex real-time RT-PCR and performs real-time fluorescence measurements to generate amplification curves.
6. The QIAstat-Dx Analyzer 1.0 Software interprets the resulting data and process controls and delivers a test report.

Materials Provided

Kit contents

QIAstat-Dx Gastrointestinal Panel 2 Cartridge*	
Catalog number	691412
Number of tests	6
QIAstat-Dx Gastrointestinal Panel 2 Cartridges*	6*
Transfer pipettes†	6*

* 6 individually packaged cartridges containing all reagents needed for sample preparation and multiplex real-time RT-PCR, plus Internal Control.

† 6 individually packaged transfer pipettes for dispensing liquid sample into the QIAstat-Dx Gastrointestinal Panel 2 Cartridge.

Materials Required but Not Provided

Equipment

QIAstat-Dx Gastrointestinal Panel 2 is designed for use with the QIAstat-Dx Analyzer 1.0. Before beginning a test, make sure the following are available:

- QIAstat-Dx Analyzer 1.0 (at least one Operational Module and one Analytical Module) with software version 1.5 or earlier*
- *QIAstat-Dx Analyzer 1.0 User Manual* (for use with software version 1.5 or earlier)
- QIAstat-Dx-specific Assay Definition File software for Gastrointestinal Panel 2 installed on the Operational Module

*Prior to use, ensure that instruments have been checked and calibrated according to the manufacturer's recommendations.

Warnings and Precautions

For in vitro diagnostic use.

The QIAstat-Dx Gastrointestinal Panel 2 is to be used by laboratory professionals trained in the use of QIAstat-Dx Analyzer 1.0.

Safety information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient PDF at www.qiagen.com/safety where you can find, view, and print the SDS for each QIAGEN kit and kit component.

Always wear appropriate personal protective equipment, including but not limited to disposable powder-free gloves, a lab coat, and protective eyewear. Protect skin, eyes, and mucus membranes. Change gloves often when handling samples.

Handle all samples, used cartridges, and transfer pipettes as if they are capable of transmitting infectious agents. Always observe safety precautions as outlined in relevant guidelines, such as the Clinical and Laboratory Standards Institute® (CLSI) *Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline (M29)*, or other appropriate documents provided by:

- OSHA®: Occupational Safety and Health Administration (United States of America)
- ACGIH®: American Conference of Government Industrial Hygienists (USA)
- COSHH: Control of Substances Hazardous to Health (United Kingdom)

Follow your institution's safety procedures for handling biological samples. Dispose of samples, QIAstat-Dx Gastrointestinal Panel 2 Cartridges, and transfer pipettes according to the appropriate regulations.

The QIAstat-Dx Gastrointestinal Panel 2 Cartridge is a closed, single-use device that contains all reagents needed for sample preparation and multiplex real-time RT-PCR within the QIAstat-Dx Analyzer 1.0. Do not use a QIAstat-Dx Gastrointestinal Panel 2 Cartridge that is past its expiration date, appears damaged, or leaks fluid. Dispose of used or damaged cartridges in accordance with all national, state, and local health and safety regulations and laws.

Observe standard laboratory procedures for keeping the working area clean and contamination-free. Guidelines are outlined in publications such as the Biosafety in Microbiological and Biomedical Laboratories from the Centers for Disease Control and Prevention and the National Institutes of Health (www.cdc.gov/od/ohs/biosfty/biosfty.htm).

Precautions

The following hazard and precautionary statements apply to components of the QIAstat-Dx Gastrointestinal Panel 2.



Contains: ethanol; guanidine hydrochloride; guanidine thiocyanate; isopropanol; proteinase K; t-Octylphenoxypolyethoxyethanol. Danger! Highly flammable liquid and vapor. Harmful if swallowed or if inhaled. May be harmful in contact with skin. Causes severe skin burns and eye damage. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Corrosive to the respiratory tract. Keep away from heat/sparks/open flames/hot surfaces. No smoking. Avoid breathing dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Immediately call a POISON CENTER or doctor/physician. Remove person to fresh air and keep comfortable for breathing.

To reduce the risk of contamination when handling stool samples, it is recommended that the below guidelines are applied:

- When handling the stool sample, a biosafety cabinet, dead air box, splash shield, or face shield should be used.
- The work area used for cartridge loading should be separate from the work area used for stool pathogen testing (i.e., stool culture, EIA).
- Prior to sample handling, the work area should be thoroughly cleaned using 10% bleach or similar disinfectant.
- QIAstat-Dx Gastrointestinal Panel 2 and samples should be processed one at a time.

- Change gloves prior to removing cartridges from shipping boxes.
- Change gloves and clean the work area between processing each sample.
- Dispose of used cartridges in a biohazard container immediately after the run is completed and avoid excessive handling.

Reagent Storage and Handling

Reagent storage and handling

Store the QIAstat-Dx Gastrointestinal Panel 2 Cartridges in a dry, clean storage space at room temperature (15–25°C). Do not remove the QIAstat-Dx Gastrointestinal Panel 2 Cartridges or the transfer pipettes from their individual packaging until actual use. Under these conditions, QIAstat-Dx Gastrointestinal Panel 2 Cartridges can be stored until the expiration date printed on the individual packaging. The expiration date is also included in the QIAstat-Dx Gastrointestinal Panel 2 Cartridge barcode and is read by the QIAstat-Dx Analyzer 1.0 when the cartridge is inserted into the instrument to run a test.

Attention should be paid to the expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components.

Specimen Handling, Storage, and Preparation

The QIAstat-Dx Gastrointestinal Panel 2 is for use with QIAstat-Dx Analyzer 1.0. All samples should be treated as potentially hazardous.

Stool samples should be collected and handled according to the Cary-Blair transport medium manufacturer's recommended procedures.

Recommended storage conditions for stool resuspended in Cary-Blair transport medium specimens are listed below:

- Room temperature up to 4 days at 15–25°C
- Refrigerated up to 4 days at 2–8°C

Quality Control

In accordance with QIAGEN's ISO-certified Quality Management System, each lot of QIAstat-Dx Gastrointestinal Panel 2 is tested against predetermined specifications to ensure consistent product quality.

External control information

All external quality control requirements and testing should be performed in accordance with local, state, and federal regulations or accreditation organizations and should follow the user's laboratory standard quality control procedures.

Blank controls are not applicable to the device because it is a single test disposable cartridge. Regular testing of negative and positive external controls is recommended by the company but controls are not provided with the QIAstat-Dx Gastrointestinal Panel 2. Use transport media as the external Negative Control and previously characterized positive samples or negative sample spiked with well characterized target organisms as external positive controls.

Procedure: Processing Raw Stool Samples in Cary Blair transport medium

Sample collection, transport, and storage

Collect and resuspend the stool sample in Cary-Blair transport medium according to the manufacturer's recommended procedures.

Loading a sample into the QIAstat-Dx Gastrointestinal Panel 2 Cartridge

Note: Applicable for QIAstat-Dx Analyzer 1.0.

1. Open the package of a QIAstat-Dx Gastrointestinal Panel 2 Cartridge using the tear notches on the sides of the packaging (Figure 2).

Important: After the package is opened, sample should be introduced into the QIAstat-Dx Gastrointestinal Panel 2 Cartridge and loaded into the QIAstat-Dx Analyzer 1.0 within 120 minutes.



Figure 2. Opening the QIAstat-Dx Gastrointestinal Panel 2 Cartridge.

2. Remove the QIAstat-Dx Gastrointestinal Panel 2 Cartridge from the packaging and position it so that the barcode on the label faces you.
3. Manually write the sample information or place a sample information label on the top of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 3).



Figure 3. Sample information placement on top of QIAstat-Dx Gastrointestinal Panel 2 Cartridge.

4. Place the QIAstat-Dx Gastrointestinal Panel 2 Cartridge flat on the clean work surface so that the barcode on the label faces upwards. Open the sample lid of the main port on the front of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge (Figure 4).

Important: Do not flip the QIAstat-Dx Gastrointestinal Panel 2 Cartridge or agitate it while the main port lid is open. The main port contains silica beads used in the sample disruption. The silica beads could fall out of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge if it is agitated while the lid is open.

Note: The swab port is not used for the QIAstat-Dx Gastrointestinal Panel 2 assay.

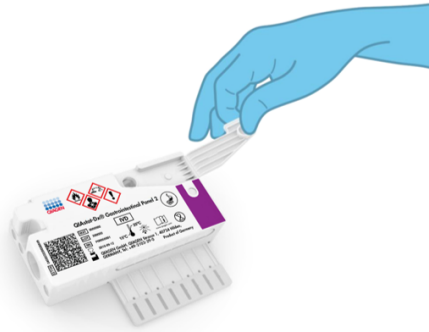


Figure 4. Opening the sample lid of main port.

Note: The swab port is not used for the QIAstat-Dx Gastrointestinal Panel 2 assay.

5. Thoroughly mix the stool in the Cary-Blair transport medium, for example, by vigorously agitating the tube 3 times (Figure 5).



Figure 5. Mixing stool sample in Cary-Blair transport medium.

6. Open the tube with the sample to be tested. Use the supplied transfer pipette to draw up fluid. Draw the sample to the second fill line on the pipette (i.e., 200 μ L) (Figure 6).

Important: Do not draw air, mucus, or particles into the pipette. If air, mucus, or particles are drawn into the pipette, carefully expel the sample fluid in the pipette back into the sample tube and draw up fluid again. In the event that the supplied transfer pipette is lost, please use another one from the package or any other commercially available pipette with a minimum volume of 200 μL .

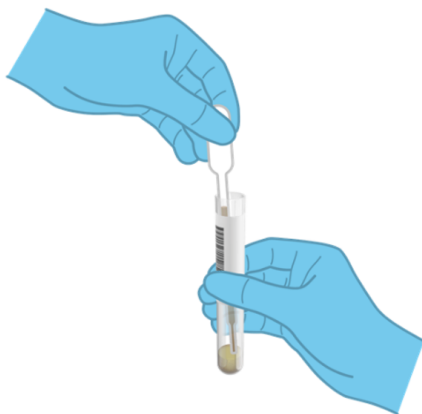


Figure 6. Drawing up sample into the supplied transfer pipette.

7. Carefully transfer the sample into the main port of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge using the supplied single-use transfer pipette (Figure 7).

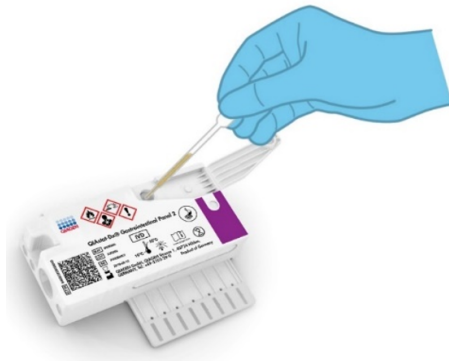


Figure 7. Transferring sample to main port of QIAstat-Dx Gastrointestinal Panel 2 Cartridge.

8. Firmly close the lid of the main port until it clicks (Figure 8).



Figure 8. Closing the lid of the main port.

9. Visually confirm that the sample has been loaded by checking the sample inspection window of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge (Figure 9). A mixture of sample and silica beads should be observed.

Important: After the sample is placed inside the QIAstat-Dx Gastrointestinal Panel 2 Cartridge, the cartridge must be loaded into the QIAstat-Dx Analyzer 1.0 within 90 minutes.

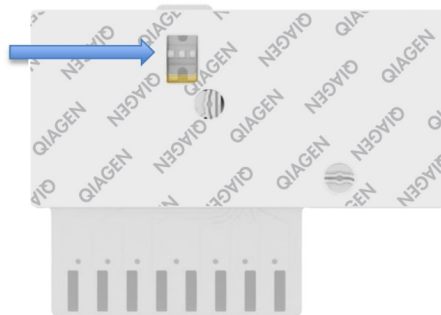


Figure 9. Sample inspection window (blue arrow).

Running a test with the QIAstat-Dx Analyzer 1.0

1. Power on the QIAstat-Dx Analyzer 1.0 using the **ON/OFF** button on the front of the instrument.

Note: The power switch on the back of the Analytical Module must be set in the “I” position. The QIAstat-Dx Analyzer 1.0 status indicators will turn blue.

2. Wait until the Main screen appears, and the QIAstat-Dx Analyzer 1.0 status indicators turn green and stop blinking.
3. Log in to the QIAstat-Dx Analyzer 1.0 by entering the user name and password.

Note: The Login screen will appear if User Access Control is activated. If the User Access Control is disabled, no username/password will be required, and the Main screen will appear.

4. If the Assay Definition File software has not been installed on QIAstat-Dx Analyzer 1.0, follow the installation instructions prior to running the test (see Appendix A: Installing the Assay Definition File for additional information).
5. Press **Run Test** in the top right corner of the touchscreen of QIAstat-Dx Analyzer 1.0.
6. When prompted, scan the sample ID barcode on the Cary-Blair sample or scan the specimen information barcode located on the top of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge (see step 3) using the integrated front barcode reader of the QIAstat-Dx Analyzer 1.0 (Figure 10).

Note: It is also possible to enter the sample ID using the virtual keyboard of the touchscreen by selecting the **Sample ID** field.

Note: Depending on the chosen system configuration, entering the patient ID may also be required at this point.

Note: Instructions from QIAstat-Dx Analyzer 1.0 appear in the Instructions Bar at the bottom of the touchscreen.



Figure 10. Scanning sample ID barcode.

7. When prompted, scan the barcode of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge to be used (Figure 11). The QIAstat-Dx Analyzer 1.0 will automatically recognize the assay to be run based on the cartridge barcode.



Figure 11. Scanning QIAstat-Dx Gastrointestinal Panel 2 Cartridge barcode.

8. The Confirm screen will appear. Review the entered data and make any necessary changes by selecting the relevant fields on the touchscreen and editing the information.
9. Press **Confirm** when all the displayed data are correct. If needed, select the appropriate field to edit its content, or press **Cancel** to cancel the test (Figure 12).

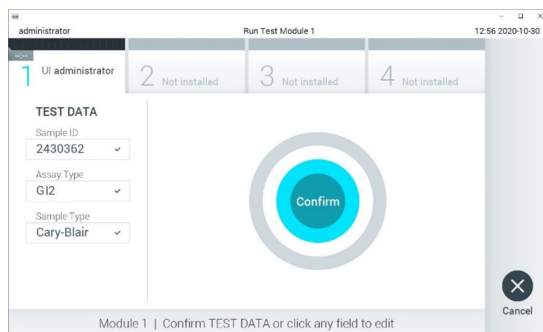


Figure 12. Confirming data entry.

10. Ensure that both sample lids of the swab port and main port of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge are firmly closed.
11. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 1.0 automatically opens, insert the QIAstat-Dx Gastrointestinal Panel 2 Cartridge with the barcode facing to the left and the reaction chambers facing down (Figure 13).

Note: Depending on the system configuration, the operator may be required to re-enter their user password to start the test run.

Note: Up to this point, it is possible to cancel the test run by pressing the **Cancel** button in the bottom right corner of the touchscreen.

12. Upon detecting the QIAstat-Dx Gastrointestinal Panel 2 Cartridge, the QIAstat-Dx Analyzer 1.0 will automatically close the lid of the cartridge entrance port and start the test run. No further action from the operator is required to start the run.

Note: There is no need to push the QIAstat-Dx Gastrointestinal Panel 2 Cartridge into the QIAstat-Dx Analyzer 1.0.

Note: The QIAstat-Dx Analyzer 1.0 will not accept a QIAstat-Dx Gastrointestinal Panel 2 Cartridge other than the one used and scanned during the test setup. If a cartridge other than the one scanned is inserted, an error will be generated, and the cartridge will be automatically ejected.

Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx Gastrointestinal Panel 2 Cartridge is not positioned in the port. If this occurs, repeat the procedure starting from step 5.



Figure 13. Inserting QIAstat-Dx Gastrointestinal Panel 2 Cartridge into QIAstat-Dx Analyzer 1.0.

13. While the test is running, the remaining run time is displayed on the touchscreen.
14. After the test run is completed, the Eject screen will appear (Figure 14) and the Module status bar will display the test result as one of the following options:
 - TEST COMPLETED: The test was completed successfully.
 - TEST FAILED: An error occurred during the test.
 - TEST CANCELED: The user canceled the test.

Important: If the test fails, refer to the “Troubleshooting” section in the *QIAstat-Dx Analyzer 1.0 User Manual* for possible reasons and instructions on how to proceed. For additional information about specific QIAstat-Dx Gastrointestinal Panel 2 error codes and messages, refer to the section of this document.

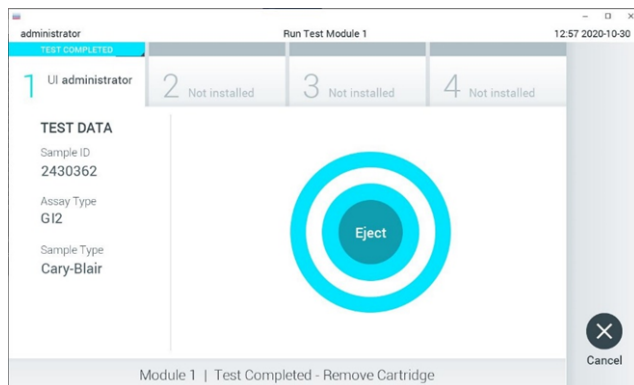


Figure 14. Eject screen display.

15. Press  **Eject** on the touchscreen to remove the QIAstat-Dx Gastrointestinal Panel 2 Cartridge and dispose of it as biohazardous waste in accordance with all national, state, and local health and safety regulations and laws. The QIAstat-Dx Gastrointestinal Panel 2 Cartridge should be removed when the cartridge entrance port opens and ejects the cartridge. If the cartridge is not removed after 30 seconds, it will automatically move back into the QIAstat-Dx Analyzer 1.0 and the cartridge entrance port lid will close. If this occurs, press **Eject** to open the lid of the cartridge entrance port again and then remove the cartridge.

Important: Used QIAstat-Dx Gastrointestinal Panel 2 Cartridges must be discarded. It is not possible to re-use cartridges for tests for which the execution was started but then subsequently canceled by the operator, or for which an error was detected.

16. After the QIAstat-Dx Gastrointestinal Panel 2 Cartridge has been ejected, the results Summary screen will appear. To begin the process for running another test, press **Run Test**.

Note: For further information on the use of the QIAstat-Dx Analyzer 1.0, refer to the *QIAstat-Dx Analyzer 1.0 User Manual*.

Viewing results with the QIAstat-Dx Analyzer 1.0

The QIAstat-Dx Analyzer 1.0 automatically interprets and saves test results. After ejecting the QIAstat-Dx Gastrointestinal Panel 2 Cartridge, the results Summary screen is automatically displayed (Figure 15).

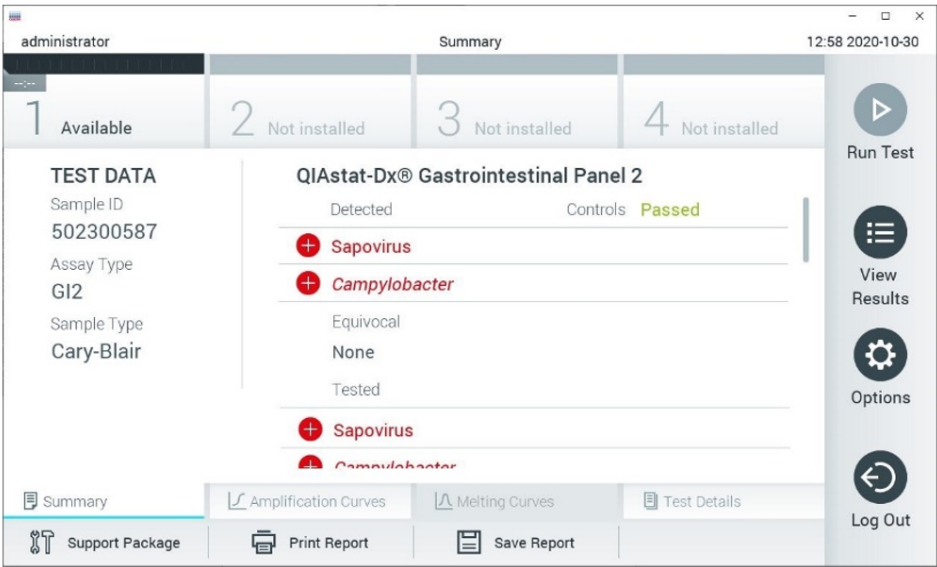


Figure 15. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel.

The main part of the screen provides the following lists and uses color-coding and symbols to indicate the results:

- The first list, under the heading “Detected”, includes all pathogens detected and identified in the sample, which are preceded by a  sign and are colored red.

- The second list, under the heading "Equivocal" is not used. "Equivocal" results are not applicable for the QIAstat-Dx Gastrointestinal Panel 2. Therefore, the "Equivocal" list will always be empty.
- The third list, under the heading "Tested", includes all pathogens tested in the sample.

Pathogens detected and identified in the sample are preceded by a  sign and are colored red. Pathogens that were tested but not detected are preceded by a  sign and are colored green. Invalid and not applicable pathogens are also displayed in this list.

Note: Pathogens detected and identified in the sample are shown in both the **Detected** and **Tested** lists.

If the test failed to complete successfully, a message will indicate **Failed** followed by the specific error code.

The following Test Data is shown on the left side of the screen:

- Sample ID
- Patient ID (if available)
- Assay Type
- Sample Type

Further data about the assay is available, depending on the operator's access rights, through the tabs at the bottom of the screen (e.g., amplification plots and test details).

A report with the assay data can be exported to an external USB storage device. Insert the USB storage device into one of the USB ports of the QIAstat-Dx Analyzer 1.0 and press **Save Report** in the bottom bar of the screen. This report can be exported later at any time by selecting the test from the **View Result** list.

The report can also be sent to the printer by pressing **Print Report** in the bottom bar of the screen.

Viewing amplification curves

Viewing amplification curves

To view test amplification curves of pathogens detected, press the  **Amplification Curves** tab (Figure 16).



Figure 16. Amplification Curves screen (PATHOGENS tab).

Details about the tested pathogens and controls are shown on the left and the amplification curves are shown in the center.

Note: If **User Access Control** is enabled on the QIAstat-Dx Analyzer 1.0, the **Amplification Curves** screen is only available for operators with access rights.

Press the **PATHOGENS** tab on the left side to display the plots corresponding to the tested pathogens. Press the pathogen name to select which pathogens are shown in the amplification plot. It is possible to select single, multiple, or no pathogens. Each pathogen in the selected list will be assigned a color corresponding to the amplification curve associated with the pathogen. Unselected pathogens will be shown in gray. The corresponding Ct and endpoint fluorescence (EP) values are shown below each pathogen name.

Press the **CONTROLS** tab on the left side to view the controls in the amplification plot. Press the circle next to the control name to select or deselect it (Figure 17).



Figure 17. Amplification Curves screen (CONTROLS tab).

The amplification plot displays the data curve for the selected pathogens or controls. To alternate between logarithmic or linear scale for the Y-axis, press the **Lin** or **Log** button at the bottom left corner of the plot.

The scale of the X-axis and Y-axis can be adjusted using the  **blue pickers** on each axis. Press and hold a blue picker and then move it to the desired location on the axis. Move a blue picker to the axis origin to return to the default values.

Viewing test details

Press  **Test Details** in the Tab Menu bar at the bottom of the touchscreen to review the results in more detail. Scroll down to see the complete report.

The following Test Details are shown in the center of the screen (Figure 18):

- User ID
- Cartridge SN (serial number)
- Cartridge Expiration Date
- Module SN (serial number)
- Test Status (Completed, Failed, or Canceled by operator)
- Error Code (if applicable)
- Test Start Date and Time
- Test Execution Time
- Assay Name
- Test ID

- Test Result
 - **Positive** (if at least one gastrointestinal pathogen is detected/identified)
 - **Positive with warning** (if at least one pathogen is detected, but the Internal Control failed)
 - **Negative** (if no gastrointestinal pathogen is detected)
 - **Failed** (an error occurred or the test was canceled by the user)
- List of analytes tested in the assay, with Ct and endpoint fluorescence in the event of a positive signal
- Internal Control, with Ct and endpoint fluorescence

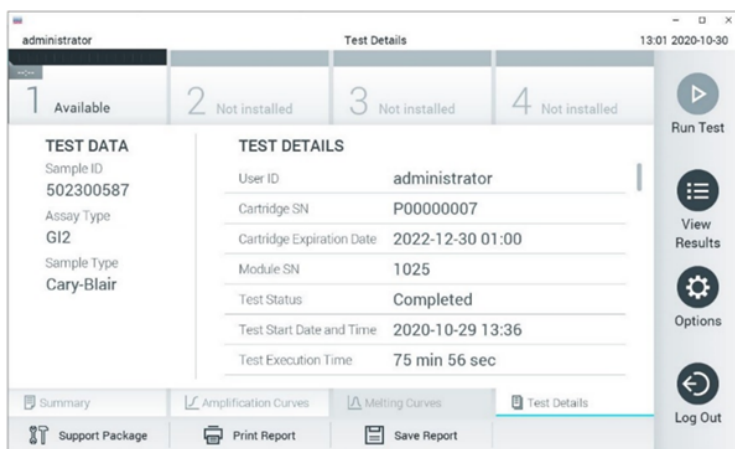


Figure 18. Example screen showing Test Data on the left panel and Test Details in the main panel.

Browsing results from previous tests

To view results from previous tests that are stored in the results repository, press  **View Results** on the Main Menu bar (Figure 19).

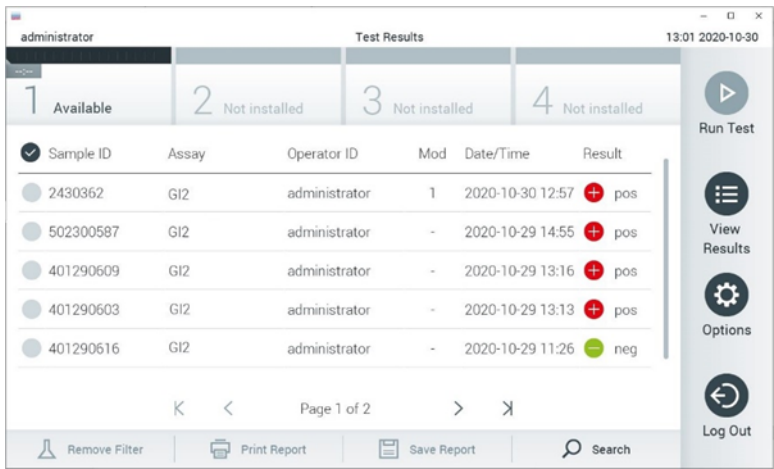


Figure 19. Example View Results screen.

The following information is available for every executed test (Figure 20):

- Sample ID
- Assay (name of test assay which is “GI2” for Gastrointestinal Panel 2)
- Operator ID
- Mod (Analytical Module on which the test was executed)
- Date/Time (date and time when the test was finished)
- Result (outcome of the test: positive [pos], positive with warning [pos*], negative [neg], failed [fail], or successful [suc])

Note: If **User Access Control** is enabled on the QIAstat-Dx Analyzer 1.0, the data for which the user has no access rights will be hidden with asterisks.

Select one or more test results by pressing the **gray circle** to the left of the sample ID. A checkmark will appear next to selected results. Unselect test results by pressing this **checkmark**. The entire list of results can be selected by pressing the  **checkmark** in the top row (Figure 20).

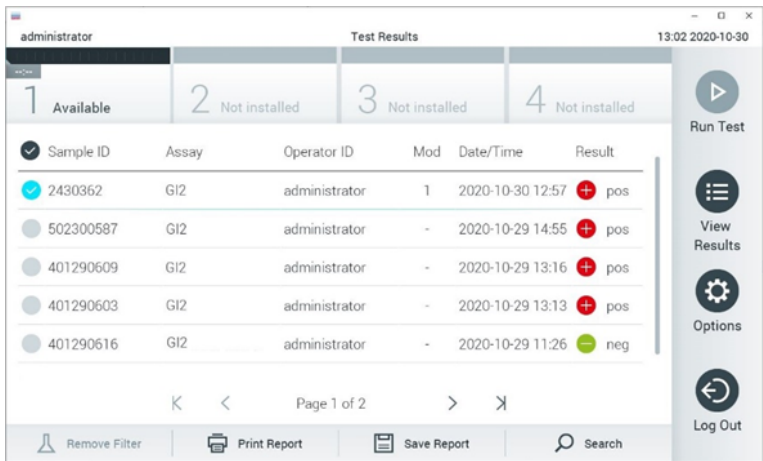


Figure 20. Example of selecting Test Results in the View Results screen.

Press anywhere in the test row to view the result for a particular test.

Press a column headline (e.g., Sample ID) to sort the list in ascending or descending order according to that parameter. The list can be sorted according to only one column at a time.

The Result column shows the outcome of each test (Table 2).

Table 2. Descriptions of the test results in View Results screen

Outcome	Result	Description	Action
Positive	 pos	At least one pathogen is positive	Refer to the Summary Result Screen or Result Printout for pathogen specific results. Description of pathogen results can be found in Table 5.
Positive with warning	 lpos*	At least one pathogen is positive, but the Internal Control failed	Refer to the Summary Result Screen or Result Printout for pathogen specific results. Description of pathogen results can be found in Table 5.
Negative	 neg	No pathogens were detected	Refer to the Summary Result Screen or Result Printout for pathogen specific results. Description of pathogen results can be found in Table 5.
Failed	 fail	The test failed because either an error occurred, the test was canceled by the user, or no pathogens were detected and the internal control failed.	Repeat the test using a new cartridge. Accept the results of the repeat testing. If the error persists, contact QIAGEN Technical Service for further instructions.
Successful	 Suc	The test is either positive or negative, but the user does not have the access rights to view the test results.	Login from a user profile with rights to view the results.

Make sure a printer is connected to the QIAstat-Dx Analyzer 1.0, and the proper driver is installed. Press **Print Report** to print the report(s) for the selected result(s).

Press **Save Report** to save the report(s) for the selected result(s) in PDF to an external USB storage device.

Select the report type: **List of Tests** or **Test Reports**.

Press **Search** to search the test results by Sample ID, Assay, and Operator ID. Enter the search string using the virtual keyboard and press **Enter** to start the search. Only the records containing the searched text will be displayed in the search results.

If the results list has been filtered, the search will only apply to the filtered list.

Press and hold a column headline to apply a filter based on that parameter. For some parameters, such as Sample ID, the virtual keyboard will appear so the search string for the filter can be entered.

For other parameters, such as Assay, a dialog box will open with a list of assays stored in the repository. Select one or more assays to filter only the tests that were performed with the selected assays.

The  symbol to the left of a column headline indicates that the column's filter is active.

A filter can be removed by pressing **Remove Filter** in the Submenu bar.

Exporting results to a USB drive

From any tab of the View Results screen, select **Save Report** to export and save a copy of the test results in PDF to a USB drive. The USB port is located on the front of QIAstat-Dx Analyzer 1.0.

Printing results

Make sure a printer is connected to the QIAstat-Dx Analyzer 1.0 and the proper driver is installed. Press **Print Report** to send a copy of the test results to the printer.

Sample result interpretation

A result for a gastrointestinal organism is interpreted as “Positive” when the corresponding PCR assay is positive, except for EPEC, STEC, and *E. coli* O157. The result interpretation for EPEC, STEC, and *E. coli* O157 follows the rationale explained in Table 3.

Table 3. Interpretation of EPEC, STEC, and *E.coli* O157 results

EPEC Result	STEC <i>stx1/stx2</i> Result*			<i>E. coli</i> O157 Result	Description
	<i>stx1</i>	<i>stx2</i>	<i>stx1 + stx2</i>		
Negative			Negative	N/A	Enteropathogenic <i>E. coli</i> (EPEC) was not detected and Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> is negative as both <i>stx1</i> and <i>stx2</i> have not been detected. <i>E. coli</i> O157 result is not applicable (N/A) when Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> is not detected due to <i>E. coli</i> O157 being a specific serotype of STEC.
Positive			Negative	N/A	Enteropathogenic <i>E. coli</i> (EPEC) was detected and Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> is negative as both <i>stx1</i> and <i>stx2</i> have not been detected. <i>E. coli</i> O157 result is not applicable (N/A) when Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1/stx2</i> is not detected due to <i>E. coli</i> O157 being a specific serotype of STEC.
N/A	Positive			Negative	EPEC result is not applicable because EPEC detection cannot be differentiated when STEC <i>stx1</i> or <i>stx2</i> is detected. <i>E. coli</i> O157 was not detected.

Table 3. Interpretation of EPEC, STEC, and E.coli O157 results (continued)

EPEC Result	STEC <i>stx1/stx2</i> Result*			<i>E. coli</i> O157 Result	Description
	<i>stx1</i>	<i>stx2</i>	<i>stx1 + stx2</i>		
N/A		Positive		Negative	EPEC result is not applicable because EPEC detection cannot be differentiated when STEC <i>stx1</i> or <i>stx2</i> is detected. <i>E. coli</i> O157 was not detected.
N/A			Positive	Negative	EPEC result is not applicable because EPEC detection cannot be differentiated when both STEC <i>stx1</i> and <i>stx2</i> are detected. <i>E. coli</i> O157 was not detected.
N/A	Positive			Positive	EPEC result is not applicable because EPEC detection cannot be differentiated when STEC <i>stx1</i> or <i>stx2</i> is detected. <i>E. coli</i> O157 was detected.
N/A		Positive		Positive	EPEC result is not applicable because EPEC detection cannot be differentiated when STEC <i>stx1</i> or <i>stx2</i> is detected. <i>E. coli</i> O157 was detected.
N/A			Positive	Positive	EPEC result is not applicable because EPEC detection cannot be differentiated when both STEC <i>stx1</i> and <i>stx2</i> are detected. <i>E. coli</i> O157 was detected.

*Amplification curve, EP, and Ct values, when STEC *stx1 + stx2* is detected, correspond to the STEC *stx2* only.

Internal control results are to be interpreted according to Table 4.

Table 4. Interpretation of Internal Control results

Control result	Explanation	Action
Passed	The Internal Control amplified successfully.	The run was completed with success. All results are validated and can be reported. Detected pathogens are reported as “positive” and undetected pathogens are reported as “negative”.
Failed	The Internal Control failed.	Positively detected pathogen(s) are reported, but all negative results (tested but not detected pathogen[s]) are invalid. Repeat the testing using a new Cartridge. Accept the results of the repeat testing. If the invalid result persists, contact QIAGEN Technical Service for further instruction.

The software provides an overall test result (Table 2) as well as a result for individual pathogens. Possible results for each organism include Detected/Positive, Not Detected/Negative, N/A, and Invalid (Table 5). If the internal control has failed and no positive signal was detected or if there is an instrument error, there will be no pathogen results provided.

Table 5. Description of pathogen results as displayed on Summary Result screen and the Result Printout

Result	Symbol	Explanation	Action
Positive/ Detected		A positive signal was detected for this pathogen. Result of the Internal Control is passed.	None. Report results.

Table 5. Description of pathogen results as displayed on Summary Result screen and the Result Printout (continued)

Result	Symbol	Explanation	Action
Positive/ Detected with Warning	 !pos*	A positive signal was detected for this pathogen, but the result of the Internal Control has failed.	Report positive analyte. Repeat the test using a new cartridge. Accept the results of the repeat testing. If the invalid result persists, contact QIAGEN Technical Service for further instructions.
Negative/ Not Detected		No signal was detected for this pathogen. The Internal Control passed.	None. Report results.
N/A (applies to <i>E. coli</i> O157 and EPEC only)		The run was successfully completed and the Internal Control passed. For <i>E. coli</i> O157 N/A: Shiga-like toxin-producing <i>E. coli</i> (STEC) was not detected. For EPEC N/A: Shiga-like toxin producing <i>E. coli</i> (STEC) was detected.	None. Report results.
Invalid		No signal was detected for this pathogen and the Internal Control failed (but other pathogens have been detected).	Repeat the test using a new cartridge. Accept the results of the repeat testing. If the invalid result persists, contact QIAGEN Technical Service for further instructions.

Performance Characteristics

Analytical performance

(Sensitivity) (Limit of detection)

The Analytical Sensitivity, or Limit of Detection (LoD), is defined as the lowest concentration at which $\geq 95\%$ of the tested samples generate a positive call.

The LoD for each of the QIAstat-Dx Gastrointestinal Panel 2 target pathogenic organisms was assessed, using in total 48 pathogen strains, by analyzing serial dilutions of analytical samples prepared from culture isolates from commercial suppliers (e.g., ZeptoMetrix® and ATCC®), confirmed clinical isolates, or artificial samples for target analytes commercially unavailable. Each sample tested was prepared in human stool matrix, which consists of a pool of previously tested negative clinical stool specimens resuspended in Cary-Blair transport medium.

Each of the 48 strains was tested in human stool matrix prepared following the manufacturer’s instructions for the Para-Pak C&S collection device.

Individual LoD values for each QIAstat-Dx Gastrointestinal Panel 2 target is shown in Table 6.

Table 6. LoD values obtained for the different gastrointestinal target strains tested with the QIAstat-Dx Gastrointestinal Panel 2

Pathogen	Strain	Source	Concentration (molecular units: copies/mL)	Concentration (microbiological units)	Detection rate
<i>Campylobacter</i>	<i>Campylobacter coli</i> 76-GA2 [IMG 21266]	ATCC 43478	5802	1.2 CFU/mL	20/20
	<i>Campylobacter coli</i> CIP 7080	ATCC 33559	8941	0.6 CFU/mL	20/20
	<i>Campylobacter jejuni</i> Z086	ZeptoMetrix 801650	14491	1660 CFU/mL	20/20
	<i>Campylobacter jejuni</i> subsp. <i>Jejuni</i> RM3193	ATCC BAA-1234	7210	110 CFU/mL	19/20
	<i>Campylobacter upsaliensis</i> NCTC 11541	ZeptoMetrix 0801999	56165	2259.4 CFU/mL	20/20
	<i>Campylobacter upsaliensis</i> RM3195	ATCC BAA-1059	7631	35 CFU/vial	19/20
<i>Clostridium difficile</i> toxin A/B	(NAP1A) Toxinotype III A+ B+	ZeptoMetrix 801619	11083	515 CFU/mL	19/20
	Toxinotype 0 A+ B+	ATCC 9689	101843	853.2 CFU/mL	20/20
<i>Plesiomonas shigelloides</i>	Z130	ZeptoMetrix 801899	481	2291 CFU/mL	20/20
	Bader	ATCC 14029	116	2.7 CFU/vial	19/20

Table 6. LoD values obtained for the different gastrointestinal target strains tested with the QIAstat-Dx Gastrointestinal Panel 2 (continued)

Pathogen	Strain	Source	Concentration (molecular units: copies/mL)	Concentration (microbiological units)	Detection rate
<i>Salmonella</i>	<i>Salmonella enterica</i> Serovar choleraesuis	ATCC 13312	647	91.6 CFU/mL	20/20
	<i>Salmonella enterica</i> Serovar Typhimurium Z005	ZeptoMetrix 801437	1441	4518.8 CFU/mL	20/20
<i>Vibrio cholerae</i>	Z132; toxigenic	ZeptoMetrix 801901	28298	13600 CFU/mL	20/20
	Z133; non-toxigenic	ZeptoMetrix 801902	79749	54668 CFU/mL	20/20
<i>Vibrio parahaemolyticus</i>	EB 101	ATCC 17802	12862	1600 CFU/mL	20/20
	Z134	ZeptoMetrix 801903	8904	143 CFU/mL	20/20
<i>Vibrio vulnificus</i>	329 [CDC B3547]	ATCC 33817	109131	260 CFU/mL	20/20
	324 [CDC B629]	ATCC 27562	2983	1305.1 CFU/mL	20/20
<i>Yersinia enterocolitica</i>	Z036	ZeptoMetrix 0801734	719	2070 CFU/mL	20/20
	subsp. <i>enterocolitica</i> NTCC 11175, Biotype 4, serotype 3	ATCC 700822	2496	120.1 CFU/mL	20/20

Table 6. LoD values obtained for the different gastrointestinal target strains tested with the QIAstat-Dx Gastrointestinal Panel 2 (continued)

Pathogen	Strain	Source	Concentration (molecular units: copies/mL)	Concentration (microbiological units)	Detection rate
Enteroaggregative <i>E. coli</i> (EAEC)	<i>Escherichia coli</i> 92.0147, O77:HN	ZeptoMetrix 0801919	1075	634 CFU/mL	20/20
	<i>Escherichia coli</i> CDC3250-76, O111a, 111b: K58:H21	ATCC 29552	842	87 CFU/mL	19/20
Enteroinvasive <i>E. coli</i> (EIEC)/ <i>Shigella</i>	<i>Shigella sonnei</i> Z004	ZeptoMetrix 25931	488	0.2 CFU/mL	20/20
	<i>Escherichia coli</i> CDC EDL 1282, O29:NM	ATCC 43892	1431	41.3 CFU/mL	20/20
Enteropathogenic <i>E. coli</i> (EPEC)	<i>Escherichia coli</i> O111:NM (EPEC)	ZeptoMetrix 0801747	1817	2581.7 CFU/mL	20/20
	<i>Escherichia coli</i> 7.1493; EPEC; O84:H28	Zeptomatrix 801938	29021	1190 CFU/mL	20/20
Enterotoxigenic <i>E. coli</i> (ETEC) lt/st	<i>Escherichia coli</i> H10407, O78:H11	ATCC 35401	367	10.1 CFU/mL	19/20
	<i>Escherichia coli</i> ETEC; ST+, LT+	ZeptoMetrix 801624	855	567 CFU/mL	20/20
Shiga-like toxin-producing <i>E. coli</i> (STEC) stx1/stx2	<i>Escherichia coli</i> O26:H4	ZeptoMetrix 801748	2012	726.8 CFU/mL	20/20

Table 6. LoD values obtained for the different gastrointestinal target strains tested with the QIAstat-Dx Gastrointestinal Panel 2 (continued)

Pathogen	Strain	Source	Concentration (molecular units: copies/mL)	Concentration (microbiological units)	Detection rate
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>E. coli</i> O157	<i>Escherichia coli</i> O157:H7; EDL933	ZeptoMetrix 801622	1217	2281.5 CFU/mL	STEC stx 1: 19/20 STEC stx2: 19/20 O157: 19/20
<i>Cryptosporidium</i>	<i>Cryptosporidium hominis</i>	Public Health Wales UKM 84	357	N/A	20/20
	<i>Cryptosporidium parvum</i> – Iowa isolate	Waterborne® P102C	661	N/A	20/20
<i>Cyclospora cayentanensis</i>	N/A	LACNY-Clinical sample LAC2825	53	N/A	19/20
	N/A	LACNY Clinical sample LAC2827	137	N/A	20/20
<i>Entamoeba histolytica</i>	HM-1:IMSS (Mexico City 1967)	ATCC 30459	7	0.2 cells/mL	20/20
	HK-9 (Korea)	ATCC 30015	1	0.01 cells/mL	19/20
<i>Giardia lamblia</i>	WB (Bethesda)	ATCC 30957	11850	632 cells/mL	19/20
	Portland-1	ATCC 30888	14500	635 cells/mL	20/20
Adenovirus F40/F41	Type 40 (Dugan)	ZeptoMetrix 0810084CF	11726	0.1 TCID ₅₀ /mL	20/20
	Type 41 (Tak)	ZeptoMetrix 0810085CF	979	0.5 TCID ₅₀ /mL	19/20

Table 6. LoD values obtained for the different gastrointestinal target strains tested with the QIAstat-Dx Gastrointestinal Panel 2 (continued)

Pathogen	Strain	Source	Concentration (molecular units: copies/mL)	Concentration (microbiological units)	Detection rate
Astrovirus	ERE IID 2371 (type 8)	Zeptomatrix 0810277CF	11586371	11.7 TCID ₅₀ /mL	20/20
	ERE IID 2868 (type 4)	Zeptomatrix 0810276CF	52184	1.3 TCID ₅₀ /mL	19/20
Norovirus GI	GI.1 (recombinant)	ZeptoMatrix 0810086CF	24629	891.1 TCID ₅₀ /mL	19/20
Norovirus GII	GII.4 (recombinant)	ZeptoMatrix 0810087CF	8998	1.1 TCID ₅₀ /mL	20/20
Rotavirus A	69M	ZeptoMatrix 0810280CF	5787	436.1 TCID ₅₀ /mL	19/20
	Wa	ZeptoMatrix 0810041CF	5201	14.1 TCID ₅₀ /mL	19/20
Sapovirus	Genogroup I, genotype 1	QIAGEN Barcelona - Clinical sample GI-88	187506	N/A	20/20
	Genogroup V	Universitat de Barcelona 160523351	3007	N/A	20/20

Exclusivity (Analytical Specificity)

The analytical specificity study was carried out by in vitro testing and in silico analysis (9) to assess the potential cross-reactivity and exclusivity of the QIAstat-Dx Gastrointestinal Panel 2. On-panel organisms were tested to assess the potential for intra-panel cross-reactivity and Off-panel organisms were tested to evaluate cross-reactivity with organisms not covered by the

panel content. The On-panel and Off-panel organisms tested are shown in Table 7 and Table 8, respectively.

Samples were prepared by single spiking organisms into negative stool resuspended in Cary-Blair at the highest concentration possible based on the organism stock, preferably at 10⁵ TCID₅₀/mL for viral, 10⁵ cells/mL for parasite targets and 10⁶ CFU/mL for bacterial targets. The pathogens were tested in 3 replicates. There was no intra-panel or Off-panel cross-reactivity for all pathogens tested in vitro, except for two non-targeted *Campylobacter* species (*C. helveticus* and *C. lari*) that cross-reacted with the *Campylobacter* assay oligonucleotides included in the QIAstat-Dx Gastrointestinal Panel 2.

Table 7. List of Analytical Specificity on-panel pathogens tested

Type	Pathogen	
Bacteria	<i>Campylobacter coli</i>	<i>Plesiomonas shigelloides</i>
	<i>Campylobacter jejuni</i>	<i>Salmonella enterica</i>
	<i>Campylobacter upsaliensis</i>	<i>Shigella sonnei</i>
	<i>Clostridium difficile</i>	<i>Vibrio cholerae</i>
	<i>Escherichia coli</i> (EAEC)	<i>Vibrio parahaemolyticus</i>
	<i>Escherichia coli</i> (EPEC)	<i>Vibrio vulnificus</i>
	<i>Escherichia coli</i> (ETEC)	<i>Yersinia enterocolitica</i>
	<i>Escherichia coli</i> (STEC)	
Parasites	<i>Cryptosporidium parvum</i>	<i>Entamoeba histolytica</i>
	<i>Cyclospora cayetanensis</i>	<i>Giardia lamblia</i>
Viruses	Adenovirus F41	Norovirus GII
	Astrovirus	Rotavirus A
	Norovirus GI	Sapovirus

Table 8. List of Analytical` Specificity off-panel pathogens tested

Type	Pathogen (potential cross-reactant)	
Bacteria	<i>Abiotrophia defectiva</i>	<i>Enterobacter cloacae</i>
	<i>Acinetobacter baumannii</i>	<i>Enterococcus faecalis</i> <i>Enterococcus faecium</i>
	<i>Aeromonas hydrophila</i>	<i>Escherichia fergusonii</i>
	<i>Arcobacter cryaerophilus</i>	<i>Escherichia hermannii</i>
	<i>Bacillus subtilis</i>	<i>Escherichia vulneris</i>
	<i>Bifidobacterium bifidum</i>	<i>Faecalibacterium prausnitzii</i>
	<i>Campylobacter fetus</i>	<i>Gardnerella vaginalis</i>
	<i>Campylobacter gracilis</i>	<i>Haemophilus influenzae</i>
	<i>Campylobacter helveticus</i>	<i>Helicobacter pylori</i>
	<i>Campylobacter hominis</i>	<i>Klebsiella pneumoniae</i>
	<i>Campylobacter lari</i>	<i>Lactobacillus casei</i>
	<i>Campylobacter mucosalis</i>	<i>Listeria monocytogenes</i>
	<i>Campylobacter rectus</i>	<i>Proteus mirabilis</i>
	<i>Chlamydia trachomatis</i>	<i>Proteus vulgaris</i>
	<i>Citrobacter freundii</i>	<i>Pseudomonas aeruginosa</i>
	<i>Clostridium difficile</i> non-toxigenic	<i>Staphylococcus aureus</i>
	<i>Clostridium perfringens</i>	<i>Staphylococcus aureus</i> subsp. <i>Aureus</i>
	<i>Clostridium septicum</i>	<i>Staphylococcus epidermidis</i>
	<i>Clostridium tetani</i>	<i>Streptococcus agalactiae</i>
	<i>Corynebacterium genitalium</i>	<i>Streptococcus pyogenes</i>
Fungi	<i>Enterobacter aerogenes</i>	
Fungi	<i>Aspergillus fumigatus</i>	<i>Saccharomyces boulardii</i>
	<i>Candida albicans</i>	<i>Saccharomyces cerevisiae</i>
Parasites	<i>Babesia microti</i>	<i>Toxoplasma gondii</i>
	<i>Blastocystis hominis</i>	<i>Trichomonas tenax</i>
	<i>Giardia muris</i>	

Table 8. List of Analytical` Specificity off-panel pathogens tested (continued)

Type	Pathogen (potential cross-reactant)	
Viruses	Adenovirus C:2	Coronavirus 229E
	Adenovirus B:34	Coxsackievirus B3
	Adenovirus B3	Cytomegalovirus
	Adenovirus E:4a	Enterovirus 6 (Echovirus)
	Adenovirus serotype 1	Enterovirus 68
	Adenovirus serotype 5	Herpes Simplex Virus Type 2
	Adenovirus serotype 8	Rhinovirus 1A
	Bocavirus Type 1	

In silico predictions of potential cross-reactions showed that the following cross-reactions may occur when testing stool samples with the QIAstat-Dx Gastrointestinal Panel 2 (Table 9) (5, 15–17).

Table 9. Potential cross-reactions based on in silico analysis

QIAstat-Dx Gastrointestinal Panel 2 Target	Potential cross-reactive organisms
Enteropathogenic <i>E. coli</i> (EPEC)	<i>Shigella boydii</i> ^{††} , <i>Escherichia albertii</i> ^{††}
<i>Campylobacter</i> spp.	<i>Campylobacter lari</i> [§] , <i>Campylobacter helveticus</i> [§]
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx1</i>	<i>Shigella sonnei</i> ^{*†} , <i>Shigella dysenteriae</i> ^{*†}
Shiga-like toxin-producing <i>E. coli</i> (STEC) <i>stx2</i>	<i>Acinetobacter haemolyticus</i> ^{*¶} , <i>Citrobacter freundii</i> ^{*¶} , <i>Enterobacter cloacae</i> ^{*¶} , <i>Aeromonas caviae</i> ^{*¶} <i>Escherichia albertii</i> ^{*¶}

Table 9. Potential cross-reactions based on in silico analysis (continued)

QIAstat-Dx Gastrointestinal Panel 2 Target	Potential cross-reactive organisms
<i>E. coli</i> O157	Non-STEC <i>E. coli</i> O157 strains**
* Note that these potential cross-reactions affect designs with target genes responsible of the pathogenicity of the corresponding QIAstat-Dx Gastrointestinal Panel 2 target pathogens which can be acquired within species in a known biological process in bacteria called horizontal gene transfer.	
† Rare or less common eae intimin carrier organisms.	
‡ On-panel target.	
§ In vitro testing of <i>Campylobacter lari</i> and <i>Campylobacter helveticus</i> strains at high concentration confirmed potential cross-reaction of these <i>Campylobacter</i> species with the QIAstat-Dx Gastrointestinal Panel 2 assay.	
¶ Rare or less common Stx toxins producers.	
** <i>E. coli</i> O157 will only be called when there is a positive amplification for the <i>E. coli</i> (STEC) design according to the calling algorithm. An infrequent case of an <i>E. coli</i> (STEC) and an <i>E. coli</i> O157 co-infection will not be differentiated from a single infection caused by an STEC O157:H7 strain.	

Inclusivity

Analytical Reactivity (Inclusivity) was evaluated with gastrointestinal pathogen isolates/strains that were selected based on clinical relevance and genetic, temporal and geographical diversity. Based on in vitro (wet) testing and in silico analysis, the QIAstat-Dx Gastrointestinal Panel 2 primers and probes are specific and inclusive for clinically prevalent and relevant strains for each pathogen tested.

In vitro (wet) testing

QIAstat-Dx Gastrointestinal Panel 2 is inclusive for 100% (143 out of 143) of the pathogen strains tested in vitro. Most pathogen strains evaluated in wet testing (133/143) were detected at ≤3-fold of the corresponding LoD reference strain. (Table 10).

Table 10. Inclusivity test results for all the pathogens tested with the QIAstat-Dx Gastrointestinal Panel 2 Assay. LoD reference strain for every pathogen is written in bold.

Table 10a. Inclusivity test results for *Campylobacter* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Campylobacter</i>	<i>Campylobacter coli</i>	76-GA2 [LMG 21266]	ATCC	43478 *	1x LoD
	<i>Campylobacter coli</i>	Z293	ZeptoMetrix	0804272	1x LoD
	<i>Campylobacter coli</i>	CIP 7080 [1407, CIP 70.80]	ATCC	33559 *	3x LoD
	<i>Campylobacter jejuni</i>	Z086	ZeptoMetrix	0801650 *	1x LoD
	<i>Campylobacter jejuni</i>	subsp. <i>jejuni</i> RM3193	ATCC	BAA-1234 *	0.1x LoD
	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:19 HL7; D3180	ATCC	BAA-218	0.1x LoD
	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	AS-83-79	ATCC	33291	0.1x LoD
	<i>Campylobacter jejuni</i> subsp. <i>doylei</i>	NCTC 11951	ATCC	49349	0.1x LoD
	<i>Campylobacter upsaliensis</i>	NCTC 11541	ZeptoMetrix	0801999 *	1x LoD
	<i>Campylobacter upsaliensis</i>	RM 3195 (1994)	ATCC	BAA-1059 *	0.3x LoD
	<i>Campylobacter upsaliensis</i>	NCTC 11541 [C231]	ATCC	43954	1x LoD

* Strain tested during LoD verification study.

Table 10b. Inclusivity test results for *Clostridium difficile* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Clostridium difficile</i> toxin A/B	<i>Clostridium difficile</i>	(90556-M6S) Toxinotype 0 A+ B+	ATCC	9689*	1 x LoD
	<i>Clostridium difficile</i>	NAP1, toxinotype IIIb A+B+	ATCC	BAA-1805	1 x LoD
	<i>Clostridium difficile</i>	5325, toxinotype V A+B+	ATCC	BAA-1875	1 x LoD
	<i>Clostridium difficile</i>	1470, toxinotype VIII A-B+	ATCC	43598	1 x LoD
	<i>Clostridium difficile</i>	toxinotype XII A+B+	ATCC	BAA-1812	1 x LoD
	<i>Clostridium difficile</i>	toxinotype XXII A+B (unknown)	ATCC	BAA-1814	1 x LoD
	<i>Clostridium difficile</i>	NAP1A, toxinotype III A+B+	ATCC	0801619*	0.1x LoD
	<i>Clostridium difficile</i>	NAP1, toxinotype III A+B+	ZeptoMetrix	0801620	3x LoD

* Strain tested during LoD verification study.

Table 10c. Inclusivity test results for *Plesiomonas shigelloides* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Plesiomonas shigelloides</i>	<i>Plesiomonas shigelloides</i>	Z130	ZeptoMetrix	0801899*	1 x LoD
	<i>Plesiomonas shigelloides</i>	GNI 14	ATCC	51903	1 x LoD
	<i>Plesiomonas shigelloides</i>	CDC 3085-55 [Bader M51, NCIB 9242, NCTC 10360, RH 798]	ATCC	14029*	0.3x LoD

* Strain tested during LoD verification study.

Table 10d. Inclusivity test results for *Salmonella* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Salmonella</i>	<i>Salmonella enterica</i>	Serovar Typhimurium Z005	ZeptoMetrix	0801437*	1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Bareilly	NCTC	NC05745	1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar typhi, Z152	ZeptoMetrix	0801933	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Enteridis, CDC K-1891 [ATCC 25928]	ATCC	13076	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Infantis, MZ1479 [SARB27]	ATCC	BAA-1675	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Montevideo, G4639	ATCC	BAA-710	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Javiana	NCTC	NC06495	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Thompson	NCTC	NC08496	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Saintpaul	ATCC	9712	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Berta	NCTC	NC05770	0.1x LoD
	<i>Salmonella enterica</i>	Subps. Salame, II NCTC 10310 [JT945, SS140/61]	ATCC	700151	0.1x LoD
	<i>Salmonella enterica</i>	Subps. diarizonae IIIb, 62	ATCC	29934	0.1x LoD
<i>Salmonella enterica</i>		Subps. houtenae IV, CIP 82.32 [264.66]	ATCC	43974	0.1x LoD

Table 10d. Inclusivity test results for *Salmonella* strains (continued)

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
	<i>Salmonella enterica</i>	Subps. Indica VI, CIP 102501 [F. Kauffmann 1240]	ATCC	43976	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Agona, CDC 873 [CDC 1111-61]	ATCC	51957	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Muenchen, 54	ATCC	8388	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Oranienburg, E1093	ATCC	9239	0.1x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Paratyphi B var. Java, CDC 5	ATCC	51962	0.1x LoD
	<i>Salmonella enterica</i>	CIP 82.33 [1224.72]	ATCC	43975	0.3x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Choleraesuis, NCTC 5735 [1348, K.34]	ATCC	13312*	0.3x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Newport, C487-69	ATCC	27869	0.3x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, 4, 5, 12:7:-, serovar Typhimurium	NCTC	NC13952	0.3x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Braenderup	ATCC	700136	0.3x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Anatum	NCTC	NC05779	0.3x LoD
	<i>Salmonella enterica</i>	Subps. arizonae IIIa, NCTC 7311 [CDAL 426]	ATCC	700156	0.3x LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Heidelberg, [16]	ATCC	8326	0.3x LoD

Table 10d. Inclusivity test results for *Salmonella* strains (continued)

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
	<i>Salmonella enterica</i>	Subsp. Enterica, serovar Mississippi, CDC 2012K-0487	ATCC	BAA-2739	0.3x LoD

* Strain tested during LoD verification study.

Table 10e. Inclusivity test results for *Vibrio cholerae* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Vibrio cholerae</i>	<i>Vibrio cholerae</i>	Z133; non-toxigenic	ZeptoMetrix	801902*	1x LoD
	<i>Vibrio cholerae</i>	Pacini 1854; NCTC 8021, O:1 Ogawa	CECT	514	1x LoD
	<i>Vibrio cholerae</i>	Z132; toxigenic	ZeptoMetrix	0801901*	0.3x LoD

* Strain tested during LoD verification study.

Table 10f. Inclusivity test results for *Vibrio parahaemolyticus* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Vibrio parahaemolyticus</i>	<i>Vibrio parahaemolyticus</i>	EB101 [P. Baumann 113] (Japan)	ATCC	17802*	1x LoD
	<i>Vibrio parahaemolyticus</i>	VP250,O1:KUT	ATCC	BAA-242	1x LoD
	<i>Vibrio parahaemolyticus</i>	205 [9302]	ATCC	33846	3x LoD
	<i>Vibrio parahaemolyticus</i>	Z134	ZeptoMetrix	0801903*	0.3x LoD

* Strain tested during LoD verification study.

Table 10g. Inclusivity test results for *Vibrio vulnificus* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Vibrio vulnificus</i>	<i>Vibrio vulnificus</i>	324 [CDC B9629]	ATCC	27562*	1 x LoD
	<i>Vibrio vulnificus</i>	329 [CDC B3547], Biotype 2	ATCC	33817*	1 x LoD
	<i>Vibrio vulnificus</i>	Z473	ZeptoMetrix	0804349	3 x LoD

* Strain tested during LoD verification study.

Table 10h. Inclusivity test results for *Yersinia enterocolitica* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Yersinia enterocolitica</i>	<i>Yersinia enterocolitica</i>	Z036	ZeptoMetrix	801734*	1 x LoD
	<i>Yersinia enterocolitica</i>	NTCC 11175, Biotype 4, serotype 3 (O:3)	ATCC	700822*	1 x LoD
	<i>Yersinia enterocolitica</i>	33114 [CCUG 11291, CCUG 12369, CIP 80.27, DSM 4780, LMG 7899, NCTC 12982], Biovar 1, O:8	ATCC	9610	1 x LoD
	<i>Yersinia enterocolitica</i>	O:9	ATCC	55075	3 x LoD

* Strain tested during LoD verification study.

Table 10i. Inclusivity test results for Enteroaggregative *E. coli* (EAEC) strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Enteroaggregative <i>E. coli</i> (EAEC)	Enteroaggregative <i>E. coli</i> (EAEC)	92.0147	ZeptoMetrix	0801919*	1 x LoD
	Enteroaggregative <i>E. coli</i> (EAEC)	CDC3250-76, O111a, 111b: K58:H21, CVD432+, aggR+, stx1-, stx2-, eae-	ATCC	29552*	1 x LoD
	Enteroaggregative <i>E. coli</i> (EAEC)	–	Vall d'Hebrón	Clinical sample; VH 529140369015	3 x LoD

* Strain tested during LoD verification study.

Table 10j. Inclusivity test results for Enteropathogenic *E. coli* (EPEC) strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Enteropathogenic <i>E. coli</i> (EPEC)	Enteropathogenic <i>E. coli</i> (EPEC)	O111:NM	ZeptoMetrix	0801747*	1 x LoD
	Enteropathogenic <i>E. coli</i> (EPEC)	7.1493,O84:H28	ZeptoMetrix	0801938*	1 x LoD
	Enteropathogenic <i>E. coli</i> (EPEC)	Stoke W,O111:K58 (B4):H-	ATCC	33780	1 x LoD

* Strain tested during LoD verification study.

Table 10k. Inclusivity test results for Enterotoxigenic *E. coli* (ETEC) strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	ST+, LT+	ZeptoMetrix	0801624*	1x LoD
	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	H10407,O78:H11,LT (+)/ctx A11(+)	ATCC	35401*	0.3x LoD
	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	O27:H7,ST (+)/ LT (-)	SSI Diagnostica	82173	0.1x LoD
	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	O115:H15,ST (+)/ LT (-)	SSI Diagnostica	82174	3x LoD
	Enterotoxigenic <i>E. coli</i> (ETEC) <i>lt/st</i>	O169:H,ST (-)/LT (+)	SSI Diagnostica	82172	10x LoD

* Strain tested during LoD verification study.

Table 10I. Inclusivity test results for Enteroinvasive *E. coli* (EIEC)/*Shigella* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Enteroinvasive <i>E. coli</i> (EIEC)/ <i>Shigella</i>	Enteroinvasive <i>E. coli</i> (EIEC)	CDC EDL 1282, O29:NM	ATCC	43892*	1x LoD
	Enteroinvasive <i>E. coli</i> (EIEC)	O172:H-	SSI Diagnostica	82171	3x LoD
	<i>Shigella boydii</i>	Z004	ATCC	25931*	1x LoD
	<i>Shigella boydii</i> (Serogroup C)	Z131	ZeptoMetrix	0801900	1x LoD
	<i>Shigella flexneri</i> (Serogroup B)	AMC 43-G-68 [EVL 82, M134]	ATCC	9199	1x LoD
	<i>Shigella flexneri</i> (Serogroup B)	Z046	ZeptoMetrix	0801757	1x LoD
	<i>Shigella sonnei</i> (Serogroup D)	WRAIR I virulent	ATCC	29930	1x LoD
	<i>Shigella sonnei</i> (Serogroup D)	Z004	ZeptoMetrix	801627	3x LoD
	<i>Shigella boydii</i> (Serogroup C)	AMC 43-G-58 [M44 (Type 170)]	ATCC	9207	10x LoD

* Strain tested during LoD verification study.

Table 10m. Inclusivity test results for Shiga-like toxin-producing *E. coli* (STEC)(*stx1*-carrier strains)

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	O157:H7; EDL933	ZeptoMetrix	0801622*	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	O26:H4, <i>stx1</i> (+)	ZeptoMetrix	0801748*	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	O22:H8, <i>stx1c</i> (+), <i>stx2b</i> (+)	SSI Diagnostica	91350	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	O8, <i>stx1d</i> (+)	SSI Diagnostica	91349	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	Reference ATCC 35150 (EDL 931), O157:H7, <i>stx1</i> (+), <i>stx2</i> (+)	Microbiologics	617	1x LoD
Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	Reference CDC 00-3039, O45:H2, unknown	Microbiologics	1098	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	O103:H2, <i>stx1</i> (+)	SSI Diagnostica	82170	3x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx1</i>	O128ac:H, <i>stx2f</i> (+)	SSI Diagnostica	91355	10x LoD

* Strain tested during LoD verification study.

Table 10n. Inclusivity test results for Shiga-like toxin-producing *E. coli* (STEC) (*stx2*-carrier strains)

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	O157:H7; EDL933	ZeptoMetrix	0801622*	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	O22:H8, <i>stx1c</i> (+), <i>stx2b</i> (+)	SSI Diagnostica	91350	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	O26:H11, <i>stx2a</i> (+)	SSI Diagnostica	95211	1x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	O101:K32:H-, <i>stx2e</i> (+)	SSI Diagnostica	91354	0.3x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	Reference ATCC 35150 (EDL 931), O157:H7, <i>stx1</i> (+), <i>stx2</i> (+)	Microbiologics	617	3x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	O92, O107:K+:H48, <i>stx2d</i> (+)	SSI Diagnostica	91352	10x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) - <i>stx2</i>	O128ac:H-, <i>stx2f</i> (+)	SSI Diagnostica	91355	10x LoD

* Strain tested during LoD verification study.

Table 10o. Inclusivity test results for Shiga-like toxin producing *E. coli* (STEC) *stx1/stx2* O157 strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalogue ID	Times LoD
Shiga-like toxin producing <i>E. coli</i> (STEC) O157	Shiga-like toxin producing <i>E. coli</i> (STEC) O157	O157:H7; EDL933	ZeptoMetrix	0801622*	1 x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) O157	O128ac:H-,stx2f (+)	SSI Diagnostica	91355†	1 x LoD
	Shiga-like toxin producing <i>E. coli</i> (STEC) O157	Reference ATCC 35150 (EDL 931), O157:H7, stx1 (+), stx2 (+)	Microbiologics	617	1 x LoD

* Strain tested during LoD verification study.

† The *E. coli* strain 91355 from SSI Diagnostica is reported as following in its catalog: *vtx2f+*, *ea+*. However, it was found to amplify for *E. coli* O157 in both QIAstat-Dx and FilmArray devices.

Table 10p. Inclusivity test results for *Cryptosporidium* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Cryptosporidium</i>	<i>Cryptosporidium parvum</i>	Iowa isolate	Waterborne	P102C*	1x LoD
	<i>Cryptosporidium hominis</i>	n/a	Public Health Wales	Clinical sample; UKM 84*	0.01x LoD
	<i>Cryptosporidium parvum</i>	–	ATCC	PRA-67DQ (isolated genomic DNA)	<0.01 LoD
	<i>Cryptosporidium meleagridis</i>	–	Public Health Wales	Clinical sample; UKMEL 14	<0.01 LoD
	<i>Cryptosporidium meleagridis</i>	–	Public Health Wales	Clinical sample; UKMEL 14	<0.01 LoD

* Strain tested during LoD verification study

Table 10q. Inclusivity test results for *Cyclospora cayetanensis* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalogue ID	Times LoD
<i>Cyclospora cayetanensis</i>	<i>Cyclospora cayetanensis</i>	n/a	Clinical sample	LAC2825*	1x LoD
	<i>Cyclospora cayetanensis</i>	n/a	Clinical sample	LAC2827*	1x LoD
	<i>Cyclospora cayetanensis</i>	–	ATCC	PRA-3000SD	1x LoD

* Strain tested during LoD verification study.

Table 10r. Inclusivity test results for *Entamoeba histolytica* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalogue ID	Times LoD
<i>Entamoeba histolytica</i>	<i>Entamoeba histolytica</i>	HM-1:IMSS (Mexico City 1967)	ATCC	30459*	1 x LoD
	<i>Entamoeba histolytica</i>	HK-9 (Korea)	ATCC	30015*	1 x LoD
	<i>Entamoeba histolytica</i>	–	Vall d'Hebrón	Clinical sample; 1	1 x LoD

* Strain tested during LoD verification study.

Table 10s. Inclusivity test results for *Giardia lamblia* strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
<i>Giardia lamblia</i>	<i>Giardia lamblia</i>	Portland -1 (Portland, OR, 1971)	ATCC	30888*	1 x LoD
	<i>Giardia lamblia</i>	WB (Bethesda, MD, 1979)	ATCC	30957*	1 x LoD
	<i>Giardia intestinalis</i>	H3 isolate	Waterborne	P101	1 x LoD

* Strain tested during LoD verification study.

Table 10t. Inclusivity test results for Adenovirus F40/F41 targets

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Adenovirus F40/F41	Human Adenovirus F41	Tak	ZeptoMetrix	0810085CF*	1x LoD
	Human Adenovirus F41	Tak (73-3544)	ATCC	VR-930	10x LoD
	Human Adenovirus F40	Dugan [79-18025]	ATCC	VR-931	10x LoD
	Human Adenovirus Type 40	Dugan	ZeptoMetrix	0810084CF*	3x LoD

* Strain tested during LoD verification study.

Table 10u. Inclusivity test results for Astrovirus strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Astrovirus	Human Astrovirus	ERE IID 2371 (type 8)	ZeptoMetrix	0810277CF*	1x LoD
	Human Astrovirus	HAsIV-1	Universitat de Barcelona	Clinical sample; 160521599	1x LoD
	Human Astrovirus	ERE IID 2868 (type 4)	ZeptoMetrix	0810276CF*	1x LoD
	Human Astrovirus	HAsIV-3	Universitat de Barcelona	Clinical sample; 151601306	1x LoD

* Strain tested during LoD verification study.

Table 10v. Inclusivity test results for Norovirus GI/GII strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Norovirus GI/GII	Human Norovirus Genogroup 1	Recombinant GI.1	ZeptoMetrix	0810086CF*	1x LoD
	Human Norovirus Genogroup 1	–	Indiana University Health	Clinical sample; IU3156	1x LoD
	Human Norovirus Genogroup 1	–	Indiana University Health	Clinical sample; IU3220	1x LoD
	Human Norovirus Genogroup 1	–	TriCore Reference Laboratories	Clinical sample; TC4274	3x LoD
	Human Norovirus Genogroup 2	Recombinant GII.4	ZeptoMetrix	0810087CF*	1x LoD
	Human Norovirus Genogroup 2	GII.2	Vall d'Hebrón	Clinical sample; 198058327	1x LoD
	Human Norovirus Genogroup 2	GII.4	Universitat de Barcelona	Clinical sample; N26.2TA	1x LoD
	Human Norovirus Genogroup 2	–	Lacny Hospital	Clinical sample; LAC2019	1x LoD
	Human Norovirus Genogroup 2	–	Nationwide Children's Hospital	Clinical sample; NWC6063	1x LoD
	Human Norovirus Genogroup 2	GII.6	QIAGEN Barcelona (STAT-Dx)	Clinical sample; GI 12	3x LoD
	Human Norovirus Genogroup 2	–	Lacny Hospital	Clinical sample; LAC2133	10x LoD
	Human Norovirus Genogroup 2	–	Lacny Hospital	Clinical sample; LAC2074	10x LoD

* Strain tested during LoD verification study.

Table 10w. Inclusivity test results for Rotavirus A strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Rotavirus A	Human Rotavirus A	69M	ZeptoMetrix	0810280CF*	1x LoD
	Human Rotavirus A	Wa, G1P1A[8]	ZeptoMetrix	0810041CF*	1x LoD
	Human Rotavirus A	DS-1, G2P1B[4]]	ATCC	VR-2550	1x LoD
	Human Rotavirus A	Va70	ZeptoMetrix	0810281CF	1x LoD
	Human Rotavirus A	RRV	ZeptoMetrix	0810530CF	10x LoD

* Strain tested during LoD verification study.

Table 10x. Inclusivity test results for Sapovirus strains

QIAstat-Dx target	Pathogen	Strain	Supplier	Catalog ID	Times LoD
Sapovirus	Human Sapovirus Genogroup I	–	QIAGEN Barcelona	Clinical sample; GI-88*	1x LoD
	Human Sapovirus Genogroup V	n/a	Universitat Barcelona	Clinical Sample; 160523351*	1x LoD
	Human Sapovirus Genogroup I	GI.1	Universitat de Barcelona	Clinical sample; 171016324	1x LoD
	Human Sapovirus Genogroup II	GII.3	Universitat de Barcelona	Clinical sample; 215512	1x LoD

* Strain tested during LoD verification study.

In silico analysis

In silico analysis of potential reactivity showed that the following organisms (including species, subspecies, subtypes, serotypes, or serovars) are predicted to be detected with the QIAstat-Dx Gastrointestinal Panel 2 (Table 11).

Table 11. Organisms with predicted reactivity based on in silico analysis

QIAstat-Dx GI Panel

2 Target

Organisms with predicted reactivity (species, subspecies, subtypes, serotypes or serovars)

Bacteria

<i>Campylobacter</i>	<i>Campylobacter coli</i> <i>Campylobacter jejuni</i> , <i>Campylobacter jejuni</i> subsp. <i>jejuni</i> , <i>Campylobacter jejuni</i> subsp. <i>doylei</i> , <i>Campylobacter upsaliensis</i>
<i>Clostridium difficile</i>	<i>Clostridium difficile</i> (including ribotypes O1 and 17 and strains BI1, BI9, NAP1, SD1, SD2, M68, M120)
<i>Salmonella</i>	<i>Salmonella bongori</i> , <i>Salmonella enterica</i> subsp. <i>salamae</i> II (e.g. serovar 55:k:z39), <i>Salmonella enterica</i> subsp. <i>arizonae</i> IIIa (e.g. serovar 63:g:z51), <i>Salmonella enterica</i> subsp. <i>diarizonae</i> IIIb (e.g. serovar 47:l,v:z), <i>Salmonella enterica</i> subsp. <i>houtenae</i> IV (e.g. serovar 43:z4), <i>Salmonella enterica</i> subsp. <i>indica</i> VI. <i>Salmonella enterica</i> subsp. <i>enterica</i> (up to 92 different serovars including Agona, Anatum, Bareilly, Choleraesuis, Enteritidis, Heidelberg, Infantis, Kentucky, Montevideo, Newport, Paratyphi A, Senftenberg, Tennessee, Thompson, Typhi, Typhimurium)
<i>Plesiomonas shigelloides</i>	<i>Plesiomonas shigelloides</i> (e.g. strains NCTC10360, ATCC 14029T, R4605035)
<i>Vibrio cholerae</i>	<i>Vibrio cholerae</i> (including serotypes O:1 and non-O:1 (O:37) and biovars El Tor, Bengal)
<i>Vibrio parahaemolyticus</i>	<i>Vibrio parahaemolyticus</i>
<i>Vibrio vulnificus</i>	<i>Vibrio vulnificus</i>
<i>Yersinia enterocolitica</i>	<i>Yersinia enterocolitica</i> , <i>Yersinia enterocolitica</i> subsp. <i>paleartica</i> , <i>Yersinia enterocolitica</i> subsp. <i>enterocolitica</i>
Enteroaggregative <i>E. coli</i> (EAEC)	Enteroaggregative <i>E. coli</i> (EAEC) (including serotypes O104:H4, O111:HND, O126:HND, O25:H4, O86:H2, O86:HND, OUT:H4, OUT:HND)
Enteroinvasive <i>E. coli</i> (EIEC)/ <i>Shigella</i>	Enteroinvasive <i>E. coli</i> (EIEC), <i>Escherichia coli</i> sp., <i>Shigella flexneri</i> , <i>Shigella dysenteriae</i> , <i>Shigella boydii</i> , <i>Shigella sonnei</i>

Table 11. Organisms with predicted reactivity based on in silico analysis (continued)

**QIAstat-Dx GI Panel
2 Target**

Organisms with predicted reactivity (species, subspecies, subtypes, serotypes or serovars)

Enteropathogenic <i>E. coli</i> (EPEC)	Enteropathogenic <i>E. coli</i> (EPEC) (e.g. including serotypes OUT: HND, OUT:H6, OUT:H34, OUT:H21, O55:H7, O119:HNM, O117) Other <i>eae</i> -carriers bacteria: some Shiga-like toxin-producing <i>E. coli</i> (STEC), STEC O157:H7 and few <i>Shigella boydii</i> strains
Enterotoxigenic <i>E. coli</i> (ETEC)	Enterotoxigenic <i>E. coli</i> (ETEC) (including H10407 and E24377A strains and serotypes O169:H41, O25:H42, O148:H28, O6:H16)
Shiga-like toxin-producing <i>E. coli</i> (STEC) - stx1	Shiga-like toxin-producing <i>E. coli</i> (STEC) (including non-O157 serotypes O111:NM, O111:H, O26:H11, O145:NM, O145:H28, O45:H2, O26:H11, ONT:NM, and including STEC O157 serotypes O157:H7) Stx1 toxin subtypes predicted to be detected include <i>stx1a</i> , <i>stx1c</i> and <i>stx1d</i> Other <i>stx</i> -carriers bacteria: <i>Shigella sonnei</i> , <i>Shigella dysenteriae</i>
Shiga-like toxin-producing <i>E. coli</i> (STEC) - stx2	Shiga-like toxin-producing <i>E. coli</i> (STEC) (including non-O157 serotypes O111:NM, O104:H4, O111:H, O26:H11, O121:H19, O145:H34, O113:H21, ONT:H, O128:H2, OUT:HNM, O124:HNM and including STEC O157 serotypes O157:H7, O157:NM) Stx2 toxin subtypes predicted to be detected include <i>stx2a</i> , <i>stx2b</i> , <i>stx2c</i> , <i>stx2d</i> , <i>stx2e</i> , <i>stx2f</i> and <i>stx2g</i>
Shiga-like toxin-producing <i>E. coli</i> (STEC) O157	<i>Escherichia coli</i> O157 including: STEC O157:H7 strains (e.g. EDL933) and <i>E. coli</i> O157: non-H7 groups including Non-Shiga-toxigenic <i>E. coli</i> O157 bacteria (e.g. serotype O157:H45) Other bacteria with O157 O-antigen: <i>Escherichia fergusonii</i> O157

Parasites

<i>Cryptosporidium</i>	<i>Cryptosporidium parvum</i> , <i>Cryptosporidium meleagridis</i> , <i>Cryptosporidium canis</i> , <i>Cryptosporidium felis</i> , <i>Cryptosporidium</i> sp. <i>Rare or non-human species: Cryptosporidium wrairi</i>
<i>Cyclospora cayetanensis</i>	<i>Cyclospora cayetanensis</i> (including strains LG, CY9, NP20 and NP21)
<i>Entamoeba histolytica</i>	<i>Entamoeba histolytica</i> (e.g. strains HM-1: IMSS, EHMfas1, HK-9)

Table 11. Organisms with predicted reactivity based on in silico analysis (continued)

QIAstat-Dx GI Panel 2 Target	Organisms with predicted reactivity (species, subspecies, subtypes, serotypes or serovars)
<i>Giardia lamblia</i>	<i>Giardia lamblia</i> (aka <i>Giardia duodenalis</i> , <i>Giardia intestinalis</i>) ^f
Viruses	
Adenovirus	Human Adenovirus F 40/41
Astrovirus	Human Astrovirus (including types 1, 2, 3, 4, 5, 6, 7, 8)
Norovirus GI/GII	Norovirus genogroup II genotypes: GII.1, GII.2, GII.3, GII.4, GII.4_Sydney 2012, GII.P4_ New Orleans 2009, GII.4_Den Haag, GII.4_Hong Kong, GII.5, GII.6, GII.7, GII.8, GII.10, GII.12, GII.13, GII.17, GII.21. Norovirus genogroup I genotypes: GI.1, GI.3, GI.4, GI.5, GI.6, GI.7, GI.8, GI.9.
Rotavirus	Rotavirus A (including strains Wa, ST3, 69M, DS-1, RVA and serotypes G1P[8], G12P[6], G2P[4], G3P[6], G4P[6], G6P[6], G8P[8], G9P[19])
Sapovirus	Genogroups GI (including genotypes GI.1, GI.2, GI.3, GI.4, GI.6), GII (including genotypes GII.1, GII.2, GII.3, GII.4, GII.5, GII.6), GIV (including genotype GIV.1) and GV (including genotypes GV.1).

Interfering substances

The effect of potentially interfering substances on the detectability of the QIAstat-Dx Gastrointestinal Panel 2 organisms was evaluated. Forty-three (43) potentially interfering substances were spiked into the sample mixes at a level predicted to be above the concentration of the substance likely to be found in stool specimens. Each organism was tested at 3x LoD and testing was performed in triplicates. Endogenous substances such as human whole blood, human genomic DNA and several pathogens were tested alongside exogenous substances like antibiotics, other gastrointestinal-related medications and different technique-specific substances.

For the vast majority of substances tested, no inhibition was observed, with the exceptions of mucin from bovine submaxillary, Human genomic DNA, bisacodyl, calcium carbonate, nonoxynol-9 and Rotavirus reassortants, that may cause inhibition at high concentration.

Mucin from bovine submaxillary was found to interfere with the detection of *Vibrio cholerae*, EAEC and *Entamoeba* at concentrations above 2.5% w/v.

Human genomic DNA was found to interfere with the detection of *E. coli* O157 and *Entamoeba* at concentrations above 5 µg/mL.

Bisacodyl was found to interfere with the detection of EAEC at concentrations above 0.15% w/v.

Calcium carbonate was found to interfere with the detection of all the QIAstat-Dx Gastrointestinal Panel 2 targets at concentrations above 0.5% w/v.

Nonoxynol-9 was found to interfere with the detection of *Entamoeba* at concentrations above 0.02% v/v.

Rotavirus reassortants WC3:2-5, R574(9) and WI79-4,9 used in Rotavirus A vaccines were predicted to be reactive with Rotavirus A in the QIAstat-Dx Gastrointestinal Panel 2. Final concentrations without observable interfering effects on the detection of targets at 3x LoD concentration for WC3:2-5, R574(9) and WI79-4,9 were 8.89×10^{-5} TCID₅₀/mL and 1.10 PFU/mL, respectively (see Table 12) for other concentrations tested.

Competitive interference was tested in a subset of pathogens. No interference was observed when evaluating competitive interference by target pathogens when two QIAstat-Dx Gastrointestinal Panel target pathogens were tested by spiking samples with one pathogen target at 3x LoD and one at 50x LoD. Results from the pathogen targets tested are provided in Table 14.

Results from the 43 interfering substances that could be present or introduced in a stool specimen are provided in Table 12.

Table 12. Final highest concentration without observable inhibitory effect

Substance tested	Concentration tested	Result
Endogenous substances		
Bovine and ovine bile	12% w/v	No Interference
Cholesterol	1.5% w/v	No Interference
Fatty acids (palmitic acid)	0.2% w/v	No Interference
Fatty acids (stearic acid)	0.4% w/v	No Interference
Human genomic DNA	20 µg/mL 10 µg/mL 5 µg/mL	Interference
		Interference
		No Interference
Human stool (overfill of Cary Blair vial)	300 mg/mL	No Interference
Human urine	50% v/v	No Interference
Human whole blood with Na Citrate	40% v/v	No Interference
Mucin from bovine submaxillary	5% w/v 2.5% w/v	Interference
		No Interference
Triglycerides	5% w/v	No Interference
Non-target microorganisms		
<i>Aeromonas hydrophila</i>	1 x 10 ⁶ units/mL	No Interference
<i>Bacteroides vulgatus</i>	1 x 10 ⁶ units/mL	No Interference
<i>Bifidobacterium bifidum</i>	1 x 10 ⁶ units/mL	No Interference
Enterovirus Species D, Serotype EV-D68	1 x 10 ⁵ units/mL	No Interference
Non-pathogenic <i>E. coli</i>	1 x 10 ⁶ units/mL	No Interference

Table 12. Final highest concentration without observable inhibitory effect (continued)

Substance tested	Concentration tested	Result
<i>Helicobacter pylori</i>	1 x 10 ⁶ units/mL	No Interference
<i>Saccharomyces cerevisiae</i> (deposited as <i>S. boulardii</i>)	1 x 10 ⁵ units/mL	No Interference
Exogenous substances		
Bacitracin	250U/ml	No Interference
Bisacodyl	0.3% w/v 0.15% w/v	Interference No Interference
Bismuth subsalicylate	0.35% w/v	No Interference
Calcium carbonate (TUMS® Extra Strength 750)	5%w/v 0.5% w/v	Interference No Interference
Docusate sodium	2.5% w/v	No Interference
Doxycycline hydrochloride	0.05% w/v	No Interference
Glycerin	50% v/v	No Interference
Hydrocortisone	0.5% w/v	No Interference
Loperamide hydrochloride	0.078% w/v	No Interference
Magnesium hydroxide	0.1% w/v	No Interference
Metronidazole	1.5% w/v	No Interference
Mineral oil	50% v/v	No Interference
Naproxen sodium	0.7% w/v	No Interference

Table 12. Final highest concentration without observable inhibitory effect (continued)

Substance tested	Concentration tested	Result
Nonoxynol-9	1.2% v/v 0.6% v/v 0.3% v/v 0.15% v/v 0.075% v/v 0.02% v/v	Interference
		Interference
		Interference
		Interference
		Interference
		No Interference
Nystatin	10000 USP units/mL	No Interference
Phenylephrine hydrochloride	0.075% w/v	No Interference
Sodium phosphate	5% w/v	No Interference
Vaccine components		
Rotavirus reassortant WC3:2-5, R574 (9) - VR 2195	8.89 x 10 ⁻³ TCID ₅₀ /mL 8.89 x 10 ⁻⁴ TCID ₅₀ /mL 8.89 x 10 ⁻⁵ TCID ₅₀ /mL	Interference
		Interference
		No Interference
Rotavirus reassortant WI79-4,9 - VR 2415	1.10 x 10 ² pfu/mL 1.10 x 10 ¹ pfu/mL 1.10 pfu/mL	Interference
		Interference
		No Interference
Technique-specific Substances		
Bleach	0.5% v/v	No Interference
Ethanol	0.2% v/v	No Interference
Fecal swab Cary-Blair Medium	100%	No Interference
Fecal Opti-Swab Cary-Blair Medium	100%	No Interference
PurSafe® DNA/RNA Preservative	100%	No Interference
Para-Pak C&S spoon	1 spoon/2mL Cary Blair	No Interference
Sigma transwab	1 swab/2mL Cary Blair	No Interference

Table 13. QIAstat-Dx Gastrointestinal Panel 2 results for competitive interference

Sample Mix	Target	Final concentration tested x LoD	Co-infection detected
Norovirus 50x - Rotavirus 3x	Norovirus GI/GII	50x	Yes
	Rotavirus A	3x	
Norovirus 3x - Rotavirus 50x	Norovirus GI/GII	3x	Yes
	Rotavirus A	50x	
Giardia 50x - Adenovirus 3x	<i>Giardia lamblia</i>	50x	Yes
	Adenovirus F40/F41	3x	
Adenovirus 50x - Giardia 3x	<i>Giardia lamblia</i>	3x	Yes
	Adenovirus F40/F41	50x	
Norovirus 50x - C.diff 3x	Norovirus GI	50x	Yes
	<i>Clostridium difficile</i> toxin A/B	3x	
Norovirus 3x - C.diff 50x	Norovirus GI	3x	Yes
	<i>Clostridium difficile</i> toxin A/B	50x	
EPEC 50x - EAEC 3x	EPEC	50x	Yes
	EAEC	3x	
EPEC 3x - EAEC 50x	EPEC	3x	Yes
	EAEC	50x	
EPEC 50x - C.diff 3x	EPEC	50x	Yes
	<i>Clostridium difficile</i> toxin A/B	3x	
EPEC 3x - C.diff 50x	EPEC	3x	Yes
	<i>Clostridium difficile</i> toxin A/B	50x	

Table 13. QIAstat-Dx Gastrointestinal Panel 2 results for competitive interference (continued)

Sample Mix	Target	Final concentration tested x LoD	Co-infection detected
EPEC 50x - ETEC 3x	EPEC	50x	Yes
	ETEC	3x	
EPEC 3x - ETEC 50x	EPEC	3x	Yes
	ETEC	50x	
ETEC 50x - EIEC 3x	ETEC	50x	Yes
	EIEC/ <i>Shigella</i>	3x	
ETEC 3x - EIEC 50x	ETEC	3x	Yes
	EIEC/ <i>Shigella</i>	50x	

Carryover

A carryover study was performed to evaluate the potential occurrence of cross-contamination between consecutive runs when using the QIAstat-Dx Gastrointestinal Panel 2 on the QIAstat-Dx Analyzer 1.0.

Pathogen samples of stool sample matrix, with alternating high-positive (10⁵-10⁶ organism/ml) and negative samples, were conducted on two QIAstat-Dx Analyzer 1.0 instruments.

No carryover between samples was observed in the QIAstat-Dx Gastrointestinal Panel 2, demonstrating that the system design and recommended sample handling and testing practices are effective in preventing false-positive results due to carryover or cross-contamination between samples.

Reproducibility

Reproducibility testing of contrived samples was performed at three test sites including one internal site (Site A) and two external sites (Site B and Site C). The study incorporated a range of potential variation introduced by sites, days, replicates, cartridge lots, operators, and QIAstat-Dx analyzers. For each site, testing was performed across 5 non-consecutive days with 6 replicates per day (leading to a total of 30 replicates per target, concentration and site), 4 QIAstat-Dx Analyzers (2 analyzers per operator and per site), and at least 2 operators on each testing day. A total of 5 sample mixes (two combined samples at 1x LoD and 3x LoD plus one negative sample) were prepared. For each mix, 6 replicates were tested and evaluated.

Table 14 shows the detection rate per target and concentration for each site of the Reproducibility study. In addition, data obtained at all three sites have been compiled to calculate the exact 2-sided 95% Confidence Interval by target and concentration.

Table 14. Detection rate per target and concentration for each site of the Reproducibility study and exact 2-sided 95% Confidence Interval by target and concentration

% Agreement with Expected Result						
Pathogen Tested	Concentration Tested	Expected Result	Site A	Site B	Site C	All Sites (95% Confidence Interval)
Adenovirus F41 ZeptoMetrix 0810085CF	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
<i>Clostridium difficile</i> ZeptoMetrix 0801619	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)

Table 14. Detection rate per target and concentration for each site of the Reproducibility study and exact 2-sided 95% Confidence Interval by target and concentration (continued)

% Agreement with Expected Result						
Pathogen Tested	Concentration Tested	Expected Result	Site A	Site B	Site C	All Sites (95% Confidence Interval)
<i>Campylobacter</i> ZeptoMetrix 0801650	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
<i>Escherichia coli</i> EPEC ZeptoMetrix 0801747	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	29/30	30/30	89/90
			100%	96.67%	100%	98.89% (93.96–99.97%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)

Table 14. Detection rate per target and concentration for each site of the Reproducibility study and exact 2-sided 95% Confidence Interval by target and concentration (continued)

% Agreement with Expected Result						
Pathogen Tested	Concentration Tested	Expected Result	Site A	Site B	Site C	All Sites (95% Confidence Interval)
<i>Entamoeba histolytica</i> ATCC 30459	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	29/30	89/90
			100%	100%	96.67%	98.89% (93.96–99.97%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
<i>Giardia lamblia</i> ATCC 30888	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)

Table 14. Detection rate per target and concentration for each site of the Reproducibility study and exact 2-sided 95% Confidence Interval by target and concentration (continued)

% Agreement with Expected Result						
Pathogen Tested	Concentration Tested	Expected Result	Site A	Site B	Site C	All Sites (95% Confidence Interval)
Norovirus GII ZeptoMetrix 0810087CF	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	29/30	30/30	30/30	89/90
			96.67%	100%	100%	98.89% (93.96–99.97%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
Rotavirus A ZeptoMetrix 0810280CF	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	29/30	30/30	89/90
			100%	96.67%	100%	98.89% (93.96–99.97%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)

Table 14. Detection rate per target and concentration for each site of the Reproducibility study and exact 2-sided 95% Confidence Interval by target and concentration (continued)

% Agreement with Expected Result						
Pathogen Tested	Concentration Tested	Expected Result	Site A	Site B	Site C	All Sites (95% Confidence Interval)
<i>Escherichia coli</i> (STEC) O157:H7 ZeptoMetrix 0801622	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	29/30	89/90
			100%	100%	96.67%	98.89% (93.96–99.97%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
<i>Escherichia coli</i> (STEC) <i>stx1</i> ZeptoMetrix 0801622	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)

Table 14. Detection rate per target and concentration for each site of the Reproducibility study and exact 2-sided 95% Confidence Interval by target and concentration (continued)

% Agreement with Expected Result						
Pathogen Tested	Concentration Tested	Expected Result	Site A	Site B	Site C	All Sites (95% Confidence Interval)
<i>Escherichia coli</i> (STEC) <i>stx2</i> ZeptoMetrix 801622	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
<i>Salmonella enterica</i> ZeptoMetrix 801437	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	29/30	29/30	88/90
			100%	96.67%	96.67%	97.78% (92.20–99.73%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)

Table 14. Detection rate per target and concentration for each site of the Reproducibility study and exact 2-sided 95% Confidence Interval by target and concentration (continued)

% Agreement with Expected Result						
Pathogen Tested	Concentration Tested	Expected Result	Site A	Site B	Site C	All Sites (95% Confidence Interval)
<i>Vibrio parahaemolyticus</i> ATCC 17802	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
<i>Yersinia enterocolitica</i> Zeptomatrix 801734	3x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	1x LoD	Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)
	None	Not Detected	30/30	30/30	30/30	90/90
			100%	100%	100%	100% (95.98–100.00%)

Clinical performance

The clinical performance shown below was demonstrated using QIAstat-Dx Analyzer 1.0. A multi-center international observational clinical study was conducted using prospectively and retrospectively collected samples to evaluate the performance of QIAstat-Dx Gastrointestinal

Panel 2 during normal conditions of use. The study was conducted in 13 clinical sites across 5 countries (4 sites in Europe and 9 sites in USA) from May 2021 to July 2021.

The final data set consisted of a total of 2,085 leftover de-identified specimens, which were prospectively collected from patients who underwent stool specimen collection for clinical indications of diarrhea caused by gastrointestinal infection at the 13 investigational sites. In addition, testing was performed on archived known positives and contrived specimens to further augment the positive specimen numbers (Table 15). Samples used in the study were all stool samples in Cary-Blair transport media collected using either Para-Pak C&S (Meridian Bioscience), FecalSwab® (COPAN), Fecal Transwab® (Medical Wire & Equipment Co. (Bath) Ltd), or C & S Medium (Medical Chemical).

Table 15. Prospective and Retrospective Specimen summary across each clinical site of all specimens used in the clinical study

Specimen Type			
Site/Country	Prospective (Fresh)	Retrospective (Archived Frozen)	Total
Germany	339	17	360
Denmark	293	37	330
Spain	246	60	306
France	63	7	70
USA site 1	186	6	192
USA site 2	43	9	52
USA site 3	281	84	365
USA site 4	177	0	177
USA site 5	44	0	44
USA site 6	39	0	39
USA site 7	148	0	148

Table 15. Prospective and Retrospective Specimen summary across each clinical site of all specimens used in the clinical study (continued)

Site/Country	Specimen Type		Total
	Prospective (Fresh)	Retrospective (Archived Frozen)	
USA site 8	131	0	131
USA site 9	95	0	95
Total	2085	220	2305

All prospectively collected specimens that had age, sex, and patient population status were collected by the site. Subject demographics (evaluable specimens) are summarized in Table 16 below.

Table 16. Demographic data for enrolled prospective specimens

Demographic data	N	%
Gender		
Female	1158	55.5
Male	927	44.5
Age Group		
0–6 years	221	10.6
6–21 years	167	8.0
22–49 years	540	25.9
50+ years	1150	55.2
Not Reported	7	0.3
Patient population		
Emergency room	114	5.5
Hospitalized	500	24.0

Table 16. Demographic data for enrolled prospective specimens (continued)

Demographic data	N	%
Immunocompromised	3	0.1
No information available	560	26.9
Outpatient	908	43.5
No. of days between symptom onset and QIAstat-Dx testing		
> 7 days	152	7.3
≤ 7 days	222	10.6
Not Reported	1711	82.1

Performance of the QIAstat-Dx Gastrointestinal Panel 2 was compared to the reference method: BioFire® FilmArray® GI Panel for all targets. For the majority of targets, direct comparison of the two results could be made as a binary result (positive or negative). However, for certain targets the QIAstat-Dx GI2 Assay provides additional differentiation, so further comparators were required to determine agreement. The appropriate comparator/reference method used for each member of the panel are detailed in the Table 17 below.

Table 17. QIAstat-Dx Gastrointestinal Panel 2 Clinical studies reference method

QIAstat-Dx Gastrointestinal Panel 2 target	Reference method
Adenovirus F40/F41	BioFire FilmArray Gastrointestinal (GI) Panel
Astrovirus	
Norovirus GI/GII	
Rotavirus A	
Sapovirus (GI, GII, GIV, GV)	
<i>Campylobacter</i> (<i>C. jejuni</i> , <i>C. coli</i> and <i>C. upsaliensis</i>)	
<i>Clostridium difficile</i> (toxin A/B)	
Enteroaggregative <i>Escherichia coli</i> (EAEC)	
<i>Shigella</i> /Enteroinvasive <i>Escherichia coli</i> (EIEC)	
Enteropathogenic <i>Escherichia coli</i> (EPEC)	
Enterotoxigenic <i>Escherichia coli</i> (ETEC) <i>lt/st</i>	
Shiga-like toxin-producing <i>Escherichia coli</i> (STEC) <i>stx1/stx2</i>	
<i>E. coli</i> O157 serogroup	
<i>Salmonella</i>	
<i>Plesiomonas shigelloides</i>	
<i>Vibrio cholerae</i>	
<i>Yersinia enterocolitica</i>	
<i>Cryptosporidium</i>	
<i>Cyclospora cayetanensis</i>	
<i>Entamoeba histolytica</i>	
<i>Vibrio parahaemolyticus</i>	BioFire FilmArray GI Panel <i>Vibrio</i> + PCR-BDS assay to identify <i>V. parahaemolyticus</i>
<i>Vibrio vulnificus</i>	BioFire FilmArray GI Panel <i>Vibrio</i> + PCR-BDS assay to identify <i>V. vulnificus</i>

When PCR-BDS is referred to: This is a targeted Polymerase Chain Reaction (PCR) assay which was developed and validated for the performance evaluation, when amplification is observed in the PCR, the amplicon was verified by Bi-Directional Sequencing (BDS).

Discordant results resolution

Upon discordance with the reference method, resolution testing was performed to determine the presence/absence of specific targets. Table 18 below details the methods used for discordance resolution.

Table 18. Discordant Specimen Testing

QIAstat-Dx Gastrointestinal Panel 2	Discordant testing method
Adenovirus F40/F41	BD-MAX Enteric Viral Panel
Astrovirus	
Norovirus GI/GII	
Rotavirus A	
Sapovirus (GI, GII, GIV, GV)	
Campylobacter (C. jejuni, C. coli and C. upsaliensis)	BD-MAX Enteric Bacterial Panel
Shigella/Enteroinvasive E. coli (EIEC)	
Salmonella	
Enterotoxigenic E. coli (ETEC) lt/st	BD-MAX Extended Enteric Bacterial Panel
Plesiomonas shigelloides	
Yersinia enterocolitica	
Clostridium difficile (toxin A/B)	PCR with Bi-directional sequencing (PCR-BDS) *
Enteroaggregative E. coli (EAEC)	
Enteropathogenic E. coli (EPEC)	
Shiga-like toxin- E. coli (STEC) stx1	
Shiga-like toxin- E. coli (STEC) stx2	
Vibrio cholerae	
Vibrio parahaemolyticus	
Vibrio vulnificus	
Cryptosporidium	
Giardia lamblia	

* All Polymerase Chain Reaction (PCR)- Bidirectional Sequencing (BDS) assays represent a validated nucleic acid amplification test (NAAT) followed by bi-directional sequencing. For *Vibrio parahaemolyticus* and *Vibrio vulnificus*, the same PCR-BDS method was used for both discordant testing and differentiation testing.

Clinical performance — PPA and NPA

A total of 2,085 prospective and 220 retrospective (archived pre-selected) clinical samples were evaluated to determine the Clinical Performance characteristics of the QIAstat-Dx Gastrointestinal Panel 2. The Positive Percentage Agreement (PPA) and Negative Percent Agreement (NPA) was calculated for each target before and after discordances resolution for each clinical samples group (prospective and retrospective).

Additionally, to supplement the prospective and retrospective clinical samples data, an evaluation of contrived specimens was performed for several pathogens (Adenovirus F40/F41, Astrovirus, Rotavirus, Sapovirus, *Campylobacter*, ETEC, EIEC/*Shigella*, STEC *stx1/stx2*, *E. coli* O157, *Plesiomonas shigelloides*, *Salmonella*, *Vibrio cholerae*, *Vibrio parahaemolyticus*, *Vibrio vulnificus*, *Yersinia enterocolitica*, *Cryptosporidium*, *Cyclospora cayetanensis*, *Entamoeba histolytica*, and *Giardia lamblia*), due to low number of prospective and archived clinical samples found during the study. Surrogate specimens were prepared using residual clinical specimens that had previously tested negative for all GI panel analytes targeted by QIAstat-Dx Gastrointestinal Panel 2 and comparator methods. Specimens were spiked around the assay LoD and at clinically relevant levels using different quantified strains for each organism. The analyte status of each contrived specimen was blinded to the users analyzing the specimens. A total of 1,254 cartridge test runs were performed for the contrived samples providing additional data on the rarer pathogens measured by QIAstat-Dx Gastrointestinal Panel 2. PPA was established for the mentioned targets on contrived samples.

The PPA and NPA per pathogen alongside with the corresponding exact binomial two-sided 95% confidence interval are presented for each analyte targeted by QIAstat-Dx Gastrointestinal Panel 2 on the prospective, retrospective and contrived samples groups in Table 19 to Table 41 below. The PPA and NPA results after resolving discordances are also included for prospective and retrospective sample groups.

Table 19. Adenovirus F40/41 – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	6 / 8*	75.00	34.91–96.81	6 / 6	100.00	54.07–100.00
	NPA	2065 / 2066 *	99.95	99.73–100.00	2067 / 2068	99.95	99.73
Retrospective	PPA	3 / 5 *	60.00	14.66–94.73	3 / 3	100.00	29.24–100.00
	NPA	214 / 214	100.00	98.29–100.00	216 / 216	100.00	98.31–100.00
Contrived	PPA	68 / 70	97.14	90.06	N/A	N/A	N/A

* There were four (4) false negatives compared to FilmArray Gastrointestinal Panel; all of these were confirmed as negatives by BD MAX™ Enteric Viral Panel. There was one false positive compared to FilmArray Gastrointestinal Panel, which was confirmed as positive by BD MAX Enteric Viral Panel.

Table 20. Astrovirus – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	11 / 11	100.00	71.51–100.00	11 / 11	100.00	71.51–100.00
	NPA	2063 / 2063	100.00	99.82–100.00	2063 / 2063	100.00	99.82–100.00
Retrospective	PPA	2 / 3 *	66.67	9.43–99.16	2 / 3	66.67	9.43–99.16
	NPA	215 / 215	100.00	98.30–100.00	215 / 215	100.00	98.30–100.00

Table 20. Astrovirus – Summary of Clinical Performance Results (continued)

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Contrived	PPA	67 / 68	98.53	92.08	N/A	N/A	N/A

* There was one (1) false negative compared to FilmArray Gastrointestinal Panel; of these no samples were confirmed as negative by BD MAX Enteric Viral Panel. There were no false positive results in the performance comparison with FilmArray Gastrointestinal Panel.

Table 21. Norovirus GI/GII – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	59 / 81 *	72.84%	61.81–2.13	60 / 63	95.24	86.71–99.01
	NPA	1991 / 1993*	99.90%	99.64–9.99	2009 / 2010	99.95	99.72–100.00
Retrospective	PPA	8 / 17 *	47.06%	22.98–2.19	9 / 10	90.00	55.50–99.75
	NPA	200 / 201 *	99.50%	97.26–9.99	208 / 208	100.00	98.24–100.00

* There were thirty-one (31) false negatives compared to FilmArray Gastrointestinal Panel; of these twenty-seven (27) were confirmed as negatives by BD MAX Enteric Viral Panel. There were three (3) false positives compared to FilmArray Gastrointestinal Panel; of these two (2) were confirmed as positive when compared with targeted PCR followed by BD MAX Enteric Viral Panel

Table 22. Rotavirus A – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	24 / 26 *	92.31	74.87–99.05	24 / 25	96.00	79.65–99.90
	NPA	2045 / 2048 *	99.85	99.57–99.97	2046 / 2049	99.85	99.57–99.97
Retrospective	PPA	10 / 11 *	90.91	58.72–99.77	10 / 11	90.91	58.72–99.77
	NPA	207 / 207	100.00	98.23–100.00	207 / 207	100.00	98.23–100.00
Contrived	PPA	69 / 70	98.57	92.30–99.96	N/A	N/A	N/A

* There were three (3) false negatives compared to FilmArray Gastrointestinal Panel; one of these samples was confirmed as negative by BD MAX Enteric Viral Panel. There were three (3) false positives compared to FilmArray Gastrointestinal Panel; of these no samples were confirmed as positive when compared with the BD MAX Enteric Viral Panel.

Table 23. Sapovirus – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	14 / 18 *	77.78	52.36–93.59	15 / 15	100.00	78.20
	NPA	2055 / 2057*	99.90	99.65–99.99	2059 / 2060	99.95	99.73–100.00
Retrospective	PPA	0 / 0	N/A	N/A	0 / 0	N/A	N/A
	NPA	218 / 218	100.00	98.32–100.00	218 / 218	100.00	98.32–100.00

Table 23. Sapovirus – Summary of Clinical Performance Results (continued)

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Contrived	PPA	69 / 69	100.00	94.79–100.00	N/A	N/A	N/A

* There were four (4) false negatives compared to FilmArray Gastrointestinal Panel; of these all samples were confirmed as negatives by BD MAX Enteric Viral Panel. There were two false positives compared to FilmArray Gastrointestinal Panel; of this one sample was confirmed as positive by BD MAX Enteric Viral Panel.

Table 24. EAEC – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	51 / 65 *	78.46	66.51–87.69	51 / 61	83.61	71.91–91.85
	NPA	2008 / 2010*	99.90	99.64–99.99	2012 / 2014	99.90	99.64–99.99
Retrospective	PPA	32 / 34 *	94.12	80.32–99.28	32 / 34	94.12	80.32–99.28
	NPA	181 / 184 *	98.37	95.31–99.66	181 / 184	98.37	95.31–99.66

* There were sixteen (16) false negatives compared to FilmArray Gastrointestinal Panel; of these four (4) were confirmed as negatives by PCR-BDS assay. There were five (5) false positives compared to FilmArray Gastrointestinal Panel; none of these samples were confirmed as positive by PCR-BDS assay.

Table 25. EPEC – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	200 / 224*	89.29	84.48–93.01	202 / 207	97.58	94.45–99.21
	NPA	1818 / 1822 *	99.78	99.44–99.94	1837 / 1841	99.78	99.44–99.94
Retrospective	PPA	35 / 39 *	89.74	75.78–97.13	35 / 35	100.00	90.00–100.00
	NPA	151 / 152 *	99.34	96.39–99.98	155 / 156	99.36	96.48–99.98

* There were twenty-eight (28) false negatives compared to FilmArray Gastrointestinal Panel; twenty-three (23) of these were confirmed as negatives by PCR-BDS assay. There were five (5) false positives compared to FilmArray Gastrointestinal Panel; of these none were confirmed as positive by PCR-BDS assay.

Table 26. ETEC – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	33 / 46 *	71.74	56.54–84.01	35 / 38	92.11	78.62–98.34
	NPA	2026 / 2029*	99.85	99.57–99.97	2038 / 2039	99.95	99.73–100.00
Retrospective	PPA	24 / 32 *	75.00	56.60–88.54	24 / 24	100.00	85.75–100.00
	NPA	186 / 186 *	100.00	98.04–100.00	193 / 193	100.00	98.11–100.00
Contrived	PPA	43 / 43	100.00	91.78	N/A	N/A	N/A

* There were twenty-one (21) false negatives compared to FilmArray® Gastrointestinal Panel; of these eighteen (18) were confirmed as negatives by BD MAX Extended Enteric Bacterial Panel. There were three (3) false positives compared to FilmArray Gastrointestinal Panel; of these two (2) were confirmed as positive by BD MAX Enteric Bacterial Panel.

Table 27. STEC – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	19 / 27 *	70.37	49.82–86.25	19 / 23	82.61	61.22–95.05
	NPA	2042 / 2047*	99.76	99.43–99.92	2047 / 2052	99.76	99.43–99.92
Retrospective	PPA	21 / 27 *	77.78	57.74–91.38	21 / 22	95.45	77.16–99.88
	NPA	191 / 191	100.00	98.09–100.00	196 / 196	100.00	98.14–100.00
Contrived	PPA	200 / 200 **	100.00	98.17–100.00	N/A	N/A	N/A

* There were fourteen (14) false negatives compared to FilmArray Gastrointestinal Panel; of these 9 samples were confirmed as negatives by targeted PCR and BDS. There were five (5) false positives compared to FilmArray Gastrointestinal Panel; none of these were confirmed as positive by BD MAX™ Enteric Bacterial Panel.

** The differentiation of stx1 and stx2 toxin genes from Shiga-like toxin-producing *E. coli* (STEC) was substantiated during the clinical evaluation of contrived specimens. Contrived specimens for STEC (stx1/stx2) evaluation were spiked with the following strains and toxinotypes: ZeptoMetrix #0801748 (stx1+), SSI #95211 (stx2a+) and ZeptoMetrix #0801622 (stx1+, stx2+). In total 134 and 135 contrived specimens were evaluated for STEC stx1 and STEC stx2 analytes, respectively, showing both a 100% detection rate. Analytical Reactivity studies evaluated additional STEC stx1-carrier and stx2-carrier strains (see Tables 10m–o)

Table 28. *E. coli* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	2 / 2	100.00	15.81–100.00	2 / 2	100.00	15.81–100.00
	NPA	17 / 17	100.00	80.49–100.00	17 / 17	100.00	80.49–100.00

Table 28. *E. coli* – Summary of Clinical Performance Results (continued)

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Retrospective	PPA	0 / 0	N/A	N/A	0 / 0	N/A	N/A
	NPA	21 / 21	100.00	83.89–100.00	21 / 21	100.00	83.89–100.00
Contrived	PPA	67 / 69	97.10	89.92–99.65	N/A	N/A	N/A

Table 29. *Shigella*/EIEC – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	12 / 12	100.00	73.54–100.00	14 / 14	100.00	76.84–100.00
	NPA	2061 / 2062*	99.95	99.73–100.00	2061 / 2061	100.00	99.82–100.00
Retrospective	PPA	22 / 24 *	91.67	73.00–98.97	22 / 23	95.65	78.05–99.89
	NPA	194 / 194	100.00	98.12–100.00	195 / 195	100.00	98.13–100.00
Contrived	PPA	69 / 69	100.00	94.79–100.00	N/A	N/A	N/A

* There were (2) false negatives compared to FilmArray Gastrointestinal Panel; of this one sample was confirmed as negative by BD MAX Enteric Bacterial Panel. There was one false positive compared to FilmArray Gastrointestinal Panel; this sample was confirmed as positive by BD MAX Enteric Bacterial Panel

Table 30. *Campylobacter* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	99 / 102 *	97.06	91.64–99.39	103 / 103	100.00	96.48–100.00
	NPA	1967 / 1974*	99.65	99.27–99.86	1970 / 1973	99.85	99.56–99.97
Retrospective	PPA	42 / 42	100.00	91.59–100.00	43 / 43	100.00	91.78–100.00
	NPA	174 / 176 *	98.86	95.96–99.86	174 / 175	99.43	96.86–99.99
Contrived	PPA	45 / 46	97.83	88.47–99.94	N/A	N/A	N/A

* There were 3 false negatives compared to FilmArray Gastrointestinal Panel; of these no samples were confirmed as negatives by BD MAX Enteric Bacterial Panel. There were nine (9) false positives compared to FilmArray Gastrointestinal Panel, of these five (5) were confirmed as positive by BD MAX Enteric Bacterial Panel.

Table 31. *Clostridium difficile* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	219 / 243 *	90.12	85.66–93.57	219 / 228	96.05	92.64–98.18
	NPA	1834 / 1836*	99.89	99.61–99.99	1849 / 1851	99.89	99.61–99.99
Retrospective	PPA	15 / 18 *	83.33	58.58–96.42	15 / 17	88.24	63.56–98.54
	NPA	199 / 200 *	99.50	97.25–99.99	200 / 201	99.50	97.26–99.99

* There were 27 false negatives compared to FilmArray Gastrointestinal Panel; of these sixteen (16) were confirmed as negative by targeted PCR and BDS. There were three (3) false positives compared to FilmArray Gastrointestinal Panel; of these none were confirmed as positive by targeted PCR and BDS.

Table 32. *Plesiomonas shigelloides* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	6 / 7 *	85.71	42.13–99.64	6 / 6	100.00	54.07–100.00
	NPA	2063 / 2067*	99.81	99.51–99.95	2064 / 2068	99.81	99.51–99.95
Retrospective	PPA	2 / 2	100.00	15.81–100.00	2 / 2	100.00	15.81–100.00
	NPA	216 / 216	100.00	98.31–100.00	216 / 216	100.00	98.31–100.00
Contrived	PPA	67 / 68	98.53	92.08–99.96	N/A	N/A	N/A

* There was one (1) false negative compared to FilmArray Gastrointestinal Panel; this sample was confirmed as negative by BD MAX Extended Enteric Bacterial Panel. There were four (4) false positives compared to FilmArray Gastrointestinal Panel; of these no samples were confirmed as positive when compared with BD MAX Extended Enteric Bacterial Panel.

Table 33. *Salmonella* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	38 / 41 *	92.68	80.08–98.46	38 / 38	100.00	90.75–100.00
	NPA	2035 / 2035	100.00	99.82–100.00	2038 / 2038	100.00	99.82–100.00
Retrospective	PPA	33 / 34 *	97.06	84.67–99.93	33 / 33	100.00	89.42–100.00
	NPA	182 / 184 *	98.91	96.13–99.87	183 / 185	98.92	96.15–99.87

Table 33. Salmonella – Summary of Clinical Performance Results (continued)

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Contrived	PPA	33 / 33	100.00	89.42–100.00	N/A	N/A	N/A

* There were four (4) false negatives compared to FilmArray Gastrointestinal Panel; of these all four were confirmed as negatives by BD MAX Enteric Bacterial Panel. There were two (2) false positives compared to FilmArray Gastrointestinal Panel; of these none were confirmed as positive by BD MAX Enteric Bacterial Panel.

Table 34. Vibrio cholerae – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	2 / 2	100.00	15.81–100.00	2 / 2	100.00	15.81–100.00
	NPA	2072 / 2072	100.00	99.82–100.00	2072 / 2072	100.00	99.82–100.00
Retrospective	PPA	0 / 1 *	0.00	0.00–97.50	0 / 0	N/A	N/A
	NPA	217 / 217	100.00	98.31–100.00	218 / 218	100.00	98.32–100.00
Contrived	PPA	67 / 70	95.71	87.98–99.11	N/A	N/A	N/A

* There was one (1) false negative compared to FilmArray Gastrointestinal Panel; this sample was confirmed as negative by PCR-BDS assay.

Table 35. *Vibrio vulnificus* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	0 / 0	N/A	N/A	0 / 0	N/A	N/A
	NPA	2074 / 2074	100.00	99.82–100.00	2074 / 2074	100.00	99.82–100.00
Retrospective	PPA	0 / 0	N/A	N/A	0 / 0	N/A	N/A
	NPA	218 / 218	100.00	98.32–100.00	218 / 218	100.00	98.32–100.00
Contrived	PPA	69 / 69	100.00	94.79–100.00	N/A	N/A	N/A

Table 36. *Yersinia enterocolitica* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	18 / 20	90.00	68.30–98.77	18 / 18	100.00	81.47–100.00
	NPA	2040 / 2054	99.32	98.86–99.63	2042 / 2056	99.32	98.86–99.63
Retrospective	PPA	33 / 35	94.29	80.84–99.30	33 / 33	100.00	89.42–100.00
	NPA	184 / 184	100.00	98.02–100.00	186 / 186	100.00	98.04–100.00
Contrived	PPA	68 / 69	98.55	92.19–99.96	N/A	N/A	N/A

* There were four (4) false negatives compared to FilmArray Gastrointestinal Panel; all four samples were confirmed as negative by BD MAX Extended Enteric Bacterial Panel. There were fourteen (14) false positives compared to FilmArray Gastrointestinal Panel; these samples were not confirmed as positives by BD MAX Extended Enteric Bacterial Panel.

Table 37. *Cryptosporidium* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	8 / 10 *	80.00	44.39–97.48	8 / 8	100.00	63.06–100.00
	NPA	2063 / 2064*	99.95	99.73–100.00	2065 / 2067*	99.90	99.65–99.99
Retrospective	PPA	9 / 9	100.00	66.37–100.00	9 / 9	100.00	66.37–100.00
	NPA	207 / 209 *	99.04	96.59–99.88	207 / 209	99.04	96.59–99.88
Contrived	PPA	58 / 58	100.00	93.84–100.00	N/A	N/A	N/A

* There were two (2) false negatives compared to FilmArray Gastrointestinal Panel; the two samples were confirmed as negative by PCR-BDS assay. There were three (3) false positives compared to FilmArray Gastrointestinal Panel; none of these samples were confirmed as positive by PCR-BDS assay.

Table 38. *Cyclospora cayetanensis* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	23 / 24 *	95.83	78.88–99.89	23 / 24	95.83	78.88–99.89
	NPA	2050 / 2050	100.00	99.82–100.00	2050 / 2050	100.00	99.82–100.00
Retrospective	PPA	2 / 2	100.00	15.81–100.00	2 / 2	100.00	15.81–100.00
	NPA	216 / 216	100.00	98.31–100.00	216 / 216	100.00	98.31–100.00

Table 38. *Cyclospora cayetanensis* – Summary of Clinical Performance Results (continued)

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Contrived	PPA	56 / 56	100.00	93.62–100.00	N/A	N/A	N/A

* There was 1 false negative compared to FilmArray Gastrointestinal Panel; this sample was not further investigated by resolution testing. There were no false positive results in the performance comparison with FilmArray Gastrointestinal Panel.

Table 39. *Entamoeba histolytica* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	0 / 0	N/A	N/A	0 / 0	N/A	N/A
	NPA	2074 / 2074	100.00	99.82–100.00	2074 / 2074	100.00	99.82–100.00
Retrospective	PPA	0 / 0	N/A	N/A	0 / 0	N/A	N/A
	NPA	218 / 218	100.00	98.32–100.00	218 / 218	100.00	98.32–100.00
Contrived	PPA	69 / 70	98.57	92.30–99.96	N/A	N/A	N/A

Table 40. *Giardia lamblia* – Summary of Clinical Performance Results

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Prospective	PPA	12 / 20 *	60.00	36.05–80.88	12 / 12	100.00	73.54–100.00
	NPA	2049 / 2054*	99.76	99.43–99.92	2057 / 2062	99.76	99.44–99.92

Table 40. Giardia lamblia – Summary of Clinical Performance Results (continued)

Samples Group	Agreement type	Fraction	%	95% CI (%)	Post-Discordant Results Resolution		
					Fraction	%	95% CI (%)
Retrospective	PPA	21 / 26 *	80.77	60.65–93.45	21 / 21	100.00	83.89–100.00
	NPA	192 / 192*	100.00	98.10–100.00	197 / 197	100.00	98.14–100.00
Contrived	PPA	56 / 56 *	100.00	93.62	N/A	N/A	N/A

* There were thirteen (13) false negatives compared to FilmArray Gastrointestinal Panel; of these thirteen (13) were confirmed as negatives when compared with targeted PCR followed by BDS. There were five (5) false positives compared to FilmArray Gastrointestinal Panel; of these none were confirmed as positive when compared with targeted PCR followed by BDS.

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP / (TP+FN)	%	Lower	Upper	TN / (TN+FP)	%	Lower	Upper
Viruses	Adenovirus F40/F41	Clinical specimens	9/9	100.00	66.37	100.00	2283 / 2284	99.96	99.76	100.00
		Contrived specimens	68/70	97.14	90.06	99.65	N/A	N/A	N/A	N/A
		Total specimens	77/79	97.47	91.15	99.69	2283 / 2284	99.96	99.76	100.00
	Astrovirus	Clinical specimens	13/14	92.86	66.13	99.82	2278 / 2278	100.00	99.84	100.00
		Contrived specimens	67/68	98.53	92.08	99.96	N/A	N/A	N/A	N/A
		Total specimens	80/82	97.56	91.47	99.70	2278 / 2278	100.00	99.84	100.00
	Norovirus GI/GII	Clinical specimens	69/73	94.52	86.56	98.49	2217 / 2218	99.95	99.75	100.00
		Contrived specimens	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		Total specimens	69/73	94.52	86.56	98.49	2217 / 2218	99.95	99.75	100.00
Rotavirus A		Clinical specimens	34/36	94.44	81.34	99.32	2253 / 2256	99.87	99.61	99.97
		Contrived specimens	69/70	98.57	92.30	99.96	N/A	N/A	N/A	N/A
		Total specimens	103/106	97.17	91.95	99.41	2253 / 2256	99.87	99.61	99.97

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI (continued)

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP/(TP+FN)	%	Lower	Upper	TN/(TN+FP)	%	Lower	Upper
Sapovirus		Clinical specimens	15/15	100.00	78.20	100.00	2277 / 2278	99.96	99.76	100.00
		Contrived specimens	69/69	100.00	94.79	100.00	N/A	N/A	N/A	N/A
		Total specimens	84/84	100.00	95.70	100.00	2277 / 2278	99.96	99.76	100.00
Campylobacter		Clinical specimens	146/146	100.00	97.51	100.00	2144 / 2148	99.81	99.52	99.95
		Contrived specimens	45/46	97.83	88.47	99.94	N/A	N/A	N/A	N/A
		Total specimens	191/192	99.48	97.13	99.99	2144 / 2148	99.81	99.52	99.95

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI (continued)

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP/ (TP+FN)	%	Lower	Upper	TN/(TN+FP)	%	Lower	Upper
Bacteria	<i>Clostridium difficile</i> toxin A/B	Clinical specimens	234/245	95.51	92.11	97.74	2049 / 2052	99.85	99.57	99.97
		Contrived specimens	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		Total specimens	234/245	95.51	92.11	97.74	2049 / 2052	99.85	99.57	99.97
	Enterotoaggre- gative <i>E. coli</i> (EAEC)	Clinical specimens	83/95	87.37	78.97	93.30	2193 / 2198	99.77	99.47	99.93
		Contrived specimens	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		Total specimens	83/95	87.37	78.97	93.30	2193 / 2198	99.77	99.47	99.93
	Enteropathogenic <i>E. coli</i> (EPEC)	Clinical specimens	237 / 242	97.93	95.24	99.33	1992 / 1997	99.75	99.42	99.92
		Contrived specimens	0/0	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		Total specimens	237 / 242	97.93	95.24	99.33	1992 / 1997	99.75	99.42	99.92
	Enterotoxigenic <i>E. coli</i> (ETEC) lt/st	Clinical specimens	59/62	95.16	86.50	98.99	2231 / 2232	99.96	99.75	100.00
		Contrived specimens	43/43	100.00	91.78	100.00	N/A	N/A	N/A	N/A
		Total specimens	102/105	97.14	91.88	99.41	2231 / 2232	99.96	99.75	100.00

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI (continued)

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP / (TP+FN)	%	Lower	Upper	TN / (TN+FP)	%	Lower	Upper
<i>Shigella</i> / Enteroinvasive <i>E. coli</i> (EIEC)		Clinical specimens	36/37	97.30	85.84	99.93	2256/2256	100.00	99.82	100.00
		Contrived specimens	69/69	100.00	94.79	100.00	N/A	N/A	N/A	N/A
		Total specimens	105/106	99.06	94.86	99.98	2256 / 2256	100.00	99.84	100.00
Shiga-like toxin <i>E. coli</i> (STEC) <i>stx1</i> / <i>stx2</i> *		Clinical specimens	40 / 45	88.89	75.95	96.29	2243 / 2248	99.78	99.38	99.93
		Contrived specimens	200/200	100.00	98.17	100.00	N/A	N/A	N/A	N/A
		Total specimens	240 / 245	97.96	95.30	99.33	2243 / 2248	99.78	99.38	99.93
<i>E. coli</i> O157		Clinical specimens	2/2	100.00	15.81	100.00	38/38	100.00	90.75	100.00
		Contrived specimens	67/69	97.10	89.92	99.65	N/A	N/A	N/A	N/A
		Total specimens	69/71	97.18	90.19	99.66	38/38	100.00	90.75	100.00
<i>Plesiomonas shigelloides</i>		Clinical specimens	8/8	100.00	63.06	100.00	2280 / 2284	99.82	99.55	99.95
		Contrived specimens	67/68	98.53	92.08	99.96	N/A	N/A	N/A	N/A
		Total specimens	75/76	98.68	92.89	99.97	2280 / 2284	99.82	99.55	99.95

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI (continued)

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP/(TP+FN)	%	Lower	Upper	TN/(TN+FP)	%	Lower	Upper
<i>Salmonella</i>		Clinical specimens	71/71	100.00	94.94	100.00	2221 / 2223	99.91	99.68	99.99
		Contrived specimens	33/33	100.00	89.42	100.00	N/A	N/A	N/A	N/A
		Total specimens	104/104	100.00	96.52	100.00	2221 / 2223	99.91	99.68	99.99
<i>Vibrio cholerae</i>		Clinical specimens	2/2	100.00	15.81	100.00	2290 / 2290	100.00	99.84	100.00
		Contrived specimens	67/70	95.71	87.98	99.11	N/A	N/A	N/A	N/A
		Total specimens	69/72	95.83	88.30	99.13	2290 / 2290	100.00	99.84	100.00
<i>Vibrio parahaemolyticus</i>		Clinical specimens	3/4	75.00	19.41	99.37	2287 / 2288	99.96	99.76	100.00
		Contrived specimens	70/70	100.00	94.87	100.00	N/A	N/A	N/A	N/A
		Total specimens	73/74	98.65	92.70	99.97	2287 / 2288	99.96	99.76	100.00
<i>Vibrio vulnificus</i>		Clinical specimens	0/0	N/A	N/A	N/A	2292 / 2292	100.00	99.84	100.00
		Contrived specimens	69/69	100.00	94.79	100.00	N/A	N/A	N/A	N/A
		Total specimens	69/69	100.00	94.79	100.00	2292 / 2292	100.00	99.84	100.00

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI (continued)

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP/(TP+FN)	%	Lower	Upper	TN/(TN+FP)	%	Lower	Upper
<i>Yersinia enterocolitica</i>		Clinical specimens	51/51	100.00	93.02	100.00	2228 / 2242	99.38	98.95	99.66
		Contrived specimens	68/69	98.55	92.19	99.96	N/A	N/A	N/A	N/A
		Total specimens	119/120	99.17	95.44	99.98	2228 / 2242	99.38	98.95	99.66

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI (continued)

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP / (TP+FN)	%	Lower	Upper	TN / (TN+FP)	%	Lower	Upper
Parasites	<i>Cryptosporidium</i> spp.	Clinical specimens	17 / 17	100.00	80.49	100.00	2272 / 2275	99.87	99.61	99.97
		Contrived specimens	58/58	100.00	93.84	100.00	N/A	N/A	N/A	N/A
		Total specimens	75 / 75	100.00	95.20	100.00	2272 / 2275	99.87	99.61	99.97
	<i>Cyclospora cayetanensis</i>	Clinical specimens	25/26	96.15	80.36	99.90	2266 / 2266	100.00	99.84	100.00
		Contrived specimens	56/56	100.00	93.62	100.00	N/A	N/A	N/A	N/A
		Total specimens	81/82	98.78	93.39	99.97	2266 / 2266	100.00	99.84	100.00
	<i>Entamoeba histolytica</i>	Clinical specimens	0/0	N/A	N/A	N/A	2292 / 2292	100.00	99.84	100.00
		Contrived specimens	69/70	98.57	92.30	99.96	N/A	N/A	N/A	N/A
		Total specimens	69/70	98.57	92.30	99.96	2292 / 2292	100.00	99.84	100.00
	<i>Giardia lamblia</i>	Clinical specimens	33/33	100.00	89.42	100.00	2254 / 2259	99.78	99.48	99.93
		Contrived specimens	56/56	100.00	93.62	100.00	N/A	N/A	N/A	N/A

Table 41. Summary of Clinical Study Results for all clinical specimens (prospective and retrospective), contrived samples and total combined, including the exact binomial two-sided 95% CI (continued)

Pathogen Type	Target	Sample Type	Sensitivity (PPA)		Specificity (NPA)					
			Fraction		95% CI		Fraction		95% CI	
			TP/(TP+FN)	%	Lower	Upper	TN/(TN+FP)	%	Lower	Upper
		Total specimens	89 / 89	100.00	95.94	100.00	2254 / 2259	99.78	99.48	99.93

*Note: The differentiation of *stx1* and *stx2* toxin genes from Shiga-like toxin-producing *E. coli* (STEC) was substantiated during the clinical evaluation of contrived specimens. Contrived specimens for STEC (*stx1*/*stx2*) evaluation were spiked with the following strains and toxinotypes: ZeptoMetrix #0801748 (*stx1*+), SSI #95211 (*stx2a*+) and ZeptoMetrix #0801622 (*stx1*+, *stx2*+). In total 134 and 135 contrived specimens were evaluated for STEC *stx1* and STEC *stx2* analytes, respectively, showing both a 100 detection rate. Analytical Reactivity studies evaluated additional STEC *stx1*-carrier and *stx2*-carrier strains (see Tables 10m-o).

Troubleshooting Guide

This troubleshooting guide may be helpful in solving any problems that may arise. For more information, see also the Frequently Asked Questions page at our Technical Support Center: www.qiagen.com/FAQ/FAQList.aspx (for contact information, visit www.qiagen.com). The scientists in QIAGEN Technical Services are always happy to answer any questions you may have about either the information and/or protocols in this handbook or sample and assay technologies (for contact information, visit www.qiagen.com).

Additional information about specific QIAstat-Dx Gastrointestinal Panel 2 error codes and messages can be found in Table 42:

Table 42. Information about specific QIAstat-Dx Gastrointestinal Panel 2 error codes and messages

Error Code	Error message displayed
0x02C9	Cartridge execution failure: Sample concentration too high.
0x032D	Please repeat by loading 100 microliters of the sample in a new cartridge (per IFU explanation).
0x0459	
0x045A	
0x04BF	
0x0524	
0x058B	
0x05E9	
0x0778	
0x077D	
0x14023	

When the sample concentration is too high and the test must be repeated by loading 100 µL, follow the workflow detailed in the of this document.

Symbols

The following symbols appear in the instructions for use or on the packaging and labeling:

Symbol	Symbol definition
 <N>	Contains reagents sufficient for <N> reactions
	Use by
	This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number (i.e., component labeling)
	Global Trade Item Number
	Unique Device Identifier
	Contains

Symbol**Symbol definition**

Component



Number



Gastrointestinal application

R_n

R is for revision of the Instructions for Use and n is the revision number



Temperature limitation



Manufacturer



Consult instructions for use



Protect from light



Do not reuse



Caution, consult accompanying documents

Symbol

Symbol definition



Serial number



Do not use if package is damaged



Flammable, risk of fire



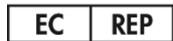
Corrosive, risk of chemical burn



Health Hazard, risk of sensitization, carcinogenicity



Risk of harm



Authorized representative in the European Community

Contact Information

For technical assistance and more information, please see our Technical Support Center at support.qiagen.com.

Appendices

Appendix A: Installing the Assay Definition File

The Assay Definition File (ADF) of the QIAstat-Dx Gastrointestinal Panel 2 must be installed on the QIAstat-Dx Analyzer 1.0 prior to testing with QIAstat-Dx Gastrointestinal Panel 2 Cartridges.

Note: Whenever a new version of the QIAstat-Dx Gastrointestinal Panel 2 assay is released, the new QIAstat-Dx Gastrointestinal Panel 2 Assay Definition File must be installed prior to testing.

The Assay Definition File (*.asy file type) is available at www.qiagen.com

The Assay Definition file (*.asy file type) must be saved onto a USB drive prior to installation on the QIAstat-Dx Analyzer 1.0. This USB drive must be formatted with a FAT32 file system.

To import an ADF from the USB to the QIAstat-Dx Analyzer 1.0, proceed with the following steps:

1. Insert the USB stick containing the Assay Definition File into one of the USB ports on the QIAstat-Dx Analyzer 1.0.
2. Press the the **Options** button and then select **Assay Management**. The Assay Management screen appears in the Content area of the display (Figure 21).

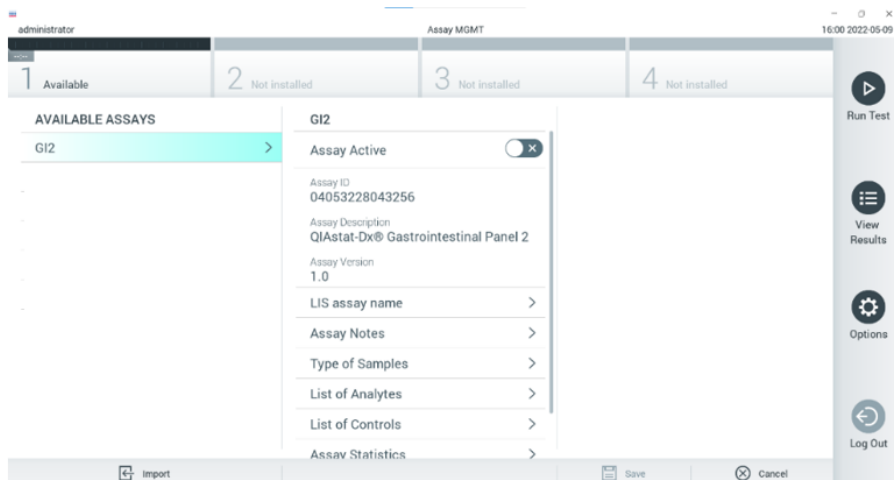


Figure 21. Assay Management screen.

3. Press the Import icon in the bottom left of the screen (Figure 21).
4. Select the file corresponding to the assay to be imported from the USB drive.
A dialog box will appear to confirm upload of the file.
5. A dialog box may appear to override the current version by a new one. Press **Yes** to override (Figure 22).

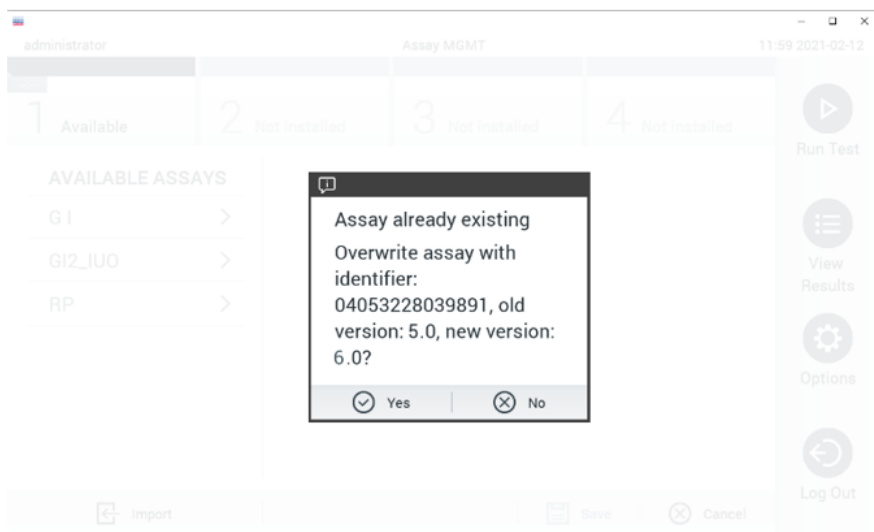


Figure 22. Dialog box that appears when upgrading the ADF version.

6. The assay becomes active by selecting **Assay Active** (Figure 23).

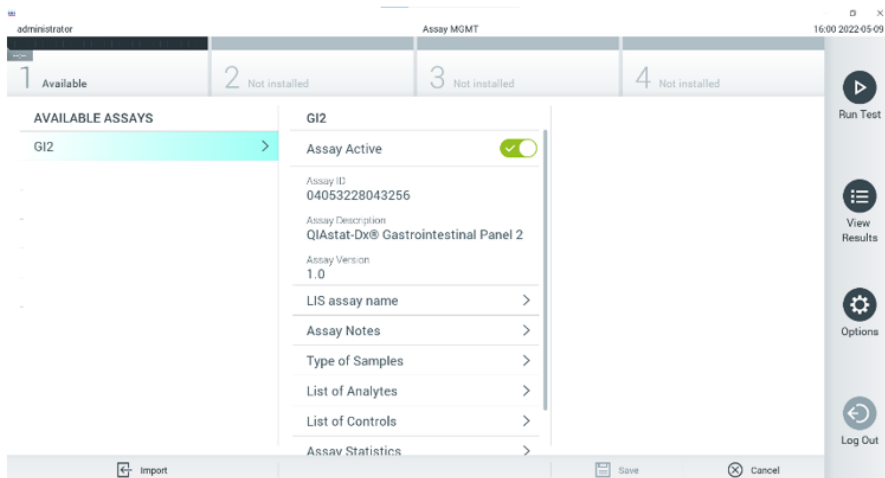


Figure 23. Activating the assay.

7. Assign the active assay to the user by pressing the **Options** button and then the **User Management** button. Select the user who should be allowed to run the assay. If it is needed, this action can be repeated for every user created in the system. Next, select **Assign Assays** from the "User Options". Enable the assay and press the Save button (Figure 24).

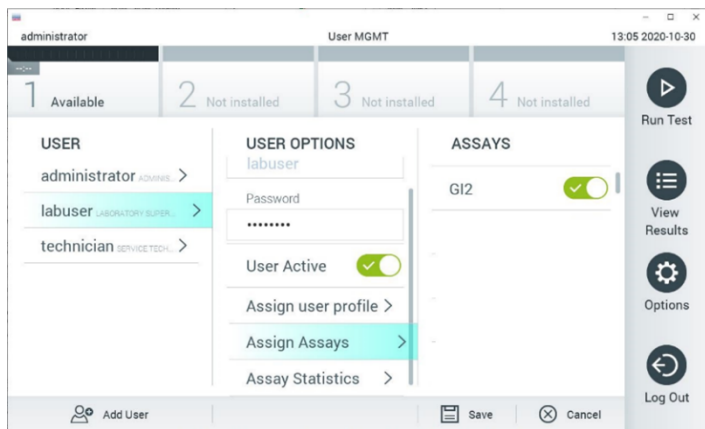


Figure 24. Assigning the active assay.

Appendix B: Glossary

Amplification curve: Graphical representation of the multiplex real-time RT-PCR amplification data.

Analytical Module (AM): The main QIAstat-Dx Analyzer 1.0 hardware module, in charge of executing tests on QIAstat-Dx Gastrointestinal Panel 2 Cartridges. It is controlled by the Operational Module. Several Analytical Modules can be connected to one Operational Module.

QIAstat-Dx Analyzer 1.0: The QIAstat-Dx Analyzer 1.0 consists of an Operational Module and an Analytical Module. The Operational Module includes elements that provide connectivity to the Analytical Module and enables user interaction with the QIAstat-Dx Analyzer 1.0. The Analytical Module contains the hardware and software for sample testing and analysis.

QIAstat-Dx Gastrointestinal Panel 2 Cartridge: A self-contained disposable plastic device with all pre-loaded reagents required for the complete execution of fully automated molecular assays for the detection of gastrointestinal pathogens.

IFU: Instructions For Use.

Main port: In the QIAstat-Dx Gastrointestinal Panel 2 Cartridge, inlet for transport medium liquid samples.

Nucleic acids: Biopolymers, or small biomolecules composed of nucleotides, which are monomers made of three components: a 5-carbon sugar, a phosphate group, and a nitrogenous base.

Operational Module (OM): The dedicated QIAstat-Dx Analyzer 1.0 hardware that provides the user interface for 1–4 Analytical Modules (AM).

PCR: Polymerase Chain Reaction.

IUO: For investigational use only

RT: Reverse Transcription.

Swab port: In the QIAstat-Dx Gastrointestinal Panel 2 Cartridge, inlet for dry swabs. The swab port is not used for the QIAstat-Dx Gastrointestinal Panel 2 assay.

User: A person who operates the QIAstat-Dx Analyzer 1.0/ QIAstat-Dx Gastrointestinal Panel 2 Cartridge in the intended way.

Appendix C: Additional instructions for use

In case cartridge execution failures corresponding to error codes (0x02C9, 0x032D, 0x0459, 0x045A, 0x04BF, 0x0524, 0x058B, 0x05E9, 0x0778, 0x077D, 0x14023) occur during the testing, the following error message will be displayed in the QIAstat-Dx Analyzer 1.0 screen after the run has finalized:

“Cartridge execution failure: Sample concentration too high. Please repeat by loading 100 microliters of the sample in a new cartridge (as per IFU explanation).”

In this case the test should be repeated using 100 µL of the same sample following equivalent testing procedures detailed in the “Procedure” section in the IFU adapted to 100 µL sample input volume:

1. Open the package of a new QIAstat-Dx Gastrointestinal Panel 2 Cartridge using the tear notches on the sides of the packaging.
2. Remove the QIAstat-Dx Gastrointestinal Panel 2 Cartridge from the packaging.
3. Manually write the sample information, or place a sample information label, on the top of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge. Make sure that the label is properly positioned and does not block the lid opening.
4. Place the QIAstat-Dx Gastrointestinal Panel 2 Cartridge flat on the clean work surface so that the barcode on the label faces upwards. Open the sample lid of the main port on the front of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge.
5. Thoroughly mix the stool in the transport medium, for example, by vigorously agitating the tube 3 times.
6. Open the tube with the sample to be tested. Use the supplied transfer pipette to draw up fluid. Draw the sample to the first fill line on the pipette (i.e., 100 µL).

Important: Do not draw air, mucus, or particles into the pipette. If air, mucus, or particles are drawn into the pipette, carefully expel the sample fluid in the pipette back into the sample tube and draw up fluid again.

7. Carefully transfer the sample into the main port of the QIAstat-Dx Gastrointestinal Panel 2 Cartridge using the supplied single-use transfer pipette (Figure 7).
8. Firmly close the lid of the main port until it clicks (Figure 8).

From this point proceed following the instructions described in the IFU.

Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx Gastrointestinal Panel 2	For 6 tests: 6 individually packaged QIAstat-Dx Gastrointestinal Panel 2 Cartridges and 6 individually packaged transfer pipettes	691412
Related Products		
QIAstat-Dx Analyzer 1.0	1 QIAstat-Dx Analytical Module, 1 QIAstat-Dx Operational Module, and related hardware and software to run molecular diagnostic QIAstat-Dx assay cartridges	9002824

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Document Revision History

Revision	Description
Rev. 01, October 2026	Initial release

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