



March 9, 2026

QIAGEN GmbH
% Sonia Pablo
Senior Manager, Regulatory Affairs
STAT-Dx Life, S.L. (A QIAGEN Company)
Carrer Baldiri Reixac, 4
Barcelona, 08028
Spain

Re: K254032

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: December 16, 2025

Received: December 16, 2025

Dear Sonia Pablo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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
2026.03.09 14:05:53 -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

510(k) Number (if known)

K254032

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 and QIAstat-Dx Rise 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 and QIAstat-Dx Rise 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 and QIAstat-Dx Rise 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary**General Information**

Submitted by: QIAGEN GmbH
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Date Prepared: December 15, 2025

Device 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, K252329
QIAstat-Dx GI Panel 2 Mini B&V, K252329
QIAstat-Dx GI Panel 2 Mini B, K252329

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 (“QIAstat-Dx Gastrointestinal Panels”) are multiplexed nucleic acid tests which are designed for use with the QIAstat-Dx Analyzer 2.0. The device modification is to add the QIAstat-Dx Rise as an additional instrument for use with the QIAstat-Dx Gastrointestinal Panels. The QIAstat-Dx Rise is a higher throughput platform, incorporating up to eight QIAstat-Dx Analytical Modules (AM) on a small footprint. The instrument allows queuing up to 18 cartridges, with processing being limited up to 16 cartridges for the QIAstat-Dx Gastrointestinal Panels. The cartridges are scheduled for processing and delivered to the appropriate AM by an integrated robotic handler. The AM used with the QIAstat-Dx Rise is the same AM that can be used with the QIAstat-Dx Analyzer 2.0.

The modified QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B are identical to the QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B (K252329), respectively, with the exception of the Instructions for Use which were updated to include the assay-specific procedure for use with the QIAstat-Dx Rise.

The QIAstat-Dx Gastrointestinal Panels 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.

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.

The QIAstat-Dx Gastrointestinal Panels Assay Definition File (ADF) automatically interprets test results and displays a summary on the instrument display screen. The detected analytes are displayed in red. All other tested but not detected analytes are listed in green. The instrument 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”).

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 and QIAstat-Dx Rise 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 and QIAstat-Dx Rise 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 QIAstatDx 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 and QIAstat-Dx Rise 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 QIAstatDx 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 with QIAstat-Dx Rise and the Predicate Devices

Similarities and differences between the QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx GI Panel 2 Mini B&V, QIAstat-Dx GI Panel 2 Mini B with QIAstat-Dx Rise and the predicate device are shown in [Table 1](#), [Table 2](#), and [Table 3](#), respectively.

Table 1: Comparison of the QIAstat-Dx Gastrointestinal Panel 2 with QIAstat-Dx Rise with the predicate device

Characteristic	Subject Device	Predicate
Name	QIAstat-Dx Gastrointestinal Panel 2	QIAstat-Dx Gastrointestinal Panel 2
510(k) No.	TBD	K252329
Regulation	21 CFR 866.3990	21 CFR 866.3990
Product Code	PCH	PCH
Device Class	Class II	Class II
Similarities		
Intended Use/Indications for Use	The QIAstat-Dx Gastrointestinal Panel 2 is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise for the simultaneous <i>in vitro</i> 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 <i>E. coli</i>/ <i>Shigella</i> pathotypes), and parasites are identified with the QIAstat-Dx Gastrointestinal Panel 2: • Adenovirus F40/F41 • Astrovirus • Norovirus GI/GII • Rotavirus A • <i>Campylobacter</i> (<i>C. jejuni</i>, <i>C. coli</i> and <i>C. upsaliensis</i>)	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 <i>in vitro</i> 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 <i>E. coli</i>/<i>Shigella</i> pathotypes), and parasites are identified with the QIAstat-Dx Gastrointestinal Panel 2: • Adenovirus F40/F41 • Astrovirus • Norovirus GI/GII • Rotavirus A • <i>Campylobacter</i> (<i>C. jejuni</i>, <i>C. coli</i> and <i>C. upsaliensis</i>) • <i>Shigella</i>/Enteroinvasive <i>Escherichia coli</i> (EIEC)

Characteristic	Subject Device	Predicate
	• <i>Shigella</i>/Enteroinvasive <i>Escherichia coli</i> (EIEC) • Enteropathogenic <i>Escherichia coli</i> (EPEC) • Enterotoxigenic <i>Escherichia coli</i> (ETEC) lt/st • Shiga-like toxin-producing <i>Escherichia coli</i> (STEC) stx1/stx2 (including specific identification of <i>E. coli</i> O157 serogroup within STEC) • <i>Salmonella</i> • <i>Plesiomonas shigelloides</i> • <i>Yersinia enterocolitica</i> • <i>Cryptosporidium</i> • <i>Cyclospora cayetanensis</i> • <i>Entamoeba histolytica</i> • <i>Giardia lamblia</i>* *Also known as <i>Giardia intestinalis</i> and <i>Giardia duodenalis</i> 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.	• Enteropathogenic <i>Escherichia coli</i> (EPEC) • Enterotoxigenic <i>Escherichia coli</i> (ETEC) lt/st • Shiga-like toxin-producing <i>Escherichia coli</i> (STEC) stx1/stx2 (including specific identification of <i>E. coli</i> O157 serogroup within STEC) • <i>Salmonella</i> • <i>Plesiomonas shigelloides</i> • <i>Yersinia enterocolitica</i> • <i>Cryptosporidium</i> • <i>Cyclospora cayetanensis</i> • <i>Entamoeba histolytica</i> • <i>Giardia lamblia</i>* *Also known as <i>Giardia intestinalis</i> and <i>Giardia duodenalis</i> 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

Characteristic	Subject Device	Predicate
	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.	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
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 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.
Assay Targets	Same	Detects sixteen (16) targets

Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise	QIAstat-Dx Analyzer 2.0

Table 2: Comparison of the QIAstat-Dx GI Panel 2 Mini B&V with QIAstat-Dx Rise with 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.	TBD	K252329
Regulation	21 CFR 866.3990	21 CFR 866.3990
Product Code	PCH	PCH
Device Class	Class II	Class II
Similarities		
Intended Use/Indications for 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 and QIAstat-Dx Rise 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 <i>E. coli</i>/ <i>Shigella</i> pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B&V: • Norovirus • <i>Campylobacter</i> • <i>Shigella</i> • Shiga-like toxin <i>E. coli</i> (STEC) • <i>Salmonella</i> Concomitant culture is necessary for organism recovery and further	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 <i>E. coli</i>/<i>Shigella</i> pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B&V: • Norovirus • <i>Campylobacter</i> • <i>Shigella</i> • Shiga-like toxin <i>E. coli</i> (STEC) • <i>Salmonella</i> Concomitant culture is necessary for organism recovery and further typing of bacterial agents. The

Characteristic	Subject Device	Predicate
	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 QIAstatDx 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&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.
Specimen Type	Same	Preserved stool in Para-Pak C&S or FecalSwab transport media
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 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.

Characteristic	Subject Device	Predicate
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.
Assay Targets	Same	Detects five (5) targets
Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise	QIAstat-Dx Analyzer 2.0

Table 3: Comparison of the QIAstat-Dx GI Panel 2 Mini B with QIAstat-Dx Rise with 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.	TBD	K252329
Regulation	21 CFR 866.3990	21 CFR 866.3990
Product Code	PCH	PCH
Device Class	Class II	Class II
Similarities		
Intended Use/Indications for 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 and QIAstat-Dx Rise 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 <i>E. coli</i> / <i>Shigella</i> 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 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 <i>E. coli</i> / <i>Shigella</i> pathotypes) are identified with the QIAstat-Dx GI Panel 2 Mini B: • <i>Campylobacter</i>

Characteristic	Subject Device	Predicate
	• <i>Campylobacter</i> • <i>Shigella</i> • Shiga-like toxin <i>Escherichia coli</i> (STEC) • <i>Salmonella</i> • <i>Yersinia enterocolitica</i> 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 QIAstatDx 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.	• <i>Shigella</i> • Shiga-like toxin <i>Escherichia coli</i> (STEC) • <i>Salmonella</i> • <i>Yersinia enterocolitica</i> 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
Amplification and Detection Technology	Same	PCR

Characteristic	Subject Device	Predicate
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 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.
Assay Targets	Same	Detects five (5) targets
Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 2.0 and QIAstat-Dx Rise	QIAstat-Dx Analyzer 2.0

Summary of Performance Data

The performance for the QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B with QIAstat-Dx Rise is equivalent to the performance for the QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B (K252329).

The following analytical studies were performed on the QIAstat-Dx Rise and successfully demonstrated the equivalent performance of the QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B:

- Equivalence at Low Analyte Concentration
- Carryover
- Reproducibility

Conclusions

The technological characteristics and the indications for use of the QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B remain the same. Validation data and information submitted in this premarket notification to add QIAstat-Dx Rise demonstrate that the modified QIAstat-Dx Gastrointestinal Panel 2, the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B are substantially equivalent to the predicate devices.