February 28, 2025

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

Re: K250324
Trade/Device Name: 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: February 5, 2025
Received: February 5, 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 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
Digitally signed by Bryan M. Grabias -S
Date: 2025.02.28 07:46:03 -05'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250324

Device Name
QIAstat-Dx GI Panel 2 Mini B

Indications for Use *(Describe)*
The QIAstat-Dx GI Panel 2 Mini B is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 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

*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.

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.

510(k) Summary

General Information

Submitted by: QIAGEN GmbH
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Contact Person: Sonia Pablo
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Spain
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Date Prepared: February 4, 2025

Device Name: 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

Device Description

The QIAstat-Dx® GI Panel 2 Mini B (Cat. no. 691423) assay is a modified device (reduced version) of the QIAstat-Dx Gastrointestinal Panel 2 (Cat. no. 691421). The QIAstat-Dx GI Panel 2 Mini B is identical to the QIAstat-Dx Gastrointestinal Panel 2 (K220062) but uses an Assay Definition File (ADF) which masks all but five pathogens (targets) from the QIAstat-Dx Gastrointestinal Panel 2. 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 *E. coli* (STEC), *Salmonella* and *Yersinia enterocolitica.* The QIAstat-Dx GI Panel 2 Mini B is part of the QIAstat-Dx system and works with the QIAstat-Dx Analyzer 1.0. It will be available in a separately labeled kit.

The QIAstat-Dx GI Panel 2 Mini B is intended to be used with stool samples in Para-Pak C&S or FecalSwab transport media.

QIAstat-Dx 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 1.0.

Once the cartridge is inserted into the instrument, the test starts automatically and runs for about 78 minutes. When the test is finished, the cartridge is removed by the user and discarded. The QIAstat-Dx Analyzer 1.0 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 GI Panel 2 Mini B cartridge. 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.

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 (TC) 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

The QIAstat-Dx® GI Panel 2 Mini B is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 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*

*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.

Comparison of the QIAstat-Dx GI Panel 2 Mini B and the Predicate Device

Similarities and differences between the QIAstat-Dx GI Panel 2 Mini B and the predicate device are shown in Table 1.

Table 1: Comparison of the QIAstat-Dx GI Panel 2 Mini B with the predicate device

Characteristic	Modified Device	Predicate
Name	QIAstat-Dx® GI Panel 2 Mini B	QIAstat-Dx Gastrointestinal Panel 2
510(k) No.	TBD	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® GI Panel 2 Mini B is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 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* *Only with Para-Pak C&S, not reported for FecalSwab	The QIAstat-Dx® Gastrointestinal Panel 2 is a multiplexed nucleic acid test intended for use with the QIAstat-Dx Analyzer 1.0 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)*

Characteristic	Modified Device	Predicate
	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.	• *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 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 only)	RNA/DNA

Characteristic	Modified Device	Predicate
Organisms Detected	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 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	QIAstat-Dx Gastrointestinal Panel 2 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.
Amplification and Detection Instrument System	Same	QIAstat-Dx Analyzer 1.0
Differences		
Assay Targets	The QIAstat-Dx GI Panel 2 Mini B detects five (5) targets	The QIAstat-Dx Gastrointestinal Panel 2 detects sixteen (16) targets

Summary of Performance Data

The performance data for the QIAstat-Dx GI Panel 2 Mini B is equivalent to the QIAstat-Dx Gastrointestinal Panel 2 (K220062) with the exception that it only includes data for the five analytes reported by the QIAstat-Dx GI Panel 2 Mini B (*Campylobacter*, *Shigella,* Shiga-like toxin *E. coli* (STEC), *Salmonella* and *Yersinia enterocolitica*). Please see the *QIAGEN QIAstat-Dx GI Panel 2 Mini B Instructions for Use* for performance tables.

Conclusions

The technological characteristics and performance of the QIAstat-Dx GI Panel 2 Mini B are the same as the predicate device except for labeling and the modified Assay Definition File (ADF) that has been verified and validated to demonstrate there is no change in safety and effectiveness. The submitted information provided in this premarket notification is complete and supports a substantial equivalence determination to the predicate device.