510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K254032

B Applicant

QIAGEN GmbH

C Proprietary and Established Names

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

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PCH	Class II	21 CFR 866.3990 - Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to modify the previously cleared (K252329) QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx GI Panel 2 Mini B&V, and QIAstat-Dx GI Panel 2 Mini B to add the QIAstat-Dx Rise instrument.

B Measurand:

Targeted nucleic acid sequences of the following gastrointestinal microorganisms:

- 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*

C Type of Test:

A multiplex nucleic acid-based test intended for use with the QIAstat-Dx system for the qualitative *in vitro* detection and identification of multiple bacteria, viruses, and parasites in preserved stool samples collected from individuals suspected of gastrointestinal infection.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

For *in vitro* diagnostic Use Only

D Special Instrument Requirements:

The QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx GI Panel 2 Mini B&V, and QIAstat-Dx GI Panel 2 Mini B are part of the QIAstat-Dx system and work only with QIAstat-Dx Analyzer 2.0 or QIAstat-Dx Rise.

IV Device/System Characteristics:

A Device Description:

The QIAstat-Dx Gastrointestinal Panels were originally cleared under K220062 (The QIAstat-Dx Gastrointestinal Panel 2), K243813 (The QIAstat-Dx Gastrointestinal Panel 2 Mini B&V), and K250324 (The QIAstat-Dx Gastrointestinal Panel 2 Mini B).

The QIAstat-Dx Gastrointestinal Panel 2 assay is performed on the QIAstat-Dx Analyze 2.0 or QIAstat-Dx Rise. The QIAstat-Dx Gastrointestinal Panel 2 cartridge is a single-use cartridge that includes all reagents needed for nucleic acid extraction, nucleic acid amplification, and detection of bacteria, viruses or parasites associated with gastrointestinal infection. Testing requires a 200 µL specimen volume and minimal hands-on time, and the results are available in approximately 80 minutes. The QIAstat-Dx GI Panel 2 Mini B&V and QIAstat-Dx GI Panel 2 Mini B panels are identical to the QIAstat-Dx Gastrointestinal Panel 2 device except only select analytes are reported as described in the intended use

statements for these devices above. Validation data obtained in the original clearance for the QIAstat-Dx Gastrointestinal Panel 2 was also relied upon to support the alternative versions of the panel.

B Principle of Operation:

The principle of operation remains unchanged from the original clearances (K220062, K243813, and K250324). Refer to the original published decision summaries for specific details on the principle of operation of each QIAstat-Dx Gastrointestinal Panel 2 device.

C Instrument Description Information:

1. Instrument Name:

   QIAstat-Dx Analyzer 2.0 with software version 1.6 or higher
   QIAstat-Dx Rise with software version 2.4 or higher

2. Specimen Identification:

   Each instrument is a fully automated instrument that is bi-directionally interfaced and accepts orders from the LIS system. While test orders can be manually programmed through the attached instrument computer, an LIS-generated barcode can also be scanned to initiate testing.

3. Specimen Sampling and Handling:

   Preserved stool samples in Para-Pak C&S or FecalSwab.

4. Calibration:

   Each instrument is provided factory-calibrated and does not require user calibration

5. Quality Control:

   Please refer to the Quality Control information previously reviewed and presented in K220062 FDA Decision Summary.

V Substantial Equivalence Information:

A Predicate Device Name(s):

QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx GI Panel 2 Mini B&V, QIAstat-Dx GI Panel 2 Mini B

B Predicate 510(k) Number(s):

K252329

C Comparison with Predicate(s):

Device & Predicate Device(s):	K254032	K252329
Device Trade Name	QIAstat-Dx Gastrointestinal Panel 2	QIAstat-Dx Gastrointestinal Panel 2
General Device Characteristic 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 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*	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*

	• *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	• *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
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
General Device Characteristic Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise	QIAstat-Dx Analyzer 2.0

Device & Predicate Device(s):	K254032	K252329
Device Trade Name	QIAstat-Dx GI Panel 2 Mini B&V	QIAstat-Dx GI Panel 2 Mini B&V
General Device Characteristic 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 *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	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,

	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.	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.
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
General Device Characteristic Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise	QIAstat-Dx Analyzer 2.0

Device & Predicate Device(s):	K254032	K252329
Device Trade Name	QIAstat-Dx GI Panel 2 Mini B	QIAstat-Dx GI Panel 2 Mini B
General Device Characteristic 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 *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	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

	not detected by this assay test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease	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 five (5) targets
General Device Characteristic Differences		
Amplification and Detection Instrument System	QIAstat-Dx Analyzer 2.0, and QIAstat-Dx Rise	QIAstat-Dx Analyzer 2.0

VI Standards/Guidance Documents Referenced:

Standards:

- ISO 14971 Medical Devices – Application of risk management to medical devices, Third edition, 2019-12
- IEC 62304 Medical Device Software – Software life cycle processes. Edition 1.1, 2015-06; Consolidated version
- IEC 81001-5-1 Health software and health IT systems effectiveness and security – Part 5-1 Security – Activities in the product life cycle. Edition 1.0, 2021-12.
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances - Requirements and tests. Edition 4.1, 2020-09 Consolidated version.

- IEC 61010-1 Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements [Including: Corrigendum 1 (2019)] - Note: This standard is recognized with relevant US national differences applied see reference #1 in Relevant FDA Guidance and/or Supportive Publication section. Edition 3.1 2017-01, Consolidated version.
- IEC 62366-1 Medical Devices – Part 1: Application of usability engineering to medical devices. Edition 1.1, 2020-06, Consolidated version.

Special controls:

- Class II special controls as per 21 CFR 866.3990 - Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay

VII Performance Characteristics

A Analytical Performance:

1. Precision/Reproducibility:
   A reproducibility study for the QIAstat-Dx Gastrointestinal Panel 2 and the automated loading in the QIAstat-Dx Rise system was conducted at three sites, with three reagent lots and three operators per site. The study included a panel of representative analytes at moderate positive, low positive, and negative concentration (Table 1) generated in negative clinical stool matrix (pooled negative stool in Para-Pack C&S transport medium). At each site, operators tested each sample in duplicates with one run per day for five non-consecutive days to generate a total of 90 replicates per analyte level.

Table 1. Sample composition of mixes used in the Reproducibility study.

Reaction Chamber	Pathogen	Low positive concentration (1x LoD)	Moderate positive concentration (3x LoD)	Units
2	Astrovirus (ZeptoMetrix 0810277CF)	3.70E+00	1.11E+01	$TCID_{50}$/mL
3	*Cryptosporidium* (Waterborne P102C)	2.09E+01	6.27E+01	copies/mL
5	Enterotoxigenic *E. coli* (ETEC) lt/st (ZeptoMetrix 0801624)	7.20E+02	2.16E+03	CFU/mL
6	*Salmonella* (ZeptoMetrix 0801437)	6.13E+02	1.84E+03	CFU/mL
7	Adenovirus (ZeptoMetrix 0810085CF)	5.00E-01	1.50E+01	$TCID_{50}$/mL
8	Enteroinvasive *E. coli* (EIEC) (ATCC 43892)	1.30E+02	3.91E+02	CFU/mL

For the QIAstat-Dx GI Panel 2 Mini B&V and the QIAstat-Dx GI Panel 2 Mini B, a reanalysis of raw data generated with the QIAstat-Dx Gastrointestinal Panel 2 study was conducted using the QIAstat-Dx GI Panel 2 Mini B&V and the QIAstat-Dx GI Panel 2 Mini B Assay Definition Files (ADFs), respectively. The study results are summarized in Tables 2 through 4 below.

Table 2. Reproducibility study results summary. (Applicable results to the QIAstat-Dx GI Panel 2 Mini B&V and QIAstat-Dx GI Panel 2 Mini B highlighted in blue**).**

Target	Sample Concentration	Site	Fraction	Percent Agreement	Two-sided Exact 95% Confidence interval	
					Lower	Upper
Adenovirus	**Low positive**	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Moderate positive	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
	Negative	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
Astrovirus	**Low positive**	**Site 1**	28 / 30	93.33%	77.93%	99.18%
		Site 2	29 / 30	96.67%	82.78%	99.92%
		Site 3	29 / 30	96.67%	82.78%	99.92%
		Overall	86 / 90	95.56%	89.01%	98.78%
	Moderate positive	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Negative	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
Cryptosporidium	**Low positive**	**Site 1**	29 / 30	96.67%	82.78%	99.92%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	89 / 90	98.89%	93.96%	99.97%
	Moderate positive	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Negative	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
ETEC	**Low positive**	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Moderate positive	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Negative	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
Salmonella	**Low positive**	**Site 1**	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%

Target	Sample Concentration	Site	Fraction	Percent Agreement	Two-sided Exact 95% Confidence interval	
					Lower	Upper
		Overall	90 / 90	100.00%	95.98%	100.00%
	Moderate positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Negative	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
EIEC	Low positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Moderate positive	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%
	Negative	Site 1	30 / 30	100.00%	88.43%	100.00%
		Site 2	30 / 30	100.00%	88.43%	100.00%
		Site 3	30 / 30	100.00%	88.43%	100.00%
		Overall	90 / 90	100.00%	95.98%	100.00%

Table 3: SD and % CV for each pathogen and concentration across each factor evaluated in the Reproducibility study. (Applicable results to the QIAstat-Dx GI Panel 2 Mini B&V and QIAstat-Dx GI Panel 2 Mini B highlighted in blue**).**

Target	Sample Concentration	Number of Amplified	Number of Non-Amplified	Mean Ct	Within Run (SD, % CV)	Between Day (SD, % CV)	Between Operator (SD, % CV)	Between Lot (SD, % CV)	Between Site (SD, % CV)	Total* (SD, % CV)
Adenovirus	Low positive	90	0	32.47	(0.5356, 1.65%)	(0.1914, 0.59%)	(0.1183, 0.36%)	(0.1027, 0.32%)	(0.0000, 0.00%)	(0.5831, 1.80%)
	Moderate positive	90	0	30.70	(0.5617, 1.83%)	(0.0000, 0.00%)	(0.0674, 0.22%)	(0.0000, 0.00%)	(0.1591, 0.52%)	(0.5802, 1.89%)
Astrovirus	Low positive	86	4	32.99	(0.5148, 1.56%)	(0.0000, 0.00%)	(0.1200, 0.36%)	(0.1536, 0.47%)	(0.0000, 0.00%)	(0.5414, 1.64%)
	Moderate positive	90	0	32.18	(0.3930, 1.22%)	(0.0948, 0.29%)	(0.0271, 0.08%)	(0.0660, 0.21%)	(0.0903, 0.28%)	(0.4148, 1.29%)
Cryptosporidium	Low positive	89	1	26.66	(0.6440, 2.42%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.2558, 0.96%)	(0.1170, 0.44%)	(0.6842, 2.57%)
	Moderate positive	90	0	24.54	(0.5341, 2.18%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.1815, 0.74%)	(0.2936, 1.20%)	(0.6046, 2.46%)
ETEC	Low positive	90	0	32.03	(0.5778, 1.80%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0695, 0.22%)	(0.2956, 0.92%)	(0.6293, 1.96%)
	Moderate positive	90	0	29.91	(0.5760, 1.93%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.2315, 0.77%)	(0.6066, 2.03%)
Salmonella	Low positive	90	0	34.25	(0.5647, 1.65%)	(0.0454, 0.13%)	(0.0000, 0.00%)	(0.1416, 0.41%)	(0.0227, 0.07%)	(0.5785, 1.69%)
	Moderate positive	90	0	32.80	(0.4695, 1.43%)	(0.0461, 0.14%)	(0.0000, 0.00%)	(0.0813, 0.25%)	(0.1254, 0.38%)	(0.4873, 1.49%)
EIEC	Low positive	90	0	32.59	(0.6148, 1.89%)	(0.0000, 0.00%)	(0.2005, 0.62%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.6435, 1.97%)

	Moderate positive	**90**	**0**	**30.58**	(0.5573, 1.82%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.1741, 0.57%)	(0.5753, 1.88%)
IC	**n/a**	**270**	**0**	**32.43**	(0.9439, 2.91%)	(0.5077, 1.57%)	(0.1103, 0.34%)	(0.6355, 1.96%)	(0.1229, 0.38%)	(1.1911, 3.67%)

* TOTAL means total variability observed across the study

Table 4: SD and %CV for each Site, pathogen and concentration across each factor evaluated in the Reproducibility study. (Applicable results to the QIAstat-Dx GI Panel 2 Mini B&V and QIAstat-Dx GI Panel 2 Mini B highlighted in blue**).**

Site	Target	Sample Concentration	Number of Amplified	Number of Non-Amplified	Mean Ct	Within Run (SD, % CV)	Between Day (SD, % CV)	Between Operator (SD, % CV)	Between Lot (SD, % CV)	Total* (SD, % CV)
Site 1	**Adenovirus**	**Low positive**	**30**	**0**	**32.50**	(0.7057, 2.17%)	(0.3406, 1.05%)	(0.2103, 0.65%)	(0.3464, 1.07%)	(0.8461, 2.60%)
		Moderate positive	**30**	**0**	**30.65**	(0.6086, 1.99%)	(0.0871, 0.28%)	(0.2601, 0.85%)	(0.0000, 0.00%)	(0.6506, 2.12%)
	Astrovirus	**Low positive**	**28**	**2**	**32.98**	(0.4174, 1.27%)	(0.0000, 0.00%)	(0.2809, 0.85%)	(0.2260, 0.69%)	(0.5233, 1.59%)
		Moderate positive	**30**	**0**	**32.24**	(0.3699, 1.15%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.1267, 0.39%)	(0.3846, 1.19%)
	Cryptosporidium	**Low positive**	**29**	**1**	**26.73**	(0.6447, 2.41%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.2478, 0.93%)	(0.6763, 2.53%)
		Moderate positive	**30**	**0**	**24.77**	(0.3730, 1.51%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0680, 0.27%)	(0.3772, 1.52%)
	ETEC	**Low positive**	**30**	**0**	**32.22**	(0.6723, 2.09%)	(0.0000, 0.00%)	(0.0617, 0.19%)	(0.2951, 0.92%)	(0.7165, 2.22%)
		Moderate positive	**30**	**0**	**29.98**	(0.3768, 1.26%)	(0.1237, 0.41%)	(0.0737, 0.25%)	(0.0000, 0.00%)	(0.3980, 1.33%)
	Salmonella	**Low positive**	**30**	**0**	**34.35**	(0.6234, 1.81%)	(0.2306, 0.67%)	(0.0000, 0.00%)	(0.2853, 0.83%)	(0.6991, 2.04%)
		Moderate positive	**30**	**0**	**32.83**	(0.3613, 1.10%)	(0.1229, 0.37%)	(0.0529, 0.16%)	(0.1236, 0.38%)	(0.3941, 1.20%)
	EIEC	**Low positive**	**30**	**0**	**32.72**	(0.7947, 2.43%)	(0.0000, 0.00%)	(0.3223, 0.98%)	(0.0000, 0.00%)	(0.8386, 2.56%)
		Moderate positive	**30**	**0**	**30.58**	(0.4671, 1.53%)	(0.1820, 0.60%)	(0.1195, 0.39%)	(0.0000, 0.00%)	(0.5054, 1.65%)
	IC	**n/a**	**90**	**0**	**32.65**	(0.9226, 2.83%)	(0.5657, 1.73%)	(0.1920, 0.59%)	(0.7258, 2.22%)	(1.2336, 3.78%)
Site 2	**Adenovirus**	**Low positive**	**30**	**0**	**32.37**	(0.3103, 0.96%)	(0.2028, 0.63%)	(0.0000, 0.00%)	(0.0708, 0.22%)	(0.3657, 1.13%)
		Moderate positive	**30**	**0**	**30.54**	(0.2109, 0.69%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.2109, 0.69%)
	Astrovirus	**Low positive**	**29**	**1**	**32.99**	(0.5680, 1.72%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.5680, 1.72%)
		Moderate positive	**30**	**0**	**32.04**	(0.2791, 0.87%)	(0.1900, 0.59%)	(0.1423, 0.44%)	(0.0000, 0.00%)	(0.3489, 1.09%)
	Cryptosporidium	**Low positive**	**30**	**0**	**26.78**	(0.7090, 2.65%)	(0.0000, 0.00%)	(0.2518, 0.94%)	(0.0000, 0.00%)	(0.7392, 2.76%)
		Moderate positive	**30**	**0**	**24.66**	(0.5563, 2.26%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.2443, 0.99%)	(0.5922, 2.40%)
	ETEC	**Low positive**	**30**	**0**	**31.67**	(0.5035, 1.59%)	(0.0000, 0.00%)	(0.0937, 0.30%)	(0.1531, 0.48%)	(0.5261, 1.66%)
		Moderate positive	**30**	**0**	**29.62**	(0.2979, 1.01%)	(0.1728, 0.58%)	(0.0000, 0.00%)	(0.1384, 0.47%)	(0.3559, 1.20%)

Site	Target	Sample Concentration	Number of Amplified	Number of Non-Amplified	Mean Ct	Within Run (SD, % CV)	Between Day (SD, % CV)	Between Operator (SD, % CV)	Between Lot (SD, % CV)	Total* (SD, % CV)
	Salmonella	**Low positive**	**30**	**0**	**34.14**	(0.5250, 1.54%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.5250, 1.54%)
		Moderate positive	**30**	**0**	**32.64**	(0.3750, 1.15%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0935, 0.29%)	(0.3829, 1.17%)
	EIEC	**Low positive**	**30**	**0**	**32.44**	(0.5040, 1.55%)	(0.0000, 0.00%)	(0.1483, 0.46%)	(0.1321, 0.41%)	(0.5321, 1.64%)
		Moderate positive	**30**	**0**	**30.37**	(0.3450, 1.14%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.1238, 0.41%)	(0.3600, 1.19%)
	IC	**n/a**	**90**	**0**	**32.17**	(0.7732, 2.40%)	(0.4737, 1.47%)	(0.0000, 0.00%)	(0.5215, 1.62%)	(0.9816, 3.05%)
Site 3	**Adenovirus**	**Low positive**	**30**	**0**	**32.52**	(0.4240, 1.30%)	(0.0000, 0.00%)	(0.0325, 0.10%)	(0.0000, 0.00%)	(0.4248, 1.31%)
		Moderate positive	**30**	**0**	**30.91**	(0.6986, 2.26%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.6986, 2.26%)
	Astrovirus	**Low positive**	**29**	**1**	**33.02**	(0.5487, 1.66%)	(0.0371, 0.11%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.5497, 1.66%)
		Moderate positive	**30**	**0**	**32.26**	(0.4704, 1.46%)	(0.0798, 0.25%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.4760, 1.48%)
	Cryptosporidium	**Low positive**	**30**	**0**	**26.47**	(0.5460, 2.06%)	(0.2356, 0.89%)	(0.0000, 0.00%)	(0.2104, 0.80%)	(0.6120, 2.31%)
		Moderate positive	**30**	**0**	**24.19**	(0.6292, 2.60%)	(0.0000, 0.00%)	(0.2250, 0.93%)	(0.0000, 0.00%)	(0.6564, 2.71%)
	ETEC	**Low positive**	**30**	**0**	**32.20**	(0.4705, 1.46%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.4705, 1.46%)
		Moderate positive	**30**	**0**	**30.12**	(0.8429, 2.80%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.8429, 2.80%)
	Salmonella	**Low positive**	**30**	**0**	**34.27**	(0.4878, 1.42%)	(0.0309, 0.09%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.4886, 1.43%)
		Moderate positive	**30**	**0**	**32.94**	(0.6151, 1.87%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.6151, 1.87%)
	EIEC	**Low positive**	**30**	**0**	**32.62**	(0.4577, 1.40%)	(0.1714, 0.53%)	(0.0808, 0.25%)	(0.0718, 0.22%)	(0.4921, 1.51%)
		Moderate positive	**30**	**0**	**30.78**	(0.7394, 2.40%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.0000, 0.00%)	(0.7394, 2.40%)
	IC	**n/a**	**90**	**0**	**32.46**	(1.1075, 3.41%)	(0.4657, 1.43%)	(0.1043, 0.32%)	(0.6334, 1.95%)	(1.2971, 4.00%)

* TOTAL means total variability observed across the study

All negative, moderate positive, and low positive samples for all analytes exhibited acceptable performance. There were no significant differences observed within run, between lots, between days, between operators, or between sites (Tables 3 – 4). Overall, Ct variability was low, and the study demonstrates assay variability within an acceptable range.

2. Linearity:
Not applicable, the QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx GI Panel 2 Mini B&V, QIAstat-Dx GI Panel 2 Mini B are qualitative devices.

3. Analytical Specificity/Interference:
No new Analytical Specificity/Interference data were reviewed in this 510(k). The only modification to the QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx GI Panel 2 Mini B&V, QIAstat-Dx GI Panel 2 Mini B in this 510(k) submission is the addition of the QIAstat-Dx Rise instrument. Refer to FDA decision Summary K220062 for Analytical Specificity/Interference study results for these devices.

4. Detection Limit and Assay Reportable Range:

   a. Detection Limit
   A limit of detection (LoD) study was performed to support clearance of the original QIAstat-Dx Gastrointestinal Panel 2 (K220062). Additional testing to demonstrate sample type equivalency for the FecalSwab sample type was also performed. For additional information, please refer to the original published decision summary of K220062.

   b. Assay Reportable Range
   Not applicable, the QIAstat-Dx Gastrointestinal Panel 2, QIAstat-Dx GI Panel 2 Mini B&V, QIAstat-Dx GI Panel 2 Mini B are qualitative devices.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   a. Controls No changes were made to assay controls. Please refer to the Quality Control information previously reviewed and presented in K220062 FDA Decision Summary.

   b. In-Use Sample Stability
   The in-use stability study conducted using the QIAstat-Dx Gastrointestinal Panel 2 under the QIAstat-Dx Rise condition demonstrate that the cartridge performance is not impacted when removing the cartridge from its primary package and loading with a sample re-suspended with either of the two tested transport media (Para-Pak C&S and FecalSwab) after 30 minutes, followed by a wait time up to 45 minutes at room temperature and a subsequent period of 145 minutes at 30°C in the QIAstat-Dx Rise cartridge tray before running the cartridge. Additionally, the QIAstat-Dx Rise automatically detects if a cartridge has been placed into the instrument for longer than 145 minutes and will reject cartridges exceeding the maximum on-board stability time.

   The generated raw data was reanalyzed with the ADFs corresponding to the QIAstat-Dx GI Panel 2 Mini B&V and QIAstat-Dx GI Panel 2 Mini B, demonstrating the same In-use stability claims as the QIAstat-Dx Gastrointestinal Panel 2.

6. Assay Cut-Off:
The QIAstat Dx Gastrointestinal Panel 2 includes defined Ct value cutoffs for each assay target. For additional information regarding the assay cut-offs refer to the published decision summary for the QIAstat Dx Gastrointestinal Panel 2 (K220062).

7. Carry-Over:
   a. QIAstat-Dx Analyzer 2.0
   The QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Analyzer 2.0 use the same analytical module and workflow and belong to the same instrument family. The carry-over of

QIAstat-Dx Analyzer 1.0 was evaluated in K220062. Please refer to the published K220062 decision summary for additional information.

b. QIAstat-Dx Rise Analyzer

An additional carry-over study was conducted to evaluate the potential for cross-contamination between two consecutive runs when using the QIAstat-Dx Gastrointestinal Panel 2 on the QIAstat-Dx Rise during automatic handling of cartridges by the robotic arm and during cartridge storage in the sampler input drawer of the QIAstat-Dx Rise analyzer.

A positive panel consisting of high concentration of representative pathogens (Norovirus GI/GII, *Cryptosporidium*, *Yersinia enterocolitica*, *Salmonella*, Adenovirus F40/F41, and *Shigella flexneri*) were prepare in clinical stool matrix in Para-Pak C&S transport medium. High titers were defined as $\geq 10^5$ TCID50/mL for viral targets, $\geq 10^6$ CFU/mL for bacterial targets, and 10^5 cells/mL for parasitic targets. The positive panel was tested 20 times between runs of negative (no analyte cartridge) for a total of 8 runs and 16 cartridges per run. A total of 128 cartridges were run during the study (108 negative and 20 positive). All valid runs generated the expected results, and no unexpected signals were observed. Therefore, no carry-over between cartridges was observed.

The reanalysis of the results using the QIAstat-Dx Gastrointestinal Panel2 Mini B&V and the QIAstat-Dx Gastrointestinal Panel2 Mini B Assay Definition Files showed equivalent results to all the results obtained for the targets detected by both panels.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not applicable.

2. Matrix Comparison:
   Refer to transport media equivalency data previously reviewed and presented in K220062 Decision Summary.

C Clinical Studies:

1. Clinical Sensitivity:
   Refer to clinical study data previously reviewed and presented in K220062 and K252329 FDA decision summaries.

2. Clinical Specificity:
   Refer to clinical study data previously reviewed and presented in K220062 and K252329 FDA decision summaries.

3. Clinical Cut-Off

   Not Applicable.

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not Applicable.

D Expected Values/Reference Range:

Please refer to the Expected Values data previously reviewed and presented in K220062 and K252329 FDA decision summaries.

E Other Supportive Instrument Performance Characteristics Data:

1. Instrument Equivalency Study

A study was performed to assess whether the 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 at Low Analyte Concentrations (LAC) are equivalent in the QIAstat-Dx Analyzer and the QIAstat-Dx Rise. This study was initially performed for all targets included in the QIAstat-Sc Gastrointestinal panel 2. The results of this study were reanalyzed for the targets in scope of the QIAstat-Dx GI Panel 2 Mini B&V, and the QIAstat-Dx GI Panel 2 Mini B by using the panel-specific ADFs.

The performance of each analyte detected on the QIAstat-Dx Gastrointestinal Panel 2 at LAC levels was evaluated on the QIAstat-Dx Rise and QIAstat-Dx Analyzer by testing analytical samples made from high titer stocks diluted to limited concentrations into negative clinical stool matrix (pooled negative stools in Para-Pak transport medium). The composition of the respective sample mixes and dilutions from the stock tested is described in Table 5.

Table 5: Mixes generated and tested in the instrument equivalency study

Mix	Pathogen	Strain information	Supplier Catalog ID	Concentration in 1xMix
1	*Giardia lamblia*	WB (Bethesda)	ATCC 30957	7.90E+01 cells/mL
	Enteropathogenic *E. coli* (EPEC)	*Escherichia coli* O111:NM (EPEC)	ZeptoMetrix 0801747	1.65E+03 cfu/mL
	Yersinia enterocolitica	Z036	ZeptoMetrix 0801734	7.24E+02 cfu/mL
	Salmonella	*Salmonella enterica* Serovar Typhimurium Z005	ZeptoMetrix 0801437	6.13E+02 cfu/mL
	Adenovirus F40/F41	Adenovirus Type 41 (Tak)	ZeptoMetrix 0810085CF	5.01E-02 $TCID_{50}$/mL
2	Norovirus GI/GII	GII.4 (recombinant)	ZeptoMetrix 0810087CF	1.41E-01 $TCID_{50}$/mL
	Entamoeba histolytica	HM-1:IMSS (Mexico City 1967)	ATCC 30459	6.95E-02 cells/mL
	Campylobacter spp.	*Campylobacter jejuni* subsp. *jejuni* RM3193	ATCC BAA-1234	1.10E+02 cfu/mL
	Shiga-like toxin-producing *E. coli* (STEC) O157	Serotype O157:H7	CECT 4783	3.93E+04 copies/mL
3	*Cryptosporidium*	*Cryptosporidium parvum* - Iowa isolate	Waterborne P102C	6.25E+02 oocysts/mL
	Plesiomonas shigelloides	Bader	ATCC 14029	8.50E+00 cfu/mL
	Rotavirus A	69M	ZeptoMetrix 0810280CF	1.32E+01 $TCID_{50}$/mL

4	Astrovirus	ERE IID 2371 (type 8)	ZeptoMetrix 0810277CF	1.17E+01 $TCID_{50}$/mL
	Cyclospora cayetanensis	-	Lacny LAC2827 (clinical sample)	1.37E+02 copies/mL
	Enterotoxigenic *E. coli* (ETEC) *lt/st*	ETEC; ST+, LT+	ZeptoMetrix 0801624	7.20E+02 cfu/mL
	Enteroinvasive *E. coli* (EIEC)/*Shigella*	*Escherichia coli* CDC EDL 1282, O29:NM	ATCC 43892	4.13E+01 cfu/mL
5	Astrovirus	ERE IID 2371 (type 8)	ZeptoMetrix 0810277CF	3.70+00 $TCID_{50}$/mL
	Campylobacter spp.	*Campylobacter jejuni* subsp. *jejuni* RM3193	ATCC BAA-1234	1.10E+04 cfu/mL
	Plesiomonas shigelloides	Bader	ATCC 14029	2.69E+01 cfu/mL
6	Adenovirus F40/F41	Adenovirus Type 41 (Tak)	ZeptoMetrix 0810085CF	1.58E+00 $TCID_{50}$/mL
7	*Plesiomonas shigelloides*	Bader	ATCC 14029	8.50E+00 $TCID_{50}$/mL

Samples prepared with a combination of the analytes were tested at serial dilutions on the QIAstat-Dx Analyzer until the LAC was found for all targets. The LAC was defined as the lowest concentration where the target was detected ≥ 95% of the time, running 20 replicates. Then, the high negative concentration on the QIAstat-Dx Analyzer was also tested for each target (defined as the highest concentration where the target was detected < 95% of the time). Once these two concentrations were determined for each target on the QIAstat-Dx Analyzer, the same concentrations were tested on the QIAstat-Dx Rise to demonstrate the equivalency of the assay in both platforms. Results are summarized in Table 6.

The study demonstrate equivalence between the QIAstat-Dx Rise and QIAstat-Dx Analyzer 1.0 when using QIAstat-Dx Gastrointestianl Panel 2, QIAstat-Dx Gastrointestinal Panel 2 Mini B&V and the QIAstat-Dx Gastrointestinal Panel Mini 2 B.

Table 6: Instrument Equivalency Study Results for the QIAstat-Dx Gastrointestinal Panel 2 (Applicable results to the QIAstat-Dx GI Panel 2 Mini B&V and QIAstat-Dx GI Panel 2 Mini B highlighted in blue, applicable results only to the QIAstat-Dx GI Panel 2 Mini B&V are highlighted in purple and applicable results only to the QIAstat-Dx GI Panel 2 Mini B are highlighted in dark blue).

Target	**Concentration**	**QIAstat-Dx Analyzer**		**QIAstat-Dx Rise**		**Conclusion**
		Hit rate	**Ct mean**	**Hit rate**	**Ct mean**	
Campylobacter spp.	3476.0 CFU/mL	**20/20**	32.7	**20/20**	34.7	Equivalent
	1098.4 CFU/mL	6/20	37.1	3/20	36.8	
Plesiomonas shigelloides*	8.5 CFU/mL	**20/20**	33.2	**20/20**	33.4	Equivalent
	2.7 CFU/mL	17/20	34.2	18/20	34.5	

Salmonella	1940.0 CFU/mL	**20/20**	33.4	n/a	n/a	Equivalent
	613.0 CFU/mL	18/20	33.8	**19/20**	33.8	
	193.7 CFU/mL	n/a	n/a	12/20	34.4	
Yersinia enterocolitica	2290.0 CFU/mL	**20/20**	34.7	n/a	n/a	Equivalent
	723.6 CFU/mL	18/20	35.2	**20/20**	35.5	
	228.7 CFU/mL	n/a	n/a	14/20	36.0	
Enteroinvasive *E. coli* (EIEC)/Shigella	130.5 CFU/mL	**20/20**	34.4	**20/20**	34.4	Equivalent
	41.2 CFU/mL	17/20	36.0	17/20	36.5	
Enteropathogenic *E. coli* (EPEC)	1652.7 CFU/mL	**19/20**	34.8	**20/20**	35.0	Equivalent
	522.3 CFU/mL	12/20	35.8	15/20	35.8	
Enterotoxigenic *E. coli* (ETEC) *lt/st*	720.5 CFU/mL	**20/20**	33.1	**20/20**	33.2	Equivalent
	227.7 CFU/mL	18/20	34.3	17/20	34.1	
***E. coli* O157**	39333 copies/mL	**19/20**	35.4	**20/20**	35.8	Equivalent
	12429 copies/mL	6/15	36.8	12/20	35.9	
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	39333 copies/mL	**20/20**	35.4	**20/20**	34.5	Equivalent
	12429 copies/mL	13/15	36.6	18/20	35.1	
Cryptosporidium spp.	661 copies/mL	n/a	n/a	**20/20**	32.2	Equivalent
	209 copies/mL	**20/20**	34.5	18/20	33.6	
	66 copies/mL	5/10	34.4	n/a	n/a	
Cyclospora cayetanensis	137 copies/mL	**20/20**	34.0	**20/20**	34.5	Equivalent
	43 copies/mL	18/20	35.1	16/20	35.0	
Entamoeba histolytica	0.07 cells/mL	**20/20**	34.0	n/a	n/a	Equivalent
	0.02 cells/mL	12/15	34.8	**19/20**	35.3	
	0.007 cells/mL	n/a	n/a	3/7	36.0	
Giardia lamblia	790.0 cells/mL	n/a	n/a	**20/20**	32.4	Equivalent
	250.0 cells/mL	**19/20**	32.5	15/20	32.6	

	79.0 cells/Ml	14/20	32.3	n/a	n/a	
Adenovirus F40/F41	1.6 TCID50/mL	**20/20**	30.0	n/a	n/a	Equivalent
	0.5 TCID50/mL	17/20	35.1	**19/20**	34.9	
	0.2 TCID50/mL	n/a	n/a	17/20	36.5	
Astrovirus	3.7 TCID50/mL	**20/20**	29.9	**20/20**	30.0	Equivalent
	1.2 TCID50/mL	16/20	30.6	18/20	30.9	
Norovirus GI/GII	1.1 TCID50/mL	**19/20**	31.6	**20/20**	32.1	Equivalent
	0.3 TCID50/mL	10/15	32.3	15/20	32.2	
Rotavirus A	138.0 TCID50/mL	**20/20**	37.3	**20/20**	36.8	Equivalent
	43.6 TCID50/mL	6/10	37.4	9/16	37.0	

* *Plesiomonas shigelloides* did not initially show equivalency at LAC between the QIAstat-Dx Analyzer 1.0 and the QIAstat-Dx Rise. Testing was repeated with an additional set of 20 replicates per instrument, and equivalency between instruments was observed.

2. Electromagnetic compatibility (EMC), Software and Cybersecurity
   No changes to EMC were made to the instrument in this 510(k) submission.

   Software and cybersecurity documentation was reviewed and found to be acceptable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.