

QIAstat-Dx[®] Gastrointestinal Panel

Version 1

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

Further information

- Safety Data Sheets (SDSs): www.qiagen.com/safety
- Technical assistance: support.qiagen.com



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Notes before starting

- Before starting a test, it is required to thoroughly read and understand the *QIAstat-Dx Gastrointestinal Panel Instructions for Use (Handbook)*: www.qiagen.com/HB-2641
- Before starting 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 on the Operational Module
- When working with chemicals, always wear a suitable lab coat, disposable gloves and protective goggles.

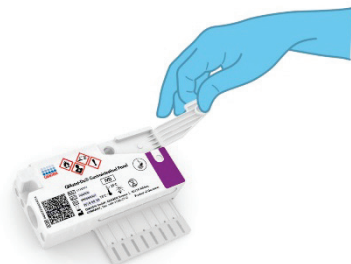
Setting up a test

Loading a sample into the QIAstat-Dx Gastrointestinal Panel Cartridge

1. Remove the QIAstat-Dx Gastrointestinal Panel Cartridge from the package and position it so that the bar code on the label faces you.
2. Write the sample information, or place a sample information label, on the top of the cartridge. Make sure the label is properly positioned and doesn't block the lid opening.

* 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.

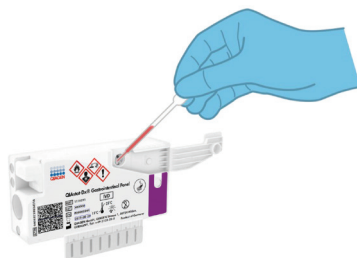
3. Open the main port sample lid on the front of the QIAstat-Dx Gastrointestinal Panel Cartridge.



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

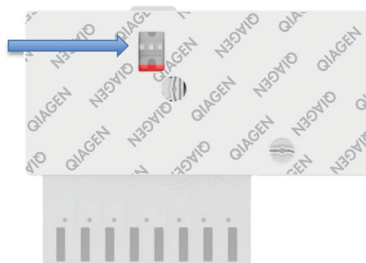


5. Open the sample tube to be tested. Use the supplied transfer pipette to draw up fluid to the second fill line (200 µl). Carefully transfer the 200 µl sample volume into the main port.



6. Firmly close the main port sample lid until it clicks. Visually confirm the sample is loaded using the sample inspection window of the QIAstat-Dx Gastrointestinal Panel Cartridge.

IMPORTANT: Once 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.



Starting 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. The status indicators will turn blue.
2. After the **Main** screen appears and the QIAstat-Dx Analyzer 1.0 status indicators turn green and stop blinking, log in to the instrument.

Running a test

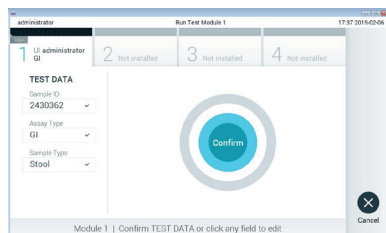
1. Press the **Run Test** button. When prompted, use the bar code reader to scan the sample ID bar code on the Cary-Blair transport medium sample tube or scan the sample information label bar code on the QIAstat-Dx Gastrointestinal Panel Cartridge.



2. When prompted, scan the bar code of the QIAstat-Dx Gastrointestinal Panel Cartridge.




3. The **Confirm** screen will appear. Review the entered data and make any necessary changes. Press **Confirm** when all the displayed data are correct.

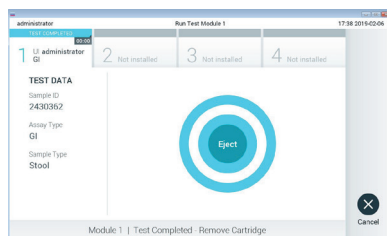


4. Make sure that both sample lids of the swab port and main port of the QIAstat-Dx Gastrointestinal Panel Cartridge are closed. Insert the cartridge into the cartridge entrance port of the QIAstat-Dx Analyzer 1.0 with the bar code facing to the left and the reaction chambers facing down. The instrument will automatically close and start the test run.



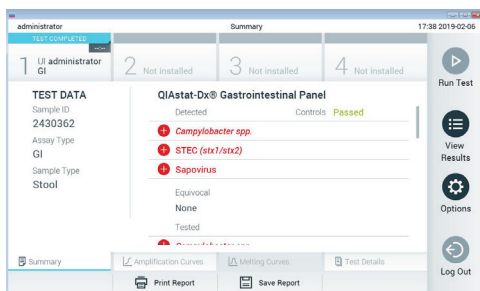
5. When the test run is completed, the **Eject** screen will appear and one of the following test results will be displayed: TEST COMPLETED, TEST FAILED or TEST CANCELED.




6. Press  Eject on the touchscreen to remove the QIAstat-Dx Gastrointestinal Panel Cartridge.





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 displayed. The main part of the screen 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 red plus sign .
- 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.
- Press  Test Details in the Tab Menu bar at the bottom of the touchscreen to review the results in more detail.
- To view test amplification curves of pathogens detected, press the  Amplification Curves tab.

Document Revision History

Revision 1 04/2019	Initial release.
Revision 2 08/2019	Corrected volume in step 5 from 300 µl to 200 µl. Updated dates, revision number.

For up-to-date licensing information and product-specific disclaimers, see the respective QIAGEN kit handbook or user manual.
Trademarks: QIAGEN[®], Sample to Insight[®], QIAstat-Dx[®], DiagCORE[®] (QIAGEN Group).
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