September 2020

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

Version 1

For in vitro diagnostic use

IVD

CE

REF 691411

QIAGEN GmbH, QIAGEN Strasse 1, D-40724 Hilden

R2

Sample to Insight

QIAGEN

Contents

Intended Use

The QIAstat-Dx® Gastrointestinal Panel is a qualitative test intended for analyzing unpreserved stool samples in Cary-Blair transport medium taken from patients suspected of gastrointestinal infection for the presence of viral, parasitic or bacterial nucleic acids. The assay is designed for use with the QIAstat-Dx Analyzer 1.0 for integrated nucleic acid extraction and multiplex real-time RT-PCR detection.

The following pathogens can be detected and differentiated with the QIAstat-Dx Gastrointestinal Panel: *Entamoeba histolytica*, *Cryptosporidium* spp., *Giardia lamblia*, *Cyclospora cayetanensis*, *Vibrio vulnificus*, *Vibrio parahaemolyticus*, *Vibrio cholerae*, *Campylobacter* spp. (*Campylobacter jejuni*, *Campylobacter upsaliensis*, *Campylobacter coli*), *Salmonella* spp., *Clostridium difficile* (*tcdA*/*tcdB*), *Yersinia enterocolitica*, Enterotoxigenic *E. coli* (ETEC), Enteropathogenic *E. coli* (EPEC), Enteroaggregative *E. coli* (EAEC), Shiga-like toxin-producing *E. coli* (STEC [enterohemorrhagic *E. coli*]), Shiga toxin-producing *E. coli* (STEC) serotype O157:H7, Enteroinvasive *E. coli* (EIEC)/*Shigella*, *Plesiomonas shigelloides*, Human Adenovirus F40/F41, Norovirus GI, Norovirus GII, Rotavirus A, Astrovirus and Sapovirus GI, GII, GIV and GV.

The results from the QIAstat-Dx Gastrointestinal Panel must be interpreted within the context of all relevant clinical and laboratory findings.

Assay performance characteristics have been established only for individuals who have shown gastrointestinal symptoms.

The QIAstat-Dx Gastrointestinal Panel is intended for professional use only and is not intended for self-testing.

The QIAstat-Dx Gastrointestinal Panel is intended for in vitro diagnostic use.

Summary and Explanation

QIAstat-Dx Gastrointestinal Panel Cartridge description

The QIAstat-Dx Gastrointestinal Panel Cartridge is a disposable plastic device that allows performance of fully automated molecular assays for the detection of gastrointestinal pathogens. Main features of the QIAstat-Dx Gastrointestinal Panel 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 Cartridge. The user does not need to come in contact with and/or manipulate any reagents. During the test, reagents are handled within the cartridge in the Analytical Module of the QIAstat-Dx Analyzer 1.0 by pneumatically-operated microfluidics and make no direct contact with the actuators. 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 QIAstat-Dx Gastrointestinal Panel Cartridge containing the sample is introduced into the QIAstat-Dx Analyzer 1.0, the following assay steps occur automatically:

- Resuspension of Internal Control
- Cell lysis using mechanical and chemical means
- Membrane-based nucleic acid purification
- Mixing of the purified nucleic acid with lyophilized master mix reagents
- Transfer of defined aliquots of eluate/master mix to different reaction chambers
- Performance of multiplex real-time RT-PCR testing within each reaction chamber.

  Note: An increase in fluorescence, indicating detection of the target analyte, is detected directly within each reaction chamber.

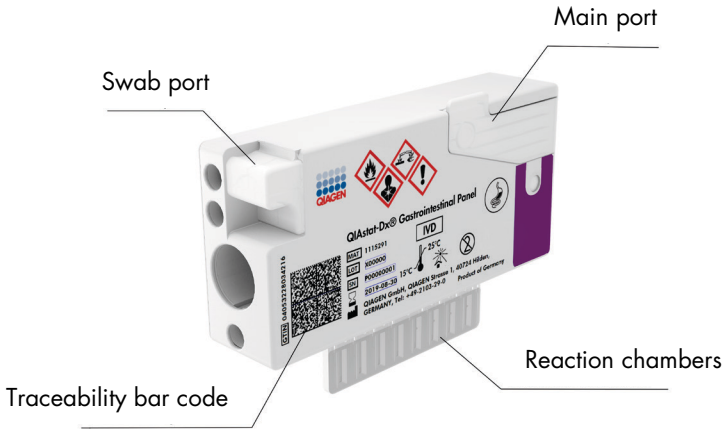

Figure 1. Layout of the QIAstat-Dx Gastrointestinal Panel Cartridge and its features.

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

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 Cartridge allows detection and differentiation of 24 parasite, viral and bacterial pathogens that cause gastrointestinal symptoms. Testing requires a small sample volume and minimal hands-on time, and the results are available in approximately one hour.

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

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

Pathogen	Classification (genome type)
Entamoeba histolytica	Parasite (DNA)
Cryptosporidium spp.	Parasite (DNA)
Giardia lamblia	Parasite (DNA)
Cyclospora cayetanensis	Parasite (DNA)
Vibrio vulnificus	Bacterium (DNA)
Vibrio parahaemolyticus	Bacterium (DNA)
Vibrio cholerae	Bacterium (DNA)
Campylobacter spp. (*C. jejuni, C. upsaliensis, C. coli*)	Bacterium (DNA)
Salmonella spp.	Bacterium (DNA)
Clostridium difficile (*tcdA*/ *tcdB*)	Bacterium (DNA)
Yersinia enterocolitica	Bacterium (DNA)
Enteroaggregative *E. coli* (EAEC)	Bacterium (DNA)
Enterotoxigenic *E. coli* (ETEC)	Bacterium (DNA)
Shiga-like toxin-producing *E. coli* (STEC)	Bacterium (DNA)
Shiga toxin-producing *E. coli* (STEC) serotype O157:H7	Bacterium (DNA)
Enteropathogenic *E. coli* (EPEC)	Bacterium (DNA)
Enteroinvasive *E. coli* (EIEC)/ *Shigella*	Bacterium (DNA)
Plesiomonas shigelloides	Bacterium (DNA)
Human Adenovirus F40/F41	Adenovirus (DNA)
Norovirus GI	Calicivirus (RNA)
Norovirus GII	Calicivirus (RNA)
Rotavirus A	Reovirus (RNA)
Astrovirus	Astrovirus (RNA)
Sapovirus GI, GII, GIV, GV	Calicivirus (RNA)

Principle of the Procedure

Description of the process

Diagnostic tests with the QIAstat-Dx Gastrointestinal Panel 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. Samples are collected and loaded manually into the QIAstat-Dx Gastrointestinal Panel Cartridge:

A transfer pipette is used for dispensing liquid sample into the main port (Figure 2).

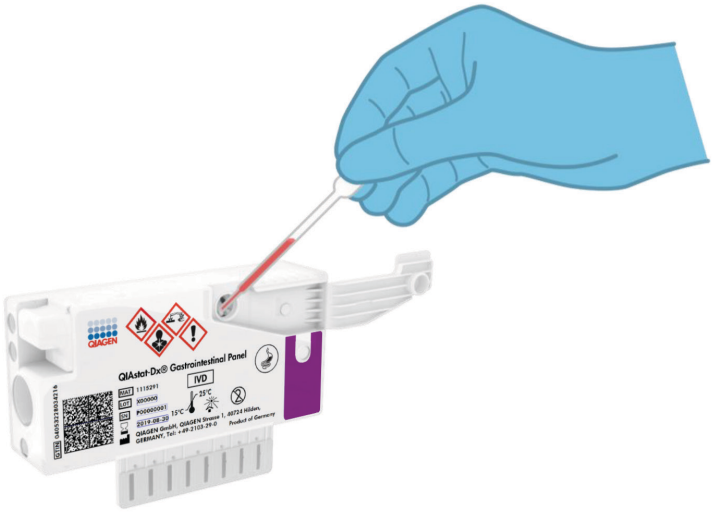

Figure 2. Dispensing liquid sample into the main port.

Sample collection and cartridge loading

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

The following steps are involved and must be executed by the user:

1. A stool sample is collected.
2. Sample is placed and resuspended in Cary-Blair transport medium following the manufacturer's instructions.

   Note: The optimal concentration of 25–100 mg of unpreserved stool per ml of Cary-Blair transport medium should be used. The maximum concentration that can be used is 250 mg of unpreserved stool per ml of Cary-Blair transport medium.
3. The sample information is manually written on or a sample label is affixed to the top of a QIAstat-Dx Gastrointestinal Panel Cartridge.
4. Liquid sample (stool resuspended in Cary-Blair transport medium) is loaded manually into the QIAstat-Dx Gastrointestinal Panel Cartridge:
   - 200 µl of the sample is transferred into the QIAstat-Dx Gastrointestinal Panel Cartridge using a transfer pipette.

     Note: The user must perform a visual check of the sample inspection window to confirm that the liquid sample has been loaded (Figure 3, next page).

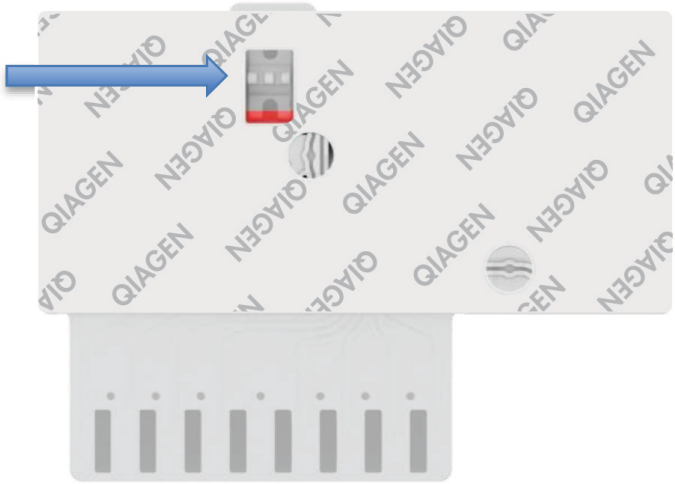

Figure 3. Sample inspection window (blue arrow).

5. The sample bar code and QIAstat-Dx Gastrointestinal Panel Cartridge bar code are scanned in the QIAstat-Dx Analyzer 1.0.
6. The QIAstat-Dx Gastrointestinal Panel Cartridge is introduced into the QIAstat-Dx Analyzer 1.0.
7. The test is started on the QIAstat-Dx Analyzer 1.0.

Sample preparation, nucleic acid amplification and detection

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 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 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 Cartridge.
4. The mixture of sample and PCR reagents is dispensed into the QIAstat-Dx Gastrointestinal Panel Cartridge PCR chambers, which contain lyophilized, 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 **Catalog no.** **Number of tests**	 **691411** **6**
QIAstat-Dx Gastrointestinal Panel Cartridge*	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 Cartridge.

Materials Required but Not Provided

The QIAstat-Dx Gastrointestinal Panel 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 1.2 or higher*
- *QIAstat-Dx Analyzer 1.0 User Manual* (for use with software version 1.2 or higher)
- QIAstat-Dx latest Assay Definition File software for Gastrointestinal Panel installed in the Operational Module

Warnings and Precautions

For in vitro diagnostic use

The QIAstat-Dx Gastrointestinal Panel 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, consult the appropriate safety data sheets (SDSs). These are available online in PDF format at **www.qiagen.com/safety** where you can find, view and print the SDS for each QIAGEN® kit and kit component.

* DiagCORE® Analyzer instruments running QIAstat-Dx software version 1.2 or higher can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

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 (United States of America)
- 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 Cartridges and transfer pipettes according to the appropriate regulations.

The QIAstat-Dx Gastrointestinal Panel 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 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**).

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

QIAstat-Dx Gastrointestinal Panel Cartridge

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.

Reagent Storage and Handling

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

Specimen Handling, Storage and Preparation

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 hours at 15–25°C
- Refrigerated up to 3 days at 2–8°C
- Frozen up to 24 days at –15 to –25°C
- Frozen up to 24 days at –70 to –80°C

Procedure

Internal Control

The QIAstat-Dx Gastrointestinal Panel Cartridge includes a full process Internal Control, which is titered *Schizosaccharomyces pombe*. *Schizosaccharomyces pombe* is a yeast (fungi) that is included in the cartridge in dried form and is rehydrated upon sample loading. This Internal Control material verifies all steps of the analysis process, including sample homogenization, lysis of viral and cellular structures (by means of chemical and mechanical disruption), nucleic acid purification, reverse transcription and real-time PCR.

A positive signal for the Internal Control indicates that all processing steps performed by the QIAstat-Dx Gastrointestinal Panel Cartridge were successful.

A negative signal of the Internal Control does not negate any positive results for detected and identified targets, but it does invalidate all negative results in the analysis. Therefore, the test should be repeated if the Internal Control signal is negative.

Protocol: Unpreserved stool samples in Cary-Blair transport medium

Sample collection, transport and storage

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

Loading a sample into the QIAstat-Dx Gastrointestinal Panel Cartridge

1. Open the package of a QIAstat-Dx Gastrointestinal Panel Cartridge using the tear notches on the sides of the packaging (Figure 4).

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

Figure 4. Opening the QIAstat-Dx Gastrointestinal Panel Cartridge.

2. Remove the QIAstat-Dx Gastrointestinal Panel Cartridge from the packaging and position it so that the bar code 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 Cartridge. Make sure that the label is properly positioned and does not block the lid opening (Figure 5).

Figure 5. Sample information placement on top of QIAstat-Dx Gastrointestinal Panel Cartridge.

4. Open the sample lid of the main port on the front of the QIAstat-Dx Gastrointestinal Panel Cartridge (Figure 6, next page).

   IMPORTANT: Do not flip the QIAstat-Dx Gastrointestinal Panel 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 Cartridge if it is agitated while the lid is open.

Figure 6. Opening the sample lid of main port.

5. Thoroughly mix the stool in the Cary-Blair transport medium, for example, by vigorously agitating the tube 3 times (Figure 7).

Figure 7. 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 to the second fill line on the pipette (i.e., 200 µl) (Figure 8).

   IMPORTANT: Do not draw air into the pipette. If air is drawn into the pipette, carefully expel the sample fluid in the pipette back into the sample tube and draw up fluid again.

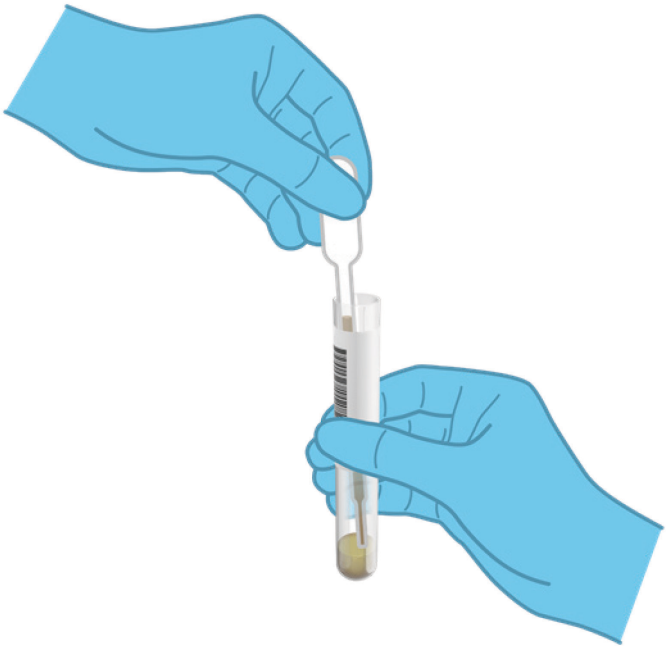

Figure 8. Drawing up sample into the supplied transfer pipette.

7. Carefully transfer 200 µl of sample into the main port of the QIAstat-Dx Gastrointestinal Panel Cartridge using the supplied single-use transfer pipette (Figure 9).

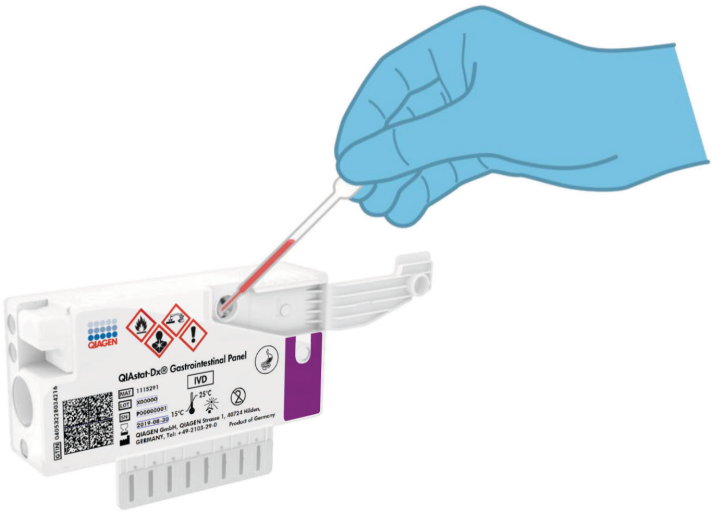

Figure 9. Transferring sample to main port of QIAstat-Dx Gastrointestinal Panel Cartridge.

8. Firmly close the lid of the main port until it clicks (Figure 10, next page).

Figure 10. 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 Cartridge (Figure 11, next page). A mixture of sample and silica beads should be observed.

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

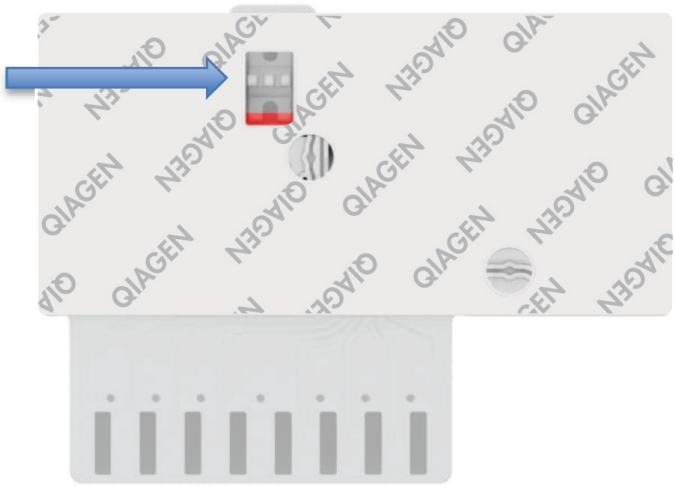

Figure 11. Sample inspection window (blue arrow).

Starting the QIAstat-Dx Analyzer 1.0

10. 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.

11. Wait until the **Main** screen appears and the QIAstat-Dx Analyzer 1.0 status indicators turn green and stop blinking.

12. 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 user name/password will be required and the **Main** screen will appear.

13. If the Assay Definition File software has not been installed on the QIAstat-Dx Analyzer 1.0, follow the installation instructions prior to running the test (see Appendix A: Installing the Assay Definition File, page 72, for additional information).

Running a test

14. Press the **Run Test** button in the top right corner of the touchscreen of the QIAstat-Dx Analyzer 1.0.
15. When prompted, scan the sample ID bar code on the Cary-Blair transport medium containing the sample, or scan the specimen information bar code located on the top of the QIAstat-Dx Gastrointestinal Panel Cartridge (see step 3), using the integrated front bar code reader of the QIAstat-Dx Analyzer 1.0 (Figure 12, next page).

    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 the QIAstat-Dx Analyzer 1.0 appear in the **Instructions Bar** at the bottom of the touchscreen.

Figure 12. Scanning sample ID bar code.

16. When prompted, scan the bar code of the QIAstat-Dx Gastrointestinal Panel Cartridge to be used (Figure 13, next page). The QIAstat-Dx Analyzer 1.0 automatically recognizes the assay to be run based on the cartridge bar code.

    Note: The QIAstat-Dx Analyzer 1.0 will not accept QIAstat-Dx Gastrointestinal Panel Cartridges with lapsed expiration dates, previously used cartridges or cartridges for assays that have not been installed on the unit. An error message will be shown in these cases and the QIAstat-Dx Gastrointestinal Panel Cartridge will be rejected. Refer to the *QIAstat-Dx Analyzer 1.0 User Manual* for further details on how to install assays.

Figure 13. Scanning QIAstat-Dx Gastrointestinal Panel Cartridge bar code.

17. 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.
18. 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 14).

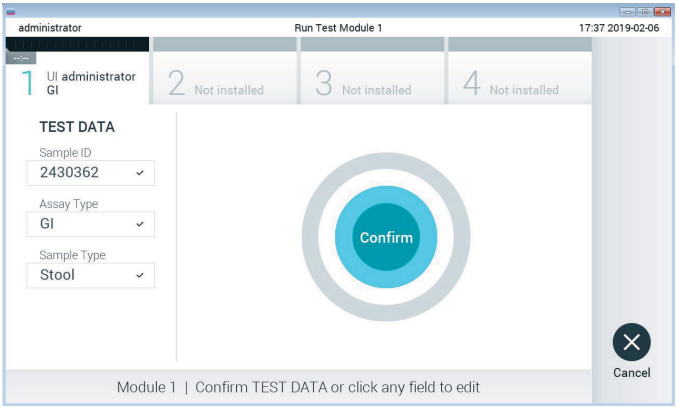

Figure 14. Confirming data entry.

19. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Gastrointestinal Panel Cartridge are firmly closed. When the cartridge entrance port on the top of the QIAstat-Dx Analyzer 1.0 automatically opens, insert the QIAstat-Dx Gastrointestinal Panel Cartridge with the bar code facing to the left and the reaction chambers facing down (Figure 15).

    Note: There is no need to push the QIAstat-Dx Gastrointestinal Panel Cartridge into the QIAstat-Dx Analyzer 1.0. Position it correctly into the cartridge entrance port and the QIAstat-Dx Analyzer 1.0 will automatically move the cartridge into the Analytical Module.

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

Figure 15. Inserting QIAstat-Dx Gastrointestinal Panel Cartridge into QIAstat-Dx Analyzer 1.0.

20. Upon detecting the QIAstat-Dx Gastrointestinal Panel 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: The QIAstat-Dx Analyzer 1.0 will not accept a QIAstat-Dx Gastrointestinal Panel 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: 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.

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

    Note: The lid of the cartridge entrance port will close automatically after 30 seconds if a QIAstat-Dx Gastrointestinal Panel Cartridge is not positioned in the port. If this occurs, repeat the procedure starting with step 18.

21. While the test is running, the remaining run time is displayed on the touchscreen.

22. After the test run is completed, the **Eject** screen will appear (Figure 16, next page) 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.

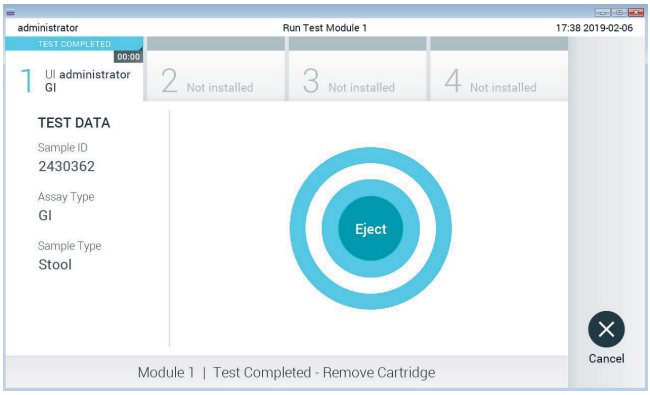

Figure 16. Eject screen display.

23. Press **Eject** on the touchscreen to remove the QIAstat-Dx Gastrointestinal Panel 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 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 Cartridges must be discarded. It is not possible to re-use cartridges for tests for which the execution was started but then subsequently cancelled by the operator, or for which an error was detected.

24. After the QIAstat-Dx Gastrointestinal Panel Cartridge has been ejected, the results **Summary** screen will appear. Refer to "Interpretation of Results", page 32, for further details. 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*.

Interpretation of Results

Viewing results

The QIAstat-Dx Analyzer 1.0 automatically interprets and saves test results. After ejecting the QIAstat-Dx Gastrointestinal Panel Cartridge, the results **Summary** screen is automatically displayed (Figure 17).

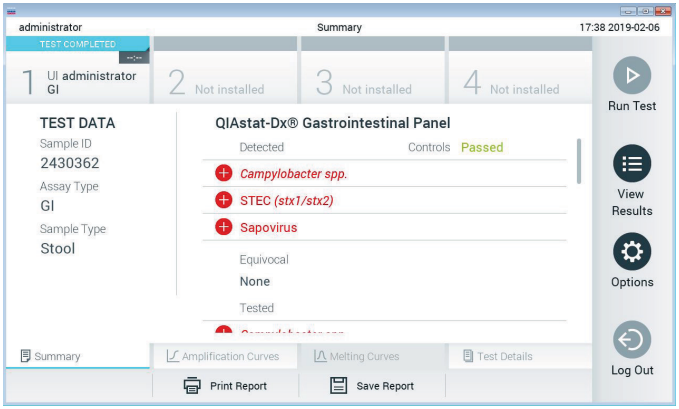

Figure 17. Results Summary screen example showing Test Data on the left panel and Test Summary in the main panel.

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. 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 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

To view test amplification curves of pathogens detected, press the **Amplification Curves** tab (Figure 18).

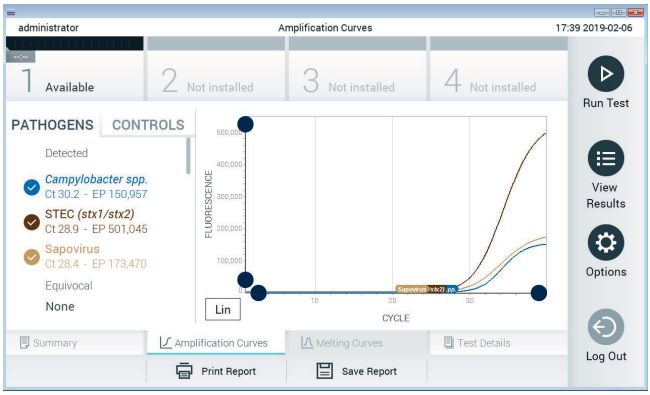

Figure 18. Amplification Curves screen (PATHOGENS tab).

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 on 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 C_T 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 19).

Figure 19. 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 20, next page):

- 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)
  - 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 C_T and endpoint fluorescence in the event of a positive signal
- Internal Control, with C_T and endpoint fluorescence

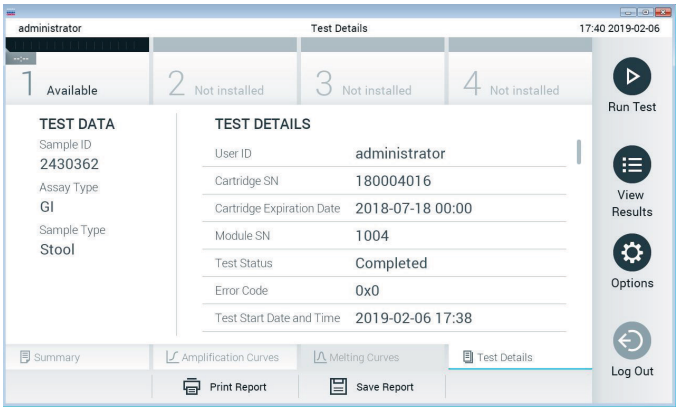

Figure 20. Example screen showing Test Data on the left panel and Test Details in the main panel.

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 21).

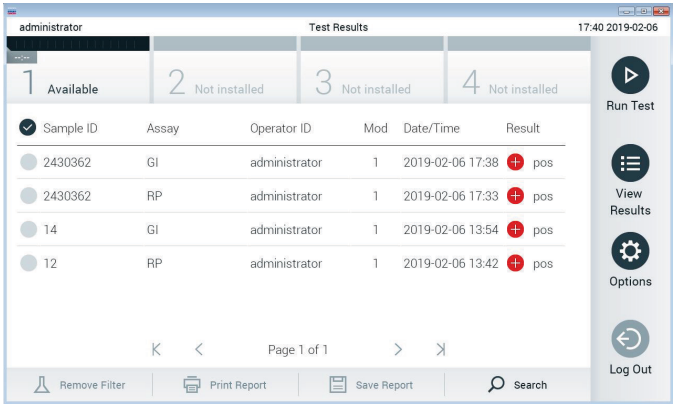

Figure 21. Example View Results screen.

The following information is available for every executed test (Figure 22):

- Sample ID
- Assay (name of test assay which is "GI" for Gastrointestinal Panel)
- 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], 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 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 circle** in the top row (Figure 22).

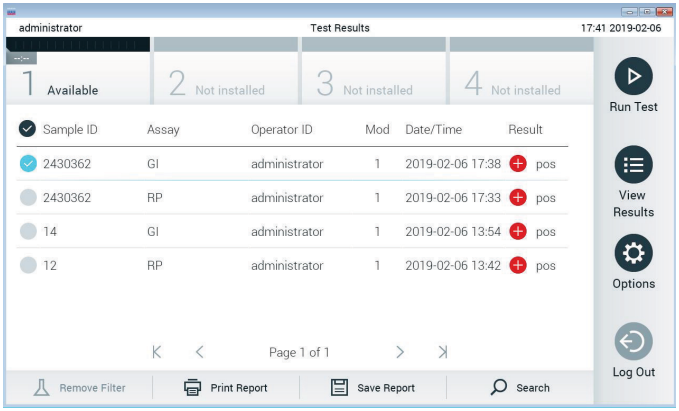

Figure 22. Example of selecting Test Results in the View Results screen.

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 test results

Outcome	Result	Description
Positive	pos	At least one pathogen is positive
Negative	neg	No analytes were detected
Failed	fail	The test failed because either an error occurred or the test was canceled by the user
Successful	suc	The test is either positive or negative, but the user does not have the access rights to view the test 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 format 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 search 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 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 T 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 format to a USB drive. The USB port is located on the front of the 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.

Result interpretation

A result for a gastrointestinal organism is interpreted as "Positive" when the corresponding PCR assay is positive, except for EPEC, STEC and STEC O157:H7. The result interpretation for EPEC, STEC and STEC O157:H7 follows the rationale explained in Table 3, below.

Table 3. Interpretation of EPEC, STEC and STEC O157:H7 results

EPEC result	STEC *stx1*/*stx2* result	STEC O157:H7 result	Description
Negative	Negative	Invalid	Enteropathogenic *E. coli* (EPEC) not detected and Shiga-like toxin-producing *E. coli* (STEC) *stx1*/*stx2* not detected. *E. coli* O157:H7 serotype result is not applicable when STEC is not detected.
Positive	Negative	Invalid	Enteropathogenic *E. coli* (EPEC) detected and Shiga-like toxin-producing *E. coli* (STEC) *stx1*/*stx2* not detected. *E. coli* O157:H7 serotype result is not applicable when STEC is not detected.
Invalid	Positive	Negative	EPEC result is not applicable (EPEC detection cannot be differentiated when STEC is detected). Shiga-like toxin-producing *E. coli* (STEC) *stx1*/*stx2* detected. STEC O157:H7 serotype not detected.
Invalid	Positive	Positive	EPEC result is not applicable (detection cannot be differentiated when STEC is detected). Shiga-like toxin-producing *E. coli* (STEC) *stx1*/*stx2* detected. STEC O157:H7 serotype detected.

Internal Control interpretation

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 QIAstat-Dx Gastrointestinal Panel Cartridge.

Quality Control

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

Limitations

- Results from the QIAstat-Dx Gastrointestinal Panel are not intended to be used as the sole basis for diagnosis, treatment or other patient management decisions.
- Positive results do not rule out co-infection with organisms not included in the QIAstat-Dx Gastrointestinal Panel. The agent detected may not be the definitive cause of the disease.
- Negative results do not preclude infection of the gastrointestinal tract. Not all agents of acute gastrointestinal infection are detected by this assay and sensitivity in some clinical settings may differ from that described in the package insert.
- A negative result with the QIAstat-Dx Gastrointestinal Panel does not exclude the infectious nature of the syndrome. Negative assay results may originate from several factors and their combinations, including sample handling mistakes, variation in the nucleic acid sequences targeted by the assay, infection by organisms not included in the assay, organism levels of included organisms that are below the limit of detection for the assay and use of certain medications, therapies or agents.
- The QIAstat-Dx Gastrointestinal Panel is not intended for testing of samples other than those described in these Instructions for Use. Test performance characteristics have been established only with unpreserved stool samples resuspended in Cary-Blair transport medium, from individuals with acute gastrointestinal symptoms.
- The QIAstat-Dx Gastrointestinal Panel is intended to be used in conjunction with standard of care culture for organism recovery, serotyping and/or antimicrobial susceptibility testing where applicable.

- The results from the QIAstat-Dx Gastrointestinal Panel must be interpreted by a trained healthcare professional within the context of all relevant clinical, laboratory and epidemiological findings.
- The QIAstat-Dx Gastrointestinal Panel can be used only with the QIAstat-Dx Analyzer 1.0.*
- The QIAstat-Dx Gastrointestinal Panel is a qualitative assay and does not provide a quantitative value for detected organisms.
- Parasitic, viral and bacterial nucleic acids may persist in vivo, even if the organism is not viable or infectious. Detection of a target marker does not imply that the corresponding organism is the causative agent of the infection or the clinical symptoms.
- Detection of viral, parasitic and bacterial nucleic acids depends on proper sample collection, handling, transportation, storage and loading into the QIAstat-Dx Gastrointestinal Panel Cartridge. Improper operations for any of the aforementioned processes can cause incorrect results, including false-positive or false-negative results.
- The assay sensitivity and specificity, for the specific organisms and for all organisms combined, are intrinsic performance parameters of a given assay and do not vary depending on prevalence. In contrast, both the negative and positive predictive values of a test result are dependent on the disease/organism prevalence. Please note that a higher prevalence favors the positive predictive value of a test result, while a lower prevalence favors the negative predictive value of a test result.

* DiagCORE Analyzer instruments running QIAstat-Dx software version 1.2 or higher can be used as an alternative to QIAstat-Dx Analyzer 1.0 instruments.

Performance Characteristics

Clinical performance

A clinical study was conducted with the objective to assess the performance of the QIAstat-Dx Gastrointestinal Panel assay for CE marking.

The study was designed as observational, retrospective, using left-over clinical samples obtained from subjects with signs and symptoms of a gastrointestinal infection. Participating site(s) were asked to test frozen retrospective samples, according to a protocol and site-specific instructions.

Eligible samples were unpreserved stool or stool in Cary-Blair obtained from patients suspected of gastrointestinal infections, presenting with a clinical gastrointestinal syndrome including any of diarrhea, vomiting, abdominal pain and/or fever as typical signs and symptoms.

One (1) hospital laboratory and the manufacturer site participated in the study.

A total of 361 clinical samples were tested by the participating hospital laboratory site and the manufacturer site, 235 and 126 samples respectively. The majority of the negative samples enrolled in the study were tested at the manufacturer site (88 samples). Samples had been previously tested with a variety of molecular methods, including the BD MAX® Enteric Parasite Panel (all parasites) Allplex® Gastrointestinal Panel assay (panels 1–3) and FilmArray® Gastrointestinal Panel assay. In case of discordant results, samples were retested with one of the above methods – majority by the FilmArray Gastrointestinal Panel assay – and the 2 out of 3 rule was applied: the result obtained by 2 methods was accepted as the true result. Prior to testing samples had been stored at –80 °C as stool in Cary-Blair medium.

All testing methods were performed according to the respective manufacturers' instructions.

Of the 361 samples enrolled, 5 samples were excluded from the study, resulting in 356 samples for evaluation and analysis. These 356 samples provided a total of 546 evaluable results. Of these results, the QIAstat-Dx Gastrointestinal Panel correctly detected 425 pathogens (true positive results), while 91 results were true negative. The QIAstat-Dx Gastrointestinal Panel failed to detect 9 pathogens (false negatives) while it detected 21 pathogens not found by any of the comparator methods (false positives). Of note is that 2 false positive results were in samples that were fully negative with the comparator methods.

Clinical Sensitivity or Positive Percent Agreement (PPA) was calculated as 100% x (TP/[TP + FN]). True positive (TP) indicates that both the QIAstat-Dx Gastrointestinal Panel and comparator(s) methods had a positive result for the organism and false negative (FN) indicates that the QIAstat-Dx Gastrointestinal Panel result was negative while the comparator resolution methods results were positive. Specificity or Negative Percent Agreement (NPA) was calculated as 100% x (TN/[TN + FP]). True negative (TN) indicates that both the QIAstat-Dx Gastrointestinal Panel and the comparator method had negative results and a false positive (FP) indicates that the QIAstat-Dx Gastrointestinal Panel result was positive but the comparator methods results were negative. For the calculation of the clinical specificity of the individual pathogens, the total available results were used with the concerning true and false positive organism results subtracted. The exact binomial two-sided 95% confidence interval was calculated for each point estimate.

The study clinical performance characteristics of the assay and its individual pathogens are shown in Table 5, next page.

Table 5. Clinical Sensitivity (PPA) and Specificity (NPA) and 95% confidence intervals for the overall QIAstat-Dx Gastrointestinal Panel assay, as well as for the individual panel organisms

	TP/(TP+FN)	Sensitivity/PPA	95% CI	TN/(TN+FP)	Specificity/NPA	95% CI
Overall	425/434	97.9%	96.1%–98.9%	91/93	97.8%	92.5%–99.4%
Viruses						
Adenovirus	24/24	100%	86.2%–100%	332/333	99.7%	98.3%–99.9%
Astrovirus	8/8	100%	67.6%–100%	348/348	100%	98.9%–100%
Norovirus GI	5/5	100%	56.6%–99.5%	349/351	99.4%	97.9%–99.8%
Norovirus GII	29/30	96.7%	83.3%–99.4%	323/327	98.8%	99.9%–99.5%
Rotavirus	29/30	96.7%	83.3%–99.4%	327/327	100%	98.8%–100%
Sapovirus	11/11	100%	74.1%–100%	345/345	100%	98.9%–100%
Diarrheagenic *E. coli*						
E. coli O157:H7	2/2	100%	34.2%–100%	354/354	100%	98.9%–100%
Enteroaggregative *E. coli*	26/27	96.3%	81.7%–99.3%	328/330	99.4%	97.8%–99.8%
Enteroinvasive *E. coli*/ *Shigella*	24/25	96.0%	80.5%–99.3%	331/332	99.7%	98.3%–99.9%
Enteropathogenic *E. coli*	54/54	100%	93.4%–100%	300/302	99.3%	97.6%–99.8%
Enterotoxigenic *E. coli*	18/20	90.0%	69.9%–97.2%	337/338	99.7%	98.3%–99.9%
Enterohemorrhagic *E. coli* (STEC)	23/23	100%	85.7%–100%	333/333	100%	98.9%–100%

(Table 5 continued)

	TP/(TP+FN)	Sensitivity/PPA	95% CI	TN/(TN+FP)	Specificity/NPA	95% CI
Bacteria						
Clostridium difficile	39/39	100%	91.0%–100%	315/317	99.4%	97.7%–99.8%
Campylobacter spp.	45/47	95.7%	85.8%–98.8%	307/311	98.7%	96.7%–99.5%
Plesiomonas shigelloides	1/1	100%	20.7%–100%	355/355	100%	98.9%–100%
Salmonella spp.	7/7	100%	64.6%–100%	349/349	100%	98.9%–100%
Vibrio cholera	2/2	100%	34.2%–100%	354/354	100%	98.9%–100%
Yersinia enterocolitica	7/7	100%	64.6%–100%	349/349	100%	98.9%–100%
Parasites						
Cryptosporidium	16/16	100%	80.6%–100%	339/340	99.7%	98.4%–99.9%
Cyclospora cayetanensis	0	–	–	355/356	99.7%	98.4%–99.9%
Entamoeba histolytica	18/18	100%	82.4%–100%	338/338	100%	98.9%–100%
Giardia lamblia	37/38	97.4%	86.5%–99.5%	319/319	100%	98.8%–100%

There were 8 samples that failed at first test. Seven (7) samples completed successfully when retested. One sample had to be retested twice. The first test success rate was 97.7% (343/351), success rate upon retest was 99.7%.

Conclusion

The QIAstat-Dx Gastrointestinal Panel demonstrated high-quality clinical performance characteristics. The overall assay Sensitivity and Specificity were 97.9% (95% CI 96.1%–98.9%) and 97.8% (95% CI 92.5%–99.4%), respectively.

The assay performed well for all individual pathogens and organism categories, including parasites, that are more easily missed in a clinical lab due to the complexity and skill required to achieve diagnosis.

Analytical performance

Sensitivity (Limit of Detection)

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

The LoD of the QIAstat-Dx Gastrointestinal Panel was determined per analyte using selected strains representing individual pathogens that are possible to detect with the QIAstat-Dx Gastrointestinal Panel. Simulated stool sample matrix (negative sample resuspened in Copan® Cary-Blair transport medium) was spiked with one or more pathogens and tested in 20 replicates.

Individual LoD values for each QIAstat-Dx Gastrointestinal Panel target is shown in Table 6 (next page).

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

Pathogen	Strain	Source	Concentration	Detection rate
Norovirus GI	–	Clinical sample	1.0E–03*	20/20
Norovirus GII	–	Clinical sample	1.0E–05*	19/20
Rotavirus	WA (TC-adapted)	ATCC® VR-2018	44.24 $TCID_{50}$/ml	19/20
	WA	ZeptoMetrix® NATGIP-BIO	1.0E–05*	19/20
Astrovirus	–	Clinical sample	1.0E–04*	19/20
Cryptosporidium parvum	Iowa isolate	Waterborne® P102C	0.06 oocysts/ml	19/20
Entamoeba histolytica	HM-1: IMSS (Mexico City 1967)	ATCC 30459	0.008 cells/ml	20/20
Giardia lamblia	WB (Bethesda)	ATCC 30957	0.03 cells/ml	20/20
Cyclospora cayetanensis	–	gDNA† ATCC PRA-3000SD	3 genome copies/µl	20/20
Vibrio parahaemolyticus	EB 101	ATCC 17802	>0.0003 CFU/ml	19/20
Clostridium difficile	Toxinotype XXII A+B+	ATCC BAA-1814	>0.005 CFU/ml	19/20
	NAP1	ZeptoMetrix NATGIP-BIO	1.0E–04*	19/20
	Toxinotype 0 A+B+, 90556-M6S	ATCC 9689	>0.003 CFU/ml	20/20
Vibrio vulnificus	329 [CDC B3547]	ATCC 33817	>0.001 CFU/ml	20/20
EPEC	*stx–, stx2–, eae+*	ATCC 33780	>0.01 CFU/ml	20/20
	–	ZeptoMetrix NATGIP-BIO	1.0E–02*	20/20
Campylobacter coli	–	ATCC 33559	0.004 CFU/ml	19/20
	NCTC 11366	ZeptoMetrix custom product	1.0E–04*	19/20

(Table 6 continued)

Pathogen	Strain	Source	Concentration	Detection rate
Campylobacter jejuni	–	ATCC BAA-1234	>0.003 CFU/ml	19/20
	–	ATCC 49349	>0.001 CFU/ml	19/20
Campylobacter upsaliensis	NCTC 11541 (C231)	ATCC 43954	>0.001 CFU/ml	20/20
	Sandstedt and Ursing	ATCC BAA-1059	>0.008 CFU/ml	20/20
Yersinia enterocolitica	Strain NTCC 11175 subsp. *Enterocolitica* (Schleifstein and Coleman)	ATCC 700822	>0.001 CFU/ml	20/20
	Strain 33114	ATCC 9610	>0.5 CFU/ml	20/20
ETEC	ETEC H10407 Serotype O78:H11	ATCC 35401	>0.001 CFU/ml	20/20
	E. coli O115:H5 *sth*+	SSI 82174	3.2E–08*	20/20
EIEC	EIEC Fr 1368 (ipaH)	SSI 82171	7.9E–09*	20/20
	EIEC O29:NM (Migula) Castellani	ATCC 43892	>0.0001 CFU/ml	20/20
Shigella sonnei	WRAIR I virulent	ATCC 29930	>0.001 CFU/ml	19/20
	Z004	ZeptoMetrix NATGIP-BIO	1.0E–03*	19/20
STEC	O22 *stx1– stx2*	SSI 91350	5.0E–08*	20/20
	O26:H11	Microbiologics® 01100	840 CFU/ml	19/20
EAEC	O111a. 111b: K58:H21; CDC3250-76	ATCC 29552	>0.001 CFU/ml	19/20
	EAEC	ZeptoMetrix NATGIP-BIO	3.2E–04*	19/20
Salmonella enterica	Serovar Enteritidis	ATCC BAA-1045	>0.002 CFU/ml	19/20
	Serovar Enteritidis, CDC K-1891	ATCC 13076	0.4 CFU/ml	20/20
Plesiomonas shigelloides	Bader	ATCC 14029	>0.005 CFU/ml	19/20
	Z130	ZeptoMetrix NATGIP-BIO	3.2E–03*	20/20

(Table 6 continued)

Pathogen	Strain	Source	Concentration	Detection rate
Sapovirus GI.1	–	Clinical sample	3.2E–05*	19/20
Vibrio cholerae	Pacini 1854 serotype O1	CECT 514 (ATCC 14035)	1.0E–07*	20/20
STEC O157:H7	O157:H7	SSI 82169	7.9E–08*	20/20
	O157:H7	Microbiologics 0617	940 CFU/ml	20/20
Adenovirus F 40/41	Tak (73-3544)	ATCC VR-930	1.1 $TCID_{50}$/ml	20/20
	Dugan	ATCC VR-931	0.002 $TCID_{50}$/ml	19/20

* Relative dilution from stock concentration.

† Quantitative synthetic *Cyclospora cayetanensis* DNA.

Assay robustness

The verification of robust assay performance was assessed by analyzing the Internal Control performance in clinical stool samples. Thirty (30) individual unpreserved stool samples in Cary-Blair transport medium, negative for all pathogens possible to detect, were analyzed with the QIAstat-Dx Gastrointestinal Panel.

All samples tested showed a positive result and valid performance for the Internal Control of the QIAstat-Dx Gastrointestinal Panel.

Exclusivity (Analytical Specificity)

The exclusivity study was carried out by in silico analysis and in vitro testing to assess the Analytical Specificity of the QIAstat-Dx Gastrointestinal Panel for gastrointestinal pathogens or non-intestinal organisms that are not covered by the panel. These organisms included specimens which are related to, but distinct from, gastrointestinal panel organisms or that could be present in specimens collected from the intended test population.

Selected organisms are clinically relevant (colonizing the gastrointestinal tract or causing gastrointestinal symptoms), are common skin flora or laboratory contaminants, or are microorganisms for which much of the population may have been infected.

Samples were prepared by spiking potential cross-reactive organisms into simulated stool sample matrix at the highest concentration possible based on the organism stock, 10^6 CFU/ml for bacterial targets, 10^6 cells/ml for parasitic targets and 10^5 $TCID_{50}$/ml for viral targets.

Table 7 shows the list of pathogens tested in this study.

Table 7. List of Analytical Specificity pathogens tested

Type	Pathogen
Bacteria	*Abiotrophia defectiva*
	Acinetobacter baumannii
	Aeromonas hydrophila
	Arcobacter cryaerophilus
	Bifidobacterium bifidum
	Campylobacter fetus
	Campylobacter gracilis
	Campylobacter helveticus
	Campylobacter hominis
	Campylobacter lari
	Campylobacter mucosalis
	Campylobacter rectus
	Chlamydia trachomatis
	Clostridium difficile non-toxigenic
	Clostridium histolyticum
	Clostridium perfringens
	Clostridium septicum
	Clostridium tetani
	Corynebacterium genitalium
	Enterobacter aerogenes
	Enterobacter cloacae
	Enterococcus faecalis

(Table 7 continued)

Type	Pathogen
Bacteria (continued)	*Enterococcus faecium* *Escherichia fergusonii* *Escherichia hermannii* *Escherichia vulneris* *Faecalibacterium prausnitzii* *Gardnerella vaginalis* *Haemophilus influenzae* *Helicobacter pylori* *Klebsiella pneumoniae* *Listeria monocytogenes* *Proteus mirabilis* *Proteus vulgaris* *Pseudomonas aeruginosa* *Staphylococcus aureus* *Staphylococcus epidermidis* *Streptococcus agalactiae* *Streptococcus pyogenes*
Parasites	*Babesia microti* *Blastocystis hominis* *Giardia muris* *Toxoplasma gondii* *Trichomonas tenax*
Viruses	Adenovirus B3 Adenovirus C:2 Adenovirus E:4a Bocavirus Type 1 Coronavirus 229E Coxsackievirus B3 Cytomegalovirus Enterovirus 6 (Echovirus) Enterovirus 68 Herpes Simplex Type 2 Rhinovirus 1A

Cross-reactivity was observed for the *Campylobacter* spp. (*C. coli*, *C. jejuni* and *C. upsaliensis*) designs against *Campylobacter rectus* and *Campylobacter helveticus*.

The rest of the pathogens tested showed a negative result and no cross-reactivity was observed for the organisms tested in the QIAstat-Dx Gastrointestinal Panel.

In silico analysis (9) was performed for all primer/probe designs included in the QIAstat-Dx Gastrointestinal Panel. A certain level of cross-reactivity with the STEC *stx2* design was predicted by sequence analysis of *Citrobacter freundii* strain carrying Shiga-like toxins (5, 15–17).

Inclusivity (Analytical Reactivity)

An inclusivity study was performed to analyze the detection of a variety of strains that represent the genetic diversity of each gastrointestinal panel target organism ("inclusivity strains"). Inclusivity strains for all analytes were included in the study, representative of the species/types for the different organisms. Table 8 shows the list of gastrointestinal pathogens tested in this study.

Table 8. List of Analytical Reactivity pathogens tested

Pathogen	Strain/serotype	Source
Norovirus GI	GI.4	Clinical sample
	GI.3	Clinical sample
Norovirus GII	GII.17	Clinical sample
Rotavirus	WA (TC-adapted)	ATCC VR-2018
	WA	ZeptoMetrix NATGIP-BIO
	WA, MA-104	ZeptoMetrix 0810041CFHI
Astrovirus	HAstV-1	Clinical sample
	HAstV-4	Clinical sample
Cryptosporidium parvum	Iowa isolate	Waterborne P102C

(Table 8 continued)

Pathogen	Strain/serotype	Source
Entamoeba histolytica	HM-1: IMSS (Mexico City 1967)	ATCC 30459
	Colonic biopsy from adult human male with amebic dysentery, Korea, (?)HK-9	ATCC 30015
Giardia lamblia	WB (Bethesda)	ATCC 30957
	H3 isolate	Waterborne Inc. P101
	Portland -1	ATCC 30888
Cyclospora cayetanensis	–	gDNA* ATCC PRA-3000SD
Vibrio parahaemolyticus	EB 101	ATCC 17802
	VP250	ATCC BAA-242
	205 [9302]	ATCC 33846
Clostridium difficile	Toxinotype XXII A+B+	ATCC BAA-1814
	NAP1	ZeptoMetrix NATGIP-BIO
	Toxinotype 0 A+B+, 90556-M6S	ATCC 9689
	–	ATCC BAA-1812
	Hall and O'Toole Prevot	ATCC BAA-1805
	Strain 1470, Serogroup F	ATCC 43598
	Hall and O'Toole Prevot, Strain 5325	ATCC BAA-1875
Vibrio vulnificus	329 [CDC B3547]	ATCC 33817
	Biogroup 1 324 [CDC B9629]	ATCC 27562
EPEC	*stx– stx2– eae+*	ATCC 33780
	–	ZeptoMetrix NATGIP-BIO
Campylobacter coli	–	ATCC 33559
	NCTC 11366	ZeptoMetrix custom product
	76-GA2 [LMG 21266]	ATCC 43478

(Table 8 continued)

Pathogen	Strain/serotype	Source
Campylobacter jejuni	–	ATCC BAA-1234
	–	ATCC 49349
	D3180	ATCC BAA-218
	AS-83-79	ATCC 33291
	NCTC 11951	ATCC 49349
Campylobacter upsaliensis	NCTC 11541 (C231)	ATCC 43954
	Sandstedt and Ursing	ATCC BAA-1059
Yersinia enterocolitica	Strain NTCC 11175 subsp. *Enterocolitica* (Schleifstein and Coleman)	ATCC 700822
	Strain 33114	ATCC 9610
	Serotype O:9	ATCC 55075
ETEC	ETEC H10407. Serotype O78:H11	ATCC 35401
	E. coli O115:H5 *sth*+	SSI 82174
	E. coli O27:H7 *sta*+	SSI 82173
	lt+	SSI 82172
EIEC	EIEC Fr 1368 (ipaH)	SSI 82171
	EIEC: O29: NM (Migula) Castellani	ATCC 43892
Shigella boydii	(Serogroup C), type 1, Strain AMC 43-G-58 [M44 (Type 170)]	ATCC 9207
Shigella flexneri	AMC 43-G-68 [EVL 82, M134]	ATCC 9199
Shigella sonnei	WRAIR I virulent	ATCC 29930
	Z004	ZeptoMetrix NATGIP-BIO
	NCDC 1120-66 [CIP 104223]	ATCC 25931
STEC O157:H7	O157:H7	SSI 82169
	O157:H7	Microbiologics 0617

(Table 8 continued)

Pathogen	Strain/serotype	Source
STEC	O22 (*stx1-stx2*)	SSI 91350
	O26:H11	Microbiologics 01100
	026:H11 (*stx2-eae*)	SSI 95211
	D3509 (*stx2g*)	SSI 91356
	O92, O107 (*stx2a-e*)	SSI 91352
	O8 (*stx2 a-e*)	SSI 91349
	O101 (*stx2ae*)	SSI 91354
	O128ac (*stx2f*)	SSI 91355
	D 3404 (*stx1, eae*)	SSI 82170
	O45:H2	Microbiologics 1098
EAEC	O111a. 111b: K58:H21; CDC3250-76	ATCC 29552
	EAEC	ZeptoMetrix NATGIP-BIO
Salmonella enterica	Serovar Enteritidis	ATCC BAA-1045
	Serovar Enteritidis, CDC K-1891	ATCC 13076
	Serovar Typhimurium, Strain CDC 6516-60	ATCC 14028
	Serovar Choleraesius, Strain NCTC 5735 [1348, K.34]	ATCC 13312
Plesiomonas shigelloides	Bader	ATCC 14029
	Z130	ZeptoMetrix NATGIP-BIO
	Strain GNI 14	ATCC 51903
Sapovirus GI.1	GI.1	Clinical sample
	GII.3	Clinical sample
	GV	Clinical sample
Vibrio cholerae	Pacini 1854. serotype O1	CECT 514 (ATCC 14035)
Adenovirus F 40/41	Tak (73-3544)	ATCC VR-930
	Dugan	ATCC VR-931

* Quantitative synthetic *Cyclospora cayetanensis* DNA.

All pathogens tested showed positive results at the concentration tested.

Coinfections

A coinfections study was performed to verify that multiple QIAstat-Dx Gastrointestinal Panel analytes included in one stool sample can be detected by the QIAstat-Dx Gastrointestinal Panel.

High and low concentrations of different organisms were combined in one sample. Selection of organisms was made based on relevance, prevalence (1–4, 6–8, 10–14, 18, 19) and layout of the QIAstat-Dx Gastrointestinal Panel Cartridge (distribution of targets in different reaction chambers).

Analytes were spiked into simulated stool sample matrix (negative stool resuspended in Cary-Blair transport medium) in high (50x LoD concentration) and low concentrations (5x LoD concentration) and tested in different combinations. Table 9 shows the combination of coinfections tested in this study.

Table 9. List of coinfections combinations tested

Pathogens	Strain	Concentration
Clostridium difficile	Toxinotype 0 A+B+	50x LoD
Norovirus GII	Clinical sample	5x LoD
Clostridium difficile	Toxinotype 0 A+B+	5x LoD
Norovirus GII	Clinical sample	50x LoD
Rotavirus A	Rotavirus A - G4[P6] NCPV#0904053v	50x LoD
Norovirus GII	Clinical Specimen	5x LoD
Rotavirus A	Rotavirus A - G4[P6] NCPV#0904053v	5x LoD
Norovirus GII	Clinical Specimen	50x LoD
Clostridium difficile	Toxinotype 0 A+B+	50x LoD
EPEC	*Escherichia coli* E2348/69; O127:H6	5x LoD
Clostridium difficile	Toxinotype 0 A+B+	5x LoD
EPEC	*Escherichia coli* E2348/69; O127:H6	50x LoD
Rotavirus A	Rotavirus A - G4[P6] NCPV#0904053v	50x LoD
Giardia lamblia	*Giardia intestinalis* (aka *G. lamblia*)	5x LoD
Rotavirus A	Rotavirus A - G4[P6] NCPV#0904053v	5x LoD
Giardia lamblia	*Giardia intestinalis* (aka *G. lamblia*)	50x LoD

(Table 9 continued)

Pathogens	Strain	Concentration
Clostridium difficile	Toxinotype 0 A+B+	50x LoD
Rotavirus A	Rotavirus A - G4[P6] NCPV#0904053v	5x LoD
Clostridium difficile	Toxinotype 0 A+B+	5x LoD
Rotavirus A	Rotavirus A - G4[P6] NCPV#0904053v	50x LoD
EPEC	*Escherichia coli* E2348/69; O127:H6	50x LoD
EAEC	*Escherichia coli* JM221; O92:H33	5x LoD
EPEC	*Escherichia coli* E2348/69; O127:H6	5x LoD
EAEC	*Escherichia coli* JM221; O92:H33	50x LoD
Norovirus GII	Clinical sample	50x LoD
Giardia lamblia	*Giardia intestinalis* (aka *G. lamblia*)	5x LoD
Norovirus GII	Clinical sample	5x LoD
Giardia lamblia	*Giardia intestinalis* (aka *G. lamblia*)	50x LoD
***Cryptosporidium* spp.**	*Cryptosporidium parvum* Iowa isolate (Harley Moon)	50x LoD
Salmonella	*Salmonella enterica* ssp. *enterica* Serovar Typhimurium; SGSC RKS#4194 SarC1	5x LoD
***Cryptosporidium* spp.**	*Cryptosporidium parvum* Iowa isolate (Harley Moon)	5x LoD
Salmonella	*Salmonella enterica* ssp. *enterica* Serovar Typhimurium; SGSC RKS#4194 SarC1	50x LoD
***Campylobacter* spp.**	*Campylobacter upsaliensis*	50x LoD
EAEC	*Escherichia coli* JM221; O92:H33	5x LoD
***Campylobacter* spp.**	*Campylobacter upsaliensis*	5x LoD
EAEC	*Escherichia coli* JM221; O92:H33	50x LoD
ETEC	*Escherichia coli* H10407; O78:H11	50x LoD
STEC	Not available	5x LoD
ETEC	*Escherichia coli* H10407; O78:H11	5x LoD
STEC	Not available	50x LoD
Norovirus GII	Clinical sample	50x LoD
Salmonella	*Salmonella enterica* ssp. *enterica* Serovar Typhimurium; SGSC RKS#4194 SarC1	5x LoD
Norovirus GII	Clinical sample	50x LoD
Salmonella	*Salmonella enterica* ssp. *enterica* Serovar Typhimurium; SGSC RKS#4194 SarC1	5x LoD

All coinfections tested gave a positive result for the two pathogens combined at low and high concentrations. No effect in results are observed due to the presence of coinfections in a sample tested with the QIAstat-Dx Gastrointestinal Panel.

Interfering substances

The influence of potential interfering substances on the performance of the QIAstat-Dx Gastrointestinal Panel was evaluated in this study. The interfering substances include endogenous as well as exogenous substances that are normally found in the gastrointestinal tract or may be introduced into stool specimens during specimen collection, respectively.

A set of selected samples that cover all the gastrointestinal pathogens from the panel were used for the interfering substances testing. Interfering substances were spiked into the selected samples at a level predicted to be above the concentration of the substance likely to be found in an authentic stool specimen. The selected samples were tested with and without addition of the potential inhibitory substance for direct sample-to-sample comparison. Additionally, pathogen-negative samples were spiked with the potential inhibitory substances.

None of the tested substances showed interference with the Internal Control or the pathogens included in the combined sample.

Tables 10, 11 and 12 (following pages) show concentrations of the interfering substances tested for the QIAstat-Dx Gastrointestinal Panel.

Table 10. Endogenous substances tested

Substance	Concentration
Human whole blood	10% v/v
Triglycerides	5% v/v
Cholesterol	1.5% w/v
Fatty acids (palmitic acid)	2 mg/ml
Fatty acids (stearic acid)	4 mg/ml
Bovine mucin	3.5% w/v
Bovine and ovine bile	25% v/v
Human urine	50% v/v
Human stool	28 mg/ml

Table 11. Competitive microorganisms tested

Microorganism (source)	Concentration
Aeromonas hydrophila (ATCC 7966)	$5x10^2$ CFU/ml
Bacteroides vulgatus (ATCC 8482)	10^4 CFU/ml
Bifidobacterium bifidum (ATCC11863)	$5x10^3$ CFU/ml
Enterovirus species D, Serotype EV-D68 (ATCC VR-1824)	10^6 $TCID_{50}$/ml
Non-pathogenic *E. coli* (SSI 82168)	10^7 CFU/ml
Helicobacter pylori (ATCC 49503)	$5x10^3$ CFU/ml
Saccharomyces cerevisiae (ATCC 9763)	10^6 CFU/ml
Rotavirus reassortant Rotateq®	0.25% v/v
Rotavirus RIX4414 Rotarix®	0.5% v/v

Table 12. Exogenous substances tested

Substance	Concentration
Bacitracin	250 U/ml
Glycerin	50% v/v
Doxycycline	0.5 mg/ml
Hydrocortisone	0.3% w/v
Nystatin	10,000 USP units/ml
Loperamide hydrochloride	0.005 mg/ml
Metronidazole	14 mg/ml
Magnesium hydroxide	1 mg/ml
Naproxen sodium	10% v/v
Mineral oil	2% v/v
Bisacodyl	0.25 mg/ml
Phenylephrine hydrochloride	0.075% w/v
Bismuth subsalicylate	3.5 mg/ml
Sodium phosphate	5% w/v
Calcium carbonate	5% w/v
Nonoxynol-9	1.2% v/v
Docusate sodium	2.5% w/v
Bleach	0.2% v/v
Ethanol	0.2% v/v

Carryover

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

Samples of simulated stool sample matrix, with alternating high-positive and negative samples, were conducted on one QIAstat-Dx Analyzer 1.0.

No carryover between samples was observed in the QIAstat-Dx Gastrointestinal Panel.

Reproducibility

To prove reproducible performance of the QIAstat-Dx Gastrointestinal Panel on the QIAstat-Dx Analyzer 1.0, a set of selected samples composed of low-concentrated analytes (3x LoD and 1x LoD) and negative samples was tested. Samples were tested in replicates using different lots of QIAstat-Dx Gastrointestinal Panel Cartridges and tests were executed on different QIAstat-Dx Analyzers 1.0 by different operators on different days.

Table 13. List of gastrointestinal pathogens tested for performance reproducibility

Pathogen	Strain
Rotavirus A	WA (TC-adapted)
Cryptosporidium parvum	Iowa isolate
Vibrio parahaemolyticus	EB 101
Yersinia enterocolitica	Strain NTCC 11175 subsp. *Enterocolitica* (Schleifstein and Coleman)
Salmonella enterica	serovar Enteritidis
Sapovirus GI.1	Clinical sample
Astrovirus	Clinical sample
Giardia lamblia	WB (Bethesda)

(Table 13 continued)

Pathogen	Strain
Vibrio vulnificus	329 [CDC B3547]
ETEC lt/st	ETEC H10407. Serotype O78:H11
EAEC	O111a. 111b: K58:H21; CDC3250-76
Adenovirus F40/41	Dugan
Norovirus GI	Clinical sample
Entamoeba histolytica	HM-1: IMSS (Mexico City 1967)
EPEC	*stx– stx2– eae+*
EIEC	EIEC Fr 1368 (ipaH)
Plesiomonas shigelloides	Bader
Vibrio cholerae	Pacini 1854. serotype O1
Norovirus GII	Clinical sample
Cyclospora cayetanensis	Quantitative synthetic *Cyclospora cayetanensis* DNA
Clostridium difficile	Toxinotype XXII A+B+
Campylobacter upsaliensis	NCTC 11541 (C231)
STEC O157:H7	O157:H7

Table 14. Summary of Positive Agreement/Negative Agreement for reproducibility testing

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Result
3x LoD	Rotavirus A	Positive	20/20	100%
	Cryptosporidium parvum	Positive	18/20	90%
	Vibrio parahaemolyticus	Positive	20/20	100%
	Yersinia enterocolitica	Positive	20/20	100%
	Salmonella enterica	Positive	20/20	100%
	Sapovirus GI.1	Positive	20/20	100%
1x LoD	Rotavirus A	Positive	20/20	100%
	Cryptosporidium parvum	Positive	19/20	95%
	Vibrio parahaemolyticus	Positive	19/20	95%
	Yersinia enterocolitica	Positive	20/20	100%
	Salmonella enterica	Positive	19/20	95%
	Sapovirus GI.1	Positive	19/20	95%
Negative	Rotavirus A	Negative	40/40	100%
	Cryptosporidium parvum	Negative	40/40	100%
	Vibrio parahaemolyticus	Negative	40/40	100%
	Yersinia enterocolitica	Negative	40/40	100%
	Salmonella enterica	Negative	40/40	100%
	Sapovirus GI.1*	Negative	38/40	95%

* Astrovirus-positive clinical sample used for the reproducibility study was known to be weakly coinfected with Sapovirus and therefore weak Sapovirus amplifications were expected in this sample. Potential cross-reactivity was ruled out for this sample based on exclusivity studies (see page 53).

(Table 14 continued)

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Result
3x LoD	Astrovirus	Positive	20/20	100%
	Giardia lamblia	Positive	20/20	100%
	Vibrio vulnificus	Positive	20/20	100%
	ETEC lt/st	Positive	20/20	100%
	EAEC	Positive	20/20	100%
	Adenovirus F40/41	Positive	20/20	100%
1x LoD	Astrovirus	Positive	20/20	100%
	Giardia lamblia	Positive	20/20	100%
	Vibrio vulnificus	Positive	20/20	100%
	ETEC lt/st	Positive	20/20	100%
	EAEC	Positive	19/20	95%
	Adenovirus F40/41	Positive	19/20	95%
Negative	Astrovirus	Negative	40/40	100%
	Giardia lamblia	Negative	40/40	100%
	Vibrio vulnificus	Negative	40/40	100%
	ETEC lt/st	Negative	40/40	100%
	EAEC	Negative	40/40	100%
	Adenovirus F40/41	Negative	40/40	100%

(Table 14 continued)

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Result
3x LoD	Norovirus GI	Positive	20/20	100%
	Entamoeba histolytica	Positive	20/20	100%
	EPEC	Positive	20/20	100%
	EIEC	Positive	20/20	100%
	Plesiomonas shigelloides	Positive	20/20	100%
	Vibrio cholerae	Positive	20/20	100%
1x LoD	Norovirus GI	Positive	20/20	100%
	Entamoeba histolytica	Positive	20/20	100%
	EPEC	Positive	19/20	95%
	EIEC	Positive	20/20	100%
	Plesiomonas shigelloides	Positive	19/20	95%
	Vibrio cholerae	Positive	20/20	100%
Negative	Norovirus GI	Negative	40/40	100%
	Entamoeba histolytica	Negative	40/40	100%
	EPEC	Negative	40/40	100%
	EIEC	Negative	40/40	100%
	Plesiomonas shigelloides	Negative	40/40	100%
	Vibrio cholerae	Negative	40/40	100%

(Table 14 continued)

Concentration	Pathogen	Expected result	Detection rate	% Agreement with Expected Result
3x LoD	Norovirus GII	Positive	20/20	100%
	Cyclospora cayetanensis	Positive	20/20	100%
	Clostridium difficile	Positive	20/20	100%
	Campylobacter upsaliensis	Positive	20/20	100%
	STEC O157:H7	Positive	20/20	100%
1x LoD	Norovirus GII	Positive	20/20	100%
	Cyclospora cayetanensis	Positive	20/20	100%
	Clostridium difficile	Positive	19/20	95%
	Campylobacter upsaliensis	Positive	20/20	100%
	STEC O157:H7	Positive	20/20	100%
Negative	Norovirus GII	Negative	40/40	100%
	Cyclospora cayetanensis	Negative	40/40	100%
	Clostridium difficile	Negative	40/40	100%
	Campylobacter upsaliensis	Negative	40/40	100%
	STEC O157:H7	Negative	40/40	100%

All samples tested generated the expected result (95–100% agreement), with the exception of *Cryptosporidium* spp. (detected in 90% of replicates at 3x LoD concentration), showing reproducible performance of the QIAstat-Dx Gastrointestinal Panel.

Reproducibility testing demonstrated that the QIAstat-Dx Gastrointestinal Panel running in the QIAstat-Dx Analyzer 1.0 provides highly reproducible test results when the same samples are tested in multiple runs, on multiple days with various operators using different QIAstat-Dx Analyzers 1.0 and multiple lots of QIAstat-Dx Gastrointestinal Panel Cartridges.

Sample stability

A sample stability study was executed to analyze storage conditions for clinical samples to be tested with the QIAstat-Dx Gastrointestinal Panel. Simulated stool sample matrix (negative sample resuspended in Copan Cary-Blair transport medium) was spiked with viral, bacterial or parasitic culture material of low concentration (e.g., 3x LoD). Samples were stored at the following conditions for testing:

- 15°C to 25°C for 4 hours
- 2°C to 8°C for 3 days
- –15°C to –25°C for 24 days
- –70°C to –80°C for 24 days

All pathogens were successfully detected at the different storage temperatures and durations, showing that samples were stable at the indicated storage conditions and durations.

Appendices

Appendix A: Installing the Assay Definition File

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

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

Note: Assay Definition Files are 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 new assays 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 **Options** button and then select **Assay Management**. The Assay Management screen appears in the Content area of the display (Figure 23, next page).

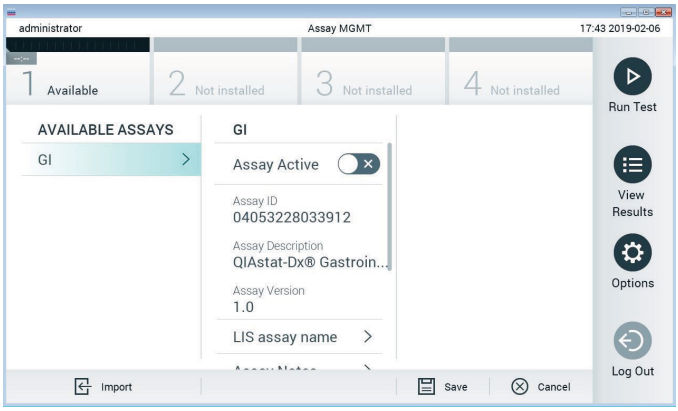

Figure 23. Assay Management screen.

3. Press the **Import** icon in the bottom left of the screen.
4. Select the file corresponding to the assay to be imported from the USB drive.
5. A dialog will appear to confirm upload of the file.
6. A dialog may appear to override the current version by a new one. Press **yes** to override.
7. The assay becomes active by selecting **Assay Active** (Figure 24).

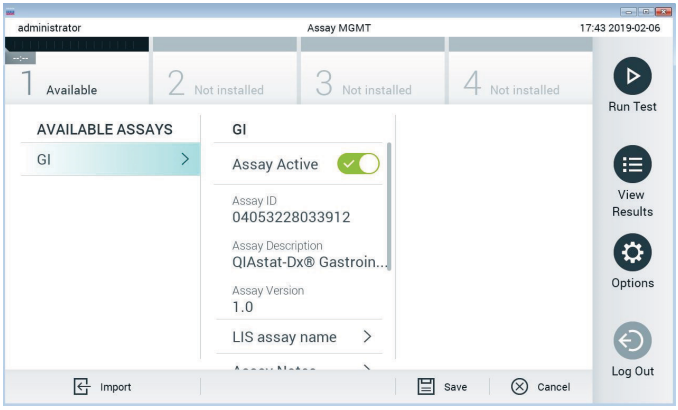

Figure 24. Activating the assay.

8. 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. Next, select **Assign Assays** from the "User Options". Enable the assay and press the **Save** button (Figure 25).

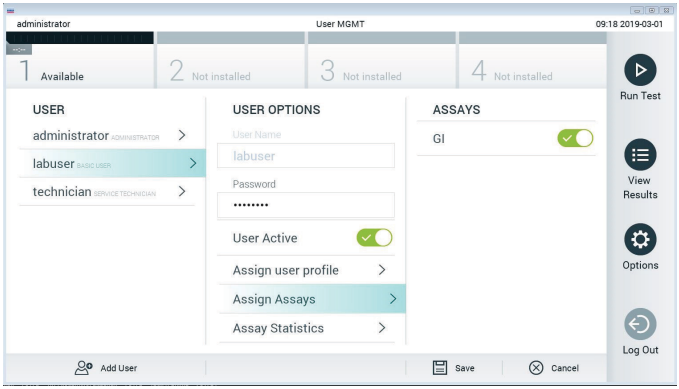

Figure 25. Assigning the active assay.

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 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 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 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.

RT: Reverse Transcription.

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

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

Appendix C: Disclaimer of warranties

EXCEPT AS PROVIDED IN QIAGEN TERMS AND CONDITIONS OF SALE FOR THE QIAstat-Dx Gastrointestinal Panel Cartridge, QIAGEN ASSUMES NO LIABILITY WHATSOEVER AND DISCLAIMS ANY EXPRESS OR IMPLIED WARRANTY RELATING TO THE USE OF THE QIAstat-Dx Gastrointestinal Panel Cartridge INCLUDING LIABILITY OR WARRANTIES RELATING TO MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR INFRINGEMENT OF ANY PATENT, COPYRIGHT, OR OTHER INTELLECTUAL PROPERTY RIGHT ANYWHERE IN THE WORLD.

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Symbols

The following table describes the symbols that may appear on the labeling or in this document.

	Contains reagents sufficient for <N> reactions
	Use by
	In vitro diagnostic medical device
	Catalog number
	Lot number
	Material number (i.e., component labeling)
	Gastrointestinal application
Rn	R is for revision of the Handbook and n is the revision number
	Temperature limitation
	Manufacturer
	Consult instructions for use
	Caution
	CE marking for European Conformity
	Serial number
	Do not reuse
	Keep away from sunlight
	Do not use if package is damaged
	Global Trade Item Number

Ordering Information

Product	Contents	Cat. no.
QIAstat-Dx Gastrointestinal Panel	For 6 tests: 6 individually packaged QIAstat-Dx Gastrointestinal Panel Cartridges and 6 individually packaged transfer pipettes	691411
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

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual. QIAGEN kit handbooks and user manuals are available at **www.qiagen.com** or can be requested from QIAGEN Technical Services or your local distributor.

Document Revision History

Document Revision History	
Revision 1, 04/2019	Initial release.
Revision 2, 09/2020	Update to the concentrations of *H. pylori* and Non-pathogenic *E. coli* in Table 11.

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