October 22, 2025

QIAGEN GmbH
% Pamela Nge
Senior Manager, Regulatory Affairs
QIAGEN
19300 Germantown Road
Germantown, Maryland 20874

Re: K252329
Trade/Device Name: QIAstat-Dx Gastrointestinal Panel 2; QIAstat-Dx GI Panel 2 Mini B&V; QIAstat-Dx GI Panel 2 Mini B
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay
Regulatory Class: Class II
Product Code: PCH
Dated: July 25, 2025
Received: July 25, 2025

Dear Pamela Nge:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bryan M. Grabias -S
2025.10.22 14:17:54 -04'00'

Bryan Grabias, Ph.D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252329

Device Name
QIAstat-Dx Gastrointestinal Panel 2
QIAstat-Dx GI Panel 2 Mini B&V
QIAstat-Dx GI Panel 2 Mini B

Indications for Use *(Describe)*
QIAstat-Dx Gastrointestinal Panel 2

The QIAstat-Dx Gastrointestinal Panel 2 is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 for the simultaneous in vitro qualitative detection and identification of nucleic acids from multiple viruses, bacteria, and parasites directly from preserved stool samples (Para-Pak C&S or FecalSwab) 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
- Campylobacter (C. jejuni, C. coli and C. upsaliensis)
- Shigella/Enteroinvasive Escherichia coli (EIEC)
- Enteropathogenic Escherichia coli (EPEC)
- Enterotoxigenic Escherichia coli (ETEC) lt/st
- Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2 (including specific identification of E. coli O157 serogroup within STEC)
- Salmonella
- Plesiomonas shigelloides
- Yersinia enterocolitica
- Cryptosporidium
- Cyclospora cayetanensis
- Entamoeba histolytica
- Giardia lamblia*

*Also known as Giardia intestinalis and Giardia duodenalis

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. 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.

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.

QIAstat-Dx GI Panel 2 Mini B&V

The QIAstat-Dx GI Panel 2 Mini B&V is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 for the simultaneous in vitro qualitative detection and identification of nucleic acids from multiple bacteria and one virus directly from preserved stool samples (Para-Pak C&S or FecalSwab) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following virus and bacteria (including several diarrheagenic E. coli/Shigella pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B&V:

• Norovirus
• Campylobacter
• Shigella
• Shiga-like toxin E. coli (STEC)
• Salmonella

Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B&V is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms not detected by the QIAstat Dx GI Panel 2 Mini B&V. The organisms detected may not be the sole or definitive cause of the disease.

Negative QIAstat-Dx GI Panel 2 Mini B&V 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.

QIAstat-Dx GI Panel 2 Mini B

The QIAstat-Dx GI Panel 2 Mini B is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0. for the simultaneous in vitro qualitative detection and identification of nucleic acids from multiple bacteria directly from preserved stool samples (Para-Pak C&S or FecalSwab) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria (including several diarrheagenic E. coli/ Shigella pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B:
• Campylobacter
• Shigella
• Shiga-like toxin Escherichia coli (STEC)
• Salmonella
• Yersinia enterocolitica

Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms not detected by the QIAstat-Dx GI Panel 2 Mini B. The organisms detected may not be the sole or definitive cause of the disease.

Negative QIAstat-Dx GI Panel 2 Mini B 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

General Information

Submitted by: QIAGEN GmbH
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Date Prepared: October 21, 2025

Device Name: QIAstat-Dx Gastrointestinal Panel 2
QIAstat-Dx GI Panel 2 Mini B&V
QIAstat-Dx GI Panel 2 Mini B

Trade Name: QIAstat-Dx Gastrointestinal Panel 2
QIAstat-Dx GI Panel 2 Mini B&V
QIAstat-Dx GI Panel 2 Mini B

Classification: 21 CFR 866.3990 - Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-Based Assay System

Product Code: PCH

Predicate Device: QIAstat-Dx Gastrointestinal Panel 2 (K220062)
QIAstat-Dx GI Panel 2 Mini B&V (K243813)
QIAstat-Dx GI Panel 2 Mini B (K250324)

Device Description

The QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B are multiplexed nucleic acid tests that are designed for use with the QIAstat-Dx Analyzer 2.0. Modification made to the devices is to:

- Unmask the results for Shiga-like toxin *E. coli* (STEC) *stx1*/*stx2*, *E. coli* O157, and Enteropathogenic *E. coli* (EPEC), for the FecalSwab sample type for the QIAstat-Dx Gastrointestinal Panel 2,
- Unmask the results for Shiga-like toxin *E. coli* (STEC) for the FecalSwab sample type for the QIAstat-Dx GI Panel 2 Mini B&V and the QIAstat-Dx GI Panel 2 Mini B, and
- Remove the QIAstat-Dx Analyzer 1.0 from the indicated amplification and detection instrument systems for all three (3) devices, leaving only the QIAstat-Dx Analyzer 2.0. The QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0 belong to the same instrument family.

The QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B are intended for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple targets directly from preserved stool samples (Para-Pak® C&S or FecalSwab™) obtained from individuals with signs and/or symptoms of gastrointestinal infection.
The QIAstat-Dx system is based on single-test cartridges with pre-packaged reagents including both wet and dry chemistry to handle the sample preparation and detection steps for the presence of a range of selected analytes by PCR technology. After insertion of the sample, the QIAstat-Dx assay cartridge is processed by the QIAstat-Dx Analyzer 2.0.

Once the cartridge has been inserted into the instrument, the test starts automatically and runs for approximately 80 minutes. When the test is finished, the cartridge is removed by the user and discarded. The QIAstat-Dx Analyzer 2.0 automatically interprets test results and displays a summary on the analyzer display screen. The results can be printed using a connected printer if needed. The detected analytes are displayed in red. For other analytes tested, they are displayed in green if not detected or in gray if not applicable or invalid. The analyzer will report if an error occurs during processing, in which case the test will fail, and no results will be provided (screen will show “FAIL”).

All the reagents required for the complete execution of the test are pre-loaded and self-contained in the QIAstat-Dx Gastrointestinal Panels. The user does not need to manipulate any reagents. During the test, reagents are handled by pneumatically operated microfluidics without any direct contact with the user or the analyzer actuators. This eliminates any possibility of exposure of the user or the analyzer to chemicals contained in the cartridge during the test and up to the disposal of used cartridges.

Within the cartridge, multiple steps are automatically performed in sequence by using pneumatic pressure and a multiport valve to transfer sample and fluids via the Transfer Chamber to their intended destinations. Following the introduction of the sample from a disposable transfer pipette, the following assay steps occur automatically and sequentially:

- Sample pre-treatment for PCR Inhibitors removal
- Resuspension of Internal Control and Proteinase K
- Cell lysis using mechanical and/or chemical means
- Membrane-based nucleic acid purification
- Rehydration of Master Mix
- Transfer of defined aliquots of eluate/master mix to different reaction chambers
- Performance of multiplex real-time RT-PCR testing within each reaction chamber.

Intended Use

QIAstat-Dx Gastrointestinal Panel 2

The QIAstat-Dx® Gastrointestinal Panel 2 is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple viruses, bacteria, and parasites directly from preserved stool samples (Para-Pak C&S or FecalSwab) 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
- *Campylobacter (C. jejuni, C. coli* and *C. upsaliensis*)
- *Shigella*/Enteroinvasive *Escherichia coli (*EIEC)
- Enteropathogenic *Escherichia coli* (EPEC)
- Enterotoxigenic *Escherichia coli* (ETEC) lt/st
- Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1*/*stx2* (including specific identification of *E. coli* O157 serogroup within STEC)
- *Salmonella*
- *Plesiomonas shigelloides*
- *Yersinia enterocolitica*
- *Cryptosporidium*
- *Cyclospora cayetanensis*

- *Entamoeba histolytica*
- *Giardia lamblia**

*Also known as *Giardia intestinalis* and *Giardia duodenalis*

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. 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.

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.

QIAstat-Dx GI Panel 2 Mini B&V

The QIAstat-Dx® GI Panel 2 Mini B&V is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 for the simultaneous in vitro qualitative detection and identification of nucleic acids from multiple bacteria and one virus directly from preserved stool samples (Para-Pak C&S or FecalSwab) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following virus and bacteria (including several diarrheagenic *E. coli*/*Shigella* pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B&V:

- Norovirus
- *Campylobacter*
- *Shigella*
- Shiga-like toxin *E. coli* (STEC)
- *Salmonella*

Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B&V is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms not detected by the QIAstat-Dx GI Panel 2 Mini B&V. The organisms detected may not be the sole or definitive cause of the disease.

Negative QIAstat-Dx GI Panel 2 Mini B&V 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.

QIAstat-Dx GI Panel 2 Mini B

The QIAstat-Dx® GI Panel 2 Mini B is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0. for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple bacteria directly from preserved stool samples (Para-Pak C&S or FecalSwab) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria (including several diarrheagenic *E. coli*/ *Shigella* pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B:

- *Campylobacter*
- *Shigella*
- Shiga-like toxin *Escherichia coli* (STEC)
- *Salmonella*
- *Yersinia enterocolitica*

Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms not detected by the QIAstat-Dx GI Panel 2 Mini B. The organisms detected may not be the sole or definitive cause of the disease.

Negative QIAstat-Dx GI Panel 2 Mini B 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.

Comparison of the QIAstat-Dx Gastrointestinal Panels and their Predicate Devices

The QIAstat-Dx Gastrointestinal Panel 2 with unmasked Shiga-like toxin *E. coli* (STEC) *stx1*/*stx2*, *E. coli* O157, and Enteropathogenic *E. coli* (EPEC) on the FecalSwab sample type using the QIAstat-Dx Analyzer 2.0 is substantially equivalent to the QIAstat-Dx Gastrointestinal Panel 2, 510(k) K220062. A detailed comparison of the features and performance of these devices is provided in Table 1.

The QIAstat-Dx GI Panel 2 Mini B&V with unmasked STEC on the FecalSwab sample type using the QIAstat-Dx Analyzer 2.0 is substantially equivalent to the QIAstat-Dx GI Panel 2 Mini B&V, 510(k) K243813. A detailed comparison of the features and performance of these devices is provided in Table 2.

The QIAstat-Dx GI Panel 2 Mini B with unmasked STEC on the FecalSwab sample type using QIAstat-Dx Analyzer 2.0 is substantially equivalent to the QIAstat-Dx GI Panel 2 Mini B, 510(k) K250324. A detailed comparison of the features and performance of these devices is provided in Table 3.

Table 1. Comparison of similarities and differences of the QIAstat-Dx Gastrointestinal Panel 2 and the predicate device

Characteristic	Subject Device	Predicate
Name	QIAstat-Dx Gastrointestinal Panel 2	QIAstat-Dx Gastrointestinal Panel 2
510(k) No.	K252329	K220062
Regulation	21 CFR 866.3990	21 CFR 866.3990
Product Code	PCH	PCH
Device Class	Class II	Class II
Similarities		
Intended Use	The QIAstat-Dx® Gastrointestinal Panel 2 is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple viruses, bacteria, and parasites directly from preserved stool samples (Para-Pak® C&S or FecalSwab™) 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 • *Campylobacter (C. jejuni, C. coli* and *C. upsaliensis*) • *Shigella*/Enteroinvasive *Escherichia coli (*EIEC) • Enteropathogenic *Escherichia coli* (EPEC)	The QIAstat-Dx® Gastrointestinal Panel 2 is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0 for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple viruses, bacteria, and parasites directly from preserved stool samples (Para-Pak® C&S or FecalSwab™) 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 • *Campylobacter* (*C. jejuni, C. coli* and *C. upsaliensis*) • *Shigella*/Enteroinvasive *Escherichia coli* (EIEC) • Enteropathogenic *Escherichia coli* (EPEC)*

Characteristic	Subject Device	Predicate
	• Enterotoxigenic *Escherichia coli* (ETEC) *lt*/*st* • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1*/*stx2* (including specific identification of *E. coli* O157 serogroup within STEC) • *Salmonella* • *Plesiomonas shigelloides* • *Yersinia enterocolitica* • *Cryptosporidium* • *Cyclospora cayetanensis* • *Entamoeba histolytica* • *Giardia lamblia** *Also known as *Giardia intestinalis* and *Giardia duodenalis* 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. 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. 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.	• Enterotoxigenic *Escherichia coli* (ETEC) *lt/st* • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2* (including specific identification of *E. coli* O157 serogroup within STEC)* • *Salmonella* • *Plesiomonas shigelloides* • *Yersinia enterocolitica* • *Cryptosporidium* • *Cyclospora cayetanensis* • *Entamoeba histolytica* • *Giardia lamblia (*also known as Giardia intestinalis and Giardia duodenalis) *Only with Para-Pak C&S, not reported for FecalSwab 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. 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. 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

Characteristic	Subject Device	Predicate
		as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.
Specimen Type	Same	Preserved stool in Para-Pak C&S or FecalSwab transport media
Analyte Detected	Same	RNA/DNA
Assay Targets	See above	See above
Amplification and Detection Technology	Same	PCR
Assay Controls	Same	One internal control in each cartridge to control for sample processing, that is, subjected to all nucleic acid extraction and amplification steps similar to patient samples. Labeling recommends the use of negative and positive external controls regularly. 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.
Nucleic Acid Extraction	Same	Extraction of nucleic acids using silica membrane
Technology	Same	Detection of amplified targets uses an increase in fluorescence due to specific probe binding to generate the assay results.
Operational	Same	The sample is loaded straight into the cartridge.
Differences		
Masking/Unmasking of Targets for the FecalSwab Sample Type	All results are reported for both Para-Pak C&S and FecalSwab sample types.	All results are reported for both Para-Pak C&S and FecalSwab sample types except for STEC, *E. coli* O157, and EPEC which are only reported with Para-Pak C&S (i.e., masked for FecalSwab).
Amplification and Detection Instrument	QIAstat-Dx Analyzer 2.0[§]	QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0[§]

[§]The QIAstat-Dx Analyzer 2.0 is an instrument family member of the QIAstat-Dx Analyzer 1.0.

Table 2. Comparison of similarities and differences of the QIAstat-Dx GI Panel 2 Mini B&V and the predicate device

Characteristic	Subject Device	Predicate
Name	QIAstat-Dx GI Panel 2 Mini B&V	QIAstat-Dx GI Panel 2 Mini B&V
510(k) No.	K252329	K243813
Regulation	21 CFR 866.3990	21 CFR 866.3990
Product Code	PCH	PCH
Device Class	Class II	Class II
Similarities		
Intended Use	The QIAstat-Dx® GI Panel 2 Mini B&V is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 for the simultaneous in vitro qualitative detection and identification of nucleic acids from multiple bacteria and one virus directly from preserved stool samples (Para-Pak® C&S or FecalSwab™) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following virus and bacteria (including several diarrheagenic *E. coli*/*Shigella* pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B&V: • Norovirus • *Campylobacter* • *Shigella* • Shiga-like toxin *E. coli* (STEC) • *Salmonella* Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B&V is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms	The QIAstat-Dx® GI Panel 2 Mini B&V is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0 for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple bacteria and one virus directly from preserved stool samples (Para-Pak® C&S or FecalSwab™) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following virus and bacteria (including several diarrheagenic *E. coli/Shigella* pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B&V: • Norovirus • *Campylobacter* • *Shigella* • Shiga-like toxin *Escherichia coli* (STEC)* • *Salmonella* *Only with Para-Pak C&S, not reported for FecalSwab Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B&V is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical,

Characteristic	Subject Device	Predicate
	not detected by the QIAstat-Dx GI Panel 2 Mini B&V. The organisms detected may not be the sole or definitive cause of the disease. Negative QIAstat-Dx GI Panel 2 Mini B&V 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.	laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms not detected by the QIAstat-Dx GI Panel 2 Mini B&V. The organisms detected may not be the sole or definitive cause of the disease. Negative QIAstat-Dx GI Panel 2 Mini B&V 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.
Specimen Type	Same	Preserved stool in Para-Pak C&S or FecalSwab transport media
Analyte Detected	Same	RNA/DNA
Assay Targets	See above	See above
Amplification and Detection Technology	Same	PCR
Assay Controls	Same	One internal control in each cartridge to control for sample processing, that is subjected to all nucleic acid extraction and amplification steps similar to patient samples. Labeling recommends the use of negative and positive external controls regularly. 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.
Nucleic Acid Extraction	Same	Extraction of nucleic acids using silica membrane
Technology	Same	Detection of amplified targets uses an increase in fluorescence due to

Characteristic	Subject Device	Predicate
		specific probe binding to generate the assay results.
Operational	Same	The sample is loaded straight into the cartridge.
Differences		
Masking/Unmasking of Targets for the FecalSwab Sample Type	All results are reported for both Para-Pak C&S and FecalSwab sample types.	All results are reported for both Para-Pak C&S and FecalSwab sample types except for STEC which is only reported with Para-Pak C&S (i.e., masked for FecalSwab).
Amplification and Detection Instrument	QIAstat-Dx Analyzer 2.0§	QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0§

§The QIAstat-Dx Analyzer 2.0 is an instrument family member of the QIAstat-Dx Analyzer 1.0.

Table 3. Comparison of similarities and differences of the QIAstat-Dx GI Panel 2 Mini B and the predicate device

Characteristic	Subject Device	Predicate
Name	QIAstat-Dx GI Panel 2 Mini B	QIAstat-Dx GI Panel 2 Mini B
510(k) No.	K252329	K250324
Regulation	21 CFR 866.3990	21 CFR 866.3990
Product Code	PCH	PCH
Device Class	Class II	Class II
Similarities		
Intended Use	The QIAstat-Dx® GI Panel 2 Mini B is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0. for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple bacteria directly from preserved stool samples (Para-Pak® C&S or FecalSwab™) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria (including several diarrheagenic *E. coli*/ *Shigella* pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B:	The QIAstat-Dx® GI Panel 2 Mini B is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0 for the simultaneous *in vitro* qualitative detection and identification of nucleic acids from multiple bacteria directly from preserved stool samples (Para-Pak® C&S or FecalSwab™) obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria (including several diarrheagenic *E. coli/Shigella* pathotypes) are

Characteristic	Subject Device	Predicate
	• *Campylobacter* • *Shigella* • Shiga-like toxin *Escherichia coli* (STEC) • *Salmonella* • *Yersinia enterocolitica* Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms not detected by the QIAstat-Dx GI Panel 2 Mini B. The organisms detected may not be the sole or definitive cause of the disease. Negative QIAstat-Dx GI Panel 2 Mini B 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.	identified with the QIAstat-Dx GI Panel 2 Mini B: • *Campylobacter* • *Shigella* • Shiga-like toxin *Escherichia coli* (STEC)* • *Salmonella* • *Yersinia enterocolitica* *Only with Para-Pak C&S, not reported for FecalSwab Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The QIAstat-Dx GI Panel 2 Mini B is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule-out co-infection with organisms not detected by the QIAstat-Dx GI Panel 2 Mini B. The organisms detected may not be the sole or definitive cause of the disease. Negative QIAstat-Dx GI Panel 2 Mini B 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.
Specimen Type	Same	Preserved stool in Para-Pak C&S or FecalSwab transport media
Analyte Detected	Same	DNA
Assay Targets	See above	See above
Amplification and Detection Technology	Same	PCR
Assay Controls	Same	One internal control in each cartridge to control for sample

Characteristic	Subject Device	Predicate
		processing, that is subjected to all nucleic acid extraction and amplification steps similar to patient samples. Labeling recommends the use of negative and positive external controls regularly. 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.
Nucleic Acid Extraction	Same	Extraction of nucleic acids using silica membrane
Technology	Same	Detection of amplified targets uses an increase in fluorescence due to specific probe binding to generate the assay results.
Operational	Same	The sample is loaded straight into the cartridge.
Differences		
Masking/Unmasking of Targets for the FecalSwab Sample Type	All results are reported for both Para-Pak C&S and FecalSwab sample types.	All results are reported for both Para-Pak C&S and FecalSwab sample types except for STEC which is only reported with Para-Pak C&S (i.e., masked for FecalSwab).
Amplification and Detection Instrument	QIAstat-Dx Analyzer 2.0[§]	QIAstat-Dx Analyzer 1.0 and QIAstat-Dx Analyzer 2.0[§]

[§]The QIAstat-Dx Analyzer 2.0 is an instrument family member of the QIAstat-Dx Analyzer 1.0.

Summary of Performance Data

The purpose of this 510(k) is to support the unmasking of Shiga-like toxin *E. coli* (STEC) *stx1*/*stx2*, *E. coli* O157, and Enteropathogenic *E. coli* (EPEC) results that are part of the QIAstat-Dx Gastrointestinal Panel 2, for stool samples collected in FecalSwab transport medium. Refer to the 510(k) Summary for K220062 for performance data of the previously cleared assays in FecalSwab-preserved specimens (Adenovirus F40/F41, Astrovirus, Norovirus GI/GII, Rotavirus A, *Campylobacter* (*C. jejuni*, *C. coli* and *C. upsaliensis*), *Shigella*/Enteroinvasive *Escherichia coli* (EIEC), Enterotoxigenic *Escherichia coli*

(ETEC) *lt*/*st*, *Salmonella*, *Plesiomonas shigelloides*, *Yersinia enterocolitica*. *Cryptosporidium*, *Cyclospora cayetanensis*, *Entamoeba histolytica*, and *Giardia lamblia*).A summary of clinical study for Shiga-like toxin *E.coli* (STEC) *stx1*/*stx2*, *E.coli* O157, and Enteropathogenic *E.coli* (EPEC) in FecalSwab preserved specimens is provided below.

This 510(k) also supports the unmasking of Shiga-like toxin *E. coli* (STEC) results for the QIAstat-Dx GI Panel 2 Mini B&V and the QIAstat-Dx GI Panel 2 Mini B, for stool samples collected in FecalSwab transport medium.

Performance Characteristics - Clinical Studies

Expected Values

A summary of the QIAstat-Dx Gastrointestinal Panel 2 test results for EPEC, STEC and *E. coli* O157 obtained during the prospective clinical performance evaluation of the QIAstat-Dx Gastrointestinal Panel 2 is provided in Table 4. In total, 1,222 eligible stool specimens preserved in FecalSwab (COPAN) were collected and tested. The number and percentage of positive results as determined by the QIAstat-Dx Gastrointestinal Panel 2, are stratified by age group. Overall, EPEC and STEC were detected in 132 and 15 subjects, respectively, across all age groups while *E.coli* O157 was detected in three subjects from the 0-5 years age group.

Table 4. Expected Values Summary by Age Group for the Prospective Clinical study as determined by the QIAstat-Dx Gastrointestinal Panel 2

Pathogen	Medium Brand	Overall	0-5 years	6-21 years	22-49 years	50+ years	Not Reported
Diarrheagenic *E. coli*/*Shigella*							
Enteropathogenic *E. coli* (EPEC)	FecalSwab	132 (10.8%)	47 (25.8%)	12 (9.9%)	34 (11.7%)	39 (6.2%)	0 (0.0%)
Shiga-like toxin *E. coli* (STEC) *stx1*/*stx2*	FecalSwab	15 (1.2%)	9 (4.9%)	1 (0.8%)	2 (0.7%)	3 (0.5%)	0 (0.0%)
***E. coli* O157**	FecalSwab	3 (0.2%)	3 (1.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Clinical Performance

The clinical performance of QIAstat-Dx Gastrointestinal Panel 2 for EPEC, *E. coli* O57 and STEC in FecalSwab-preserved specimens was established during a multi-center international prospective study conducted at thirteen clinical settings representatives of different geographical areas within USA and Europe (nine sites in USA and four sites in Europe) between May and July 2021. All study sites were hospital-associated or

independent clinical diagnostics laboratories that perform routine diagnostics of GI infections. Table 5 provides a summary of the FecalSwab-preserved prospective specimen's distribution across all study sites.

Table 5. FecalSwab-preserved Prospective Specimens Distribution Across the study sites

Site/Country	No. of FecalSwab-preserved prospective specimens
Germany	293
Denmark	293
Spain	247
France	63
USA site 1	0
USA site 2	0
USA site 3	282
USA site 4	0
USA site 5	44
USA site 6	0
USA site 7	0
USA site 8	0
USA site 9	0
Total	**1222**

Table 6 provides all demographic information for the 1,222 FecalSwab-preserved specimens evaluated in the prospective study.

Table 6. Demographic data for prospective evaluated specimens

Demographic data	FecalSwab-preserved	
	Number of specimens	Percentage (%)
Gender		
Female	628	51.4
Male	594	48.6
Age Group		
0-5 years	182	14.9
6-21 years	121	9.9
22-49 years	290	23.7
50+ years	629	51.5
Not Reported	0	0.0

Demographic data	FecalSwab-preserved	
	Number of specimens	**Percentage (%)**
Patient population		
Emergency room	46	3.8
Hospitalized	342	28.0
Immunocompromised	3	0.2
Outpatient	491	40.2
No information available	340	27.8
No. Days between Symptom Onset and QIAstat-Dx Testing		
> 7 days	89	7.3
≤ 7 days	146	11.9
Not Reported	987	80.8

The performance of the QIAstat-Dx Gastrointestinal Panel 2 was evaluated for each panel test result using one FDA-cleared test as comparator for EPEC and *E.coli* O157 while a composite comparator consisting of three independent FDA-cleared test methods was used for STEC (Table 7). The composite endpoint was determined as the majority of the three results.

Table 7. QIAstat-Dx Gastrointestinal Panel 2 Clinical studies comparator method

QIAstat-Dx GI Panel 2 Test Result	Comparator Method
E.coli O157	One FDA-cleared test method
Enteropathogenic *E.coli* (EPEC)	
Shiga-like toxin- *E.coli* (STEC) *stx1*/*stx2*	Composite of three FDA-cleared test methods

Additional prospective archived specimens positive for STEC were collected (75 specimens). These were prospectively collected samples from three different collection sites in the US, where only those positive for the pathogen by standard of care method were archived and transferred into FecalSwab collection vials for analysis alongside 17 negative specimens.

In addition, to supplement the results of the prospective clinical studies, a total of 317 preselected archived frozen (retrospective) FecalSwab specimens were also evaluated. These specimens served to increase the sample size for analytes that showed low prevalence in the clinical prospective study. The same Comparator Methods detailed in

Table 7 were used as confirmatory testing for the presence of the nucleic acids from the expected analytes.

In total 1631 specimens (1,222 prospective, 92 prospective archived and 317 retrospective) were evaluated in the clinical study. All these specimens were collected using FecalSwab.

The PPA was calculated as 100% x (TP / (TP + FN)). True positive (TP) indicates that both the QIAstat-Dx Gastrointestinal Panel 2 and comparator method showed a positive result for this specific target, and false negative (FN) indicates that the QIAstat-Dx Gastrointestinal Panel 2 result was negative while the comparator method result was positive. The NPA was calculated as 100% x (TN / (TN + FP)). True negative (TN) indicates that both the QIAstat-Dx Gastrointestinal Panel 2 and the comparator method showed negative results, and a false positive (FP) indicates that the QIAstat-Dx Gastrointestinal Panel 2 result was positive, but the comparator method result was negative. The PPA and NPA exact binomial two-sided 95% confidence interval was calculated.

Where a composite comparator was used (i.e., for STEC), the result was determined as the majority of the three individual test results (i.e., a positive composite comparator result is based on positive results for at least two comparator tests, and a negative composite comparator result is based on negative results for at least two comparator tests). If insufficient pathogen positive sample was available to obtain a majority test result a worst-case model was applied in the PPA calculation. In this model the PPA was calculated including all observed true positive and false negative samples between QIAstat-Dx and the composite comparator while for the samples where it was not possible to conduct testing with the complete comparator due to insufficient sample volume, the following was done:

- samples that were negative in QIAstat-Dx and positive for one comparator assay, negative (or insufficient volume) for a second comparator and insufficient volume for a third comparator were included in the calculations as worst-case false negatives,
- samples that were positive in QIAstat-Dx and positive in one comparator test, negative (or insufficient volume) for a second comparator and insufficient volume for the third comparator, were considered as worst-case false positives and therefore, excluded in the PPA calculations.

The results of the clinical performance of the prospective, prospective archived and retrospective studies are summarized in Table 8, Table 9, and Table 10, respectively.

Discrepancies between the QIAstat-Dx Gastrointestinal Panel 2 and the comparator methods on these samples were not further investigated.

Table 8. Clinical Performance in the Prospective Study

Analyte	Medium Brand	Positive Percent Agreement			Negative Percent Agreement		
		TP/TP+FN	%	95% CI	TN/TN+FP	%	95% CI
Diarrheagenic *E. coli*							
Enteropathogenic *E. coli* (EPEC)	FecalSwab	126 / 145	86.9	80.4-91.5	1059 / 1063	99.6	99.0-99.9
Shiga-like toxin *E. coli* (STEC) *stx1/stx2*	FecalSwab	3 / 5 [a]	60.0	23.1-88.2	434 / 438 [a]	99.1	97.7-99.6
***E. coli* O157**	FecalSwab	0 / 0 [b]	N/A	N/A	3 / 3 [b]	100.0	43.9-100.0

[a] Eight (8) FecalSwab sample positive for STEC in both QIAstat-Dx and one FDA-cleared comparator were excluded from the PPA calculations because the samples did not have sufficient volume for complete composite comparator testing. The sample size for NPA is smaller for STEC as only a portion of the samples with a negative result in QIAstat-Dx and in one FDA-cleared comparator was tested with the complete composite comparator in the prospective study.
[b] Three (3) positive and nine (9) negative samples for *E.coli* O157 by QIAstat-Dx were excluded from the PPA/NPA calculations because reporting of the *E.coli* O157 result is dependent on the preceding STEC result (*E. coli* O157 is subtype within STEC) and the STEC result for all twelve (12) samples is negative, or not available or unconfirmed with the (composite) reference test.

Table 9. Clinical Performance in the Prospective Archived Study.

Analyte	Medium Brand	Positive Percent Agreement			Negative Percent Agreement		
		TP/TP+FN	%	95% CI	TN/TN+FP	%	95% CI
Diarrheagenic *E. coli*							
Shiga-like toxin *E. coli* (STEC) *stx1/stx2*	FecalSwab	24 / 24 [a]	100.0	86.2-100.0	67 / 68 [a]	98.5	92.1-99.7

[a] For STEC fifty-one out of the seventy-five (51/75) prospectively archived FecalSwab samples (positive by standard of care) were negative by the composite comparator and therefore included as negative samples in the NPA calculations.

Table 10. Clinical Performance in the Retrospective Study.

Analyte	Medium Brand	Positive Percent Agreement			Negative Percent Agreement		
		TP/TP+FN	%	95% CI	TN/TN+FP	%	95% CI
Diarrheagenic *E. coli*							
Enteropathogenic *E. coli* (EPEC)	FecalSwab	46 / 48	95.8	86.0-98.9	164 / 164	100.0	97.7-100.0
Shiga-like toxin *E. coli* (STEC) *stx1/stx2*	FecalSwab	2 / 3 [a]	66.7	20.8-93.9	62 / 63 [b]	98.4	91.5-99.7
***E. coli* O157**	FecalSwab	0 / 0 [c]	N/A	N/A	2 / 2	100.0	34.2-100.0

[a] One (1) FecalSwab sample negative in QIAstat-Dx and positive with one (1) FDA-cleared comparator with insufficient volume for complete composite comparator testing was classed as false negative in the PPA calculations.
[b] Fifteen (15) FecalSwab sample positive for STEC in both QIAstat-Dx and one FDA-cleared comparator were excluded from the PPA calculations because the samples did not have sufficient volume for complete composite comparator testing. The sample size for NPA is smaller for STEC in FecalSwab as only a portion of the samples with a negative result in QIAstat-Dx and in one FDA-cleared comparator was tested with the complete composite comparator in the retrospective study.

[c] One (1) positive sample for *E.coli* O157 by QIAstat-Dx was excluded from the PPA calculation because reporting of the *E.coli* O157 result is dependent on the preceding STEC result (*E. coli* O157 is subtype within STEC) and the STEC result for that sample is unconfirmed.

The proportion of failed runs on initial attempt and following repeats are summarized in Table 11. The error breakdown due to instrument, invalid results, 'sample too concentrated' failures and other run failures are summarized in Table 12.

Table 11. Failures Rate Summary

Transport media	Study	Initial Runs			Final Runs		
		N/Total	%	95% CI	N/Total	%	95% CI
FecalSwab	**Prospective**	16/1227	1.3	0.8 - 2.1	3/1227	0.2	0.1 - 0.7
	Prospective Archived	0/145	0.0	0.0 - 2.6	0/145	0.0	0.0 - 2.6
	Retrospective	11/366	3.0	1.7 - 5.3	5/366	1.4	0.6 - 3.2
	Total	**27/1738**	**1.6**	**1.1 - 2.3**	**8/1738**	**0.5**	**0.2 - 0.9**

Table 12. Failures Types Breakdown

Transport Media	Study	Failure Reason	Initial Runs		Final Runs	
			N/Total	%	N/Total	%
FecalSwab	**Prospective**	**Instrument**	0/1227	0.0	0/1227	0.0
		Invalid*	0/1227	0.0	0/1227	0.0
		Sample too Concentrated†	5/1227	0.4	0/1227	0.0
		Other‡	11/1227	0.9	3/1227	0.2
	Prospective Archived	**Instrument**	0/145	0.0	0/145	0.0
		Invalid	0/145	0.0	0/145	0.0
		Sample too Concentrated	0/145	0.0	0/145	0.0
		Other	0/145	0.0	0/145	0.0
	Retrospective	**Instrument**	1/366	0.3	0/366	0.0
		Invalid	1/366	0.3	0/366	0.0
		Sample too Concentrated	0/366	0.0	0/366	0.0
		Other	9/366	2.5	5/366	1.4

* Internal Control failures with at least one analyte detected and the other analytes reported as 'invalid'
† Run failures related to 'sample concentration too high'. These specimens were repeated with 100 microliters as detailed in Appendix C.
‡ Run failures related to workflow checkpoints.

Co-infections involving EPEC, STEC and E. coli O157 in FecalSwab specimens

The QIAstat-Dx Gastrointestinal Panel 2 reported multiple organism detections (i.e., co-infections) for a total of 58 prospective specimens in FecalSwab. This represents 18.6% of positive specimens (58/312) and 4.7% of all analyzed specimens (58/1,222). The QIAstat-Dx Gastrointestinal Panel 2 detected 50 co-infections involving EPEC, *E. coli* O157 or

STEC, representing 86.2% of all co-infections detected (50/58). Most of these co-infections contained two organisms (43/50; 86.0%), while 10.0% (5/50) contained three organisms and 4.0% (2/50) contained four organisms. The most common co-infections involving EPEC, STEC or *E. coli* O157 are shown in Table 13.

Table 13. Most Prevalent Multiple Detection Combinations (≥2 instances) as Determined by the QIAstat-Dx Gastrointestinal Panel 2 in FecalSwab specimens

Multiple Detection Combination	Number of FecalSwab Specimens
Adenovirus F40/F41 + Enteropathogenic *E. coli* (EPEC)	2
Campylobacter + Rotavirus A	2
Campylobacter + Enteropathogenic *E. coli* (EPEC) + Rotavirus A	2
E. coli O157 + Shiga-like toxin *E. coli* (STEC) *stx1*/*stx2*	2
Enteropathogenic *E. coli* (EPEC) + Enterotoxigenic *E. coli* (ETEC) *lt*/*st* + Norovirus GI/GII	2
Enteropathogenic *E. coli* (EPEC) + *Giardia lamblia*	2
Enteropathogenic *E. coli* (EPEC) + Rotavirus A	2
Enteropathogenic *E. coli* (EPEC) + *Yersinia enterocolitica*	2
Enteropathogenic *E. coli* (EPEC) + Enterotoxigenic *E. coli* (ETEC) *lt*/*st*	4
Enteropathogenic *E. coli* (EPEC) + Norovirus GI/GII	12
Campylobacter + Enteropathogenic *E. coli* (EPEC)	13

The analyte most commonly found in mixed infections was EPEC (45). STEC was found in 5 mixed infections and *E. coli* O157 in 3 mixed infections. Other pathogens were found in mixed infections (72) as shown in Table 14.

Table 14. Prevalence of EPEC, STEC and *E. coli* O157 in Mixed Infections in FecalSwab specimens as determined by the QIAstat-Dx Gastrointestinal Panel 2.

Analyte	N	%
Enteropathogenic *E. coli* (EPEC)	45	36.0
Shiga-like toxin *E. coli* (STEC) *stx1*/*stx2*	5	4.0
E. coli O157	3	2.4
Other QIAstat-Dx GI2 analytes	72	57.6

Contrived Specimens Testing

Some analytes are so rare that both prospective and retrospective testing efforts were insufficient to demonstrate system performance, that was the case for *E. coli* O157 in FecalSwab specimens. Therefore, to supplement the prospective and retrospective specimens' test results, an evaluation of contrived specimens was also performed.

Contrived specimens were prepared using negative residual specimens that had previously tested negative by QIAstat-Dx Gastrointestinal Panel 2 and comparator methods. At least 50% of these specimens were spiked at concentrations slightly above the Limit of Detection (2x LoD) and the rest at 5x and 10x LoD, using quantified strains for each pathogen. Approximately half of the specimens spiked were stools preserved in FecalSwab, and the other half were stools preserved in Para-Pak C&S. The analyte status of each contrived specimen was blinded to the users analyzing the specimens. Results are summarized in Table 15.

Table 15. Test Results Summary for Contrived Specimens.

QIAstat-Dx GI2 Target	Medium Brand	Positive Percent Agreement (PPA)		
		Fraction	Percentage	95% CI
E. coli O157	FecalSwab	35 / 35	100.0	90.1-100.0
	Para-Pak C&S	34 / 34	100.0	89.9-100.0

Conclusions

The QIAstat-Dx Gastrointestinal Panels are substantially equivalent to their legally marketed predicate devices.