510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:

K190585

B. Purpose for Submission:

To obtain a substantial equivalence determination for the BioCode Gastrointestinal Pathogen Panel (GPP) for the detection of microbial nucleic acids extracted from human stool specimens for use on the Applied BioCode MDx 3000 instrument, using an alternate sample extraction system, the Roche Diagnostics MagNA Pure 96.

C. Measurands:

Target nucleic acid sequences of the following gastrointestinal microorganisms: *Campylobacter* (*C. jejuni/C. coli*), *Clostridium difficile* (*C. difficile*) toxin A/B (Fresh samples only), *Salmonella* spp., *Vibrio* (*V. parahaemolyticus/V. vulnificus/ V. cholerae*), including specific identification of *Vibrio parahaemolyticus*, *Yersinia enterocolitica*, Enteroaggregative *Escherichia coli* (EAEC), Enterotoxigenic *Escherichia coli* (ETEC) lt/st, *E. coli* O157 serogroup, Shiga-like toxin-producing *Escherichia coli* (STEC) stx1/stx2, *Shigella*/ Enteroinvasive *Escherichia coli* (EIEC), *Cryptosporidium* spp. (*C. parvum/C. hominis*), *Entamoeba histolytica*, *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*), Adenovirus F 40/41, Norovirus GI/GII and Rotavirus A

D. Type of Test:

Qualitative nucleic acid multiplex test

E. Applicant:

Applied BioCode, Inc.

F. Proprietary and Established Names:

BioCode Gastrointestinal Pathogen Panel (GPP)

G. Regulatory Information:

1.Regulation section:

21 CFR 866.3990. Gastrointestinal microorganisms multiplex nucleic acid-based assay

2.Classification:

Class II (Special Controls)

3.Product code:

PCH, OOI

4.Panel:

Microbiology (83)

H. Indication(s) for Use:

1. Indications for Use(s):

The BioCode Gastrointestinal Pathogen Panel (GPP) is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with the BioCode MDx 3000 Instrument. The BioCode GPP is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites extracted directly from unpreserved stool samples or stool preserved in Cary-Blair transport medium obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria, parasites, and viruses are identified using the BioCode Gastrointestinal Pathogen Panel:

- *Campylobacter* (*C. jejuni/C. coli*)
- *Clostridium difficile* (*C. difficile*) toxin A/B (Fresh samples only)
- *Salmonella* spp.
- *Vibrio* (*V. parahaemolyticus/V. vulnificus/ V. cholerae*), including specific identification of *Vibrio parahaemolyticus*
- *Yersinia enterocolitica*
- Enteroaggregative *Escherichia coli* (EAEC)
- Enterotoxigenic *Escherichia coli* (ETEC) lt/st
- *E. coli* O157 serogroup
- Shiga-like toxin-producing *Escherichia coli* (STEC) stx1/stx2
- *Shigella*/ Enteroinvasive *Escherichia coli* (EIEC)
- *Cryptosporidium* spp. (*C. parvum/C. hominis*)
- *Entamoeba histolytica*
- *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*)
- Adenovirus F 40/41
- Norovirus GI/GII
- Rotavirus A

The BioCode GPP is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical,

laboratory, and epidemiological data. For *In Vitro* Diagnostic Use Only. For Prescription Use Only.

Positive results do not rule out co-infection with organisms not included in the BioCode GPP. The agent detected may not be the definite cause of the disease. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease. Concomitant culture is necessary for organism recovery and further typing of bacterial agents. This device is not intended to monitor or guide treatment for *C. difficile* infection.

Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for Adenovirus 40/41, *Campylobacter*, *E. coli* O157, *Shigella*/EIEC, *Yersinia enterocolitica*, and *Giardia lamblia* were established additionally with retrospective clinical specimens. Performance characteristics for *Entamoeba histolytica*, *Giardia lamblia*, *Yersinia enterocolitica* and *Vibrio* (*V. parahaemolyticus*, *V. vulnificus*, and *V. cholerae*) were established primarily using contrived clinical specimens.

2. Special conditions for use statement(s):

   For *in vitro* diagnostic use only

   For prescription use only.

3. Special instrument requirements:

   For use with the BioCode MDx 3000 instrument.

I. Device Description:

The BioCode Gastrointestinal Pathogen Panel (GPP) is a multiplexed nucleic acid-based test designed to be used with the BioCode MDx 3000 system. The BioCode MDx 3000 is an automated system that integrates PCR amplification, target capture, signal generation and optical detection for multiple gastrointestinal pathogens from a single stool specimen, either unpreserved or in Cary Blair. Once the PCR plate is set up and sealed, all other operations are automated on MDx 3000. The BioCode MDx 3000 Gastrointestinal Infection Panel simultaneously tests for 17 pathogens (see table below) from unpreserved stool specimens or stool collected in Cary-Blair transport medium. Results from the BioCode Gastrointestinal Pathogen Panel (GPP) test are available within less than 4 hours.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   BioCode Gastrointestinal Pathogen Panel (GPP)

2. Predicate 510(k) number(s):

   K180041

3. Comparison with predicate:

Similarities		
Item	**New Device: Applied BioCode Gastrointestinal Pathogen Panel (GPP) K190585**	**Predicate: Applied BioCode Gastrointestinal Pathogen Panel (GPP) K180041**
Indications for Use	The BioCode Gastrointestinal Pathogen Panel (GPP) is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with the BioCode MDx 3000 Instrument. The BioCode GPP is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites extracted directly from unpreserved stool samples or stool preserved in Cary-Blair transport medium obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria, parasites, and viruses are identified using the BioCode Gastrointestinal Pathogen Panel: • *Campylobacter* (*C. jejuni/C. coli*) • *Clostridium difficile* (*C. difficile*) toxin A/B (Fresh samples only) • *Salmonella* spp. • *Vibrio* (*V. parahaemolyticus/V. vulnificus/ V. cholerae*), including specific identification of *Vibrio parahaemolyticus* • *Yersinia enterocolitica* • Enteroaggregative *Escherichia coli* (EAEC) • Enterotoxigenic *Escherichia coli* (ETEC) lt/st • *E. coli* O157 serogroup • Shiga-like toxin-producing *Escherichia coli* (STEC) stx1/stx2 • *Shigella*/ Enteroinvasive *Escherichia coli* (EIEC) • *Cryptosporidium* spp. (*C. parvum/C. hominis*) • *Entamoeba histolytica* • *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*) • Adenovirus F 40/41	The BioCode Gastrointestinal Pathogen Panel (GPP) is a qualitative, gastrointestinal microorganism multiplexed nucleic acid-based assay capable of detecting of nucleic acids from the following organisms in unpreserved stool and Cary-Blair media: • Adenovirus 40/41 • *Campylobacter* (*C. jejuni, C. coli*) • *Clostridium difficile* (*C. difficile*) toxin A/B (from fresh specimens only) • *Cryptosporidium* (*C. parvum, C. hominis*) • *Entamoeba histolytica* • *Escherichia coli* (*E. coli*) O157 • Enterotoxigenic *E. coli* (ETEC) LT/ST • Enteroaggregative *E. coli* (EAEC) • *Giardia lamblia (also known as G. intestinalis and G. duodenalis)* • Norovirus GI/GII • Rotavirus A • *Salmonella* spp. • Shiga-like Toxin producing *E. coli* (STEC) stx1/stx2 • *Shigella* (*S. boydii, S. sonnei, S. flexneri, S. dysenteriae*)/EIEC • *Vibrio spp*. (*V. cholerae, V. parahaemolyticus, V. vulnificus*), specific identification of *V. parahaemolyticus* • *Yersinia enterocolitica* The BioCode Gastrointestinal Pathogen Panel (GPP) is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule out co-infection with organisms not included in the

Similarities		
	• Norovirus GI/GII • Rotavirus A The BioCode GPP is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. For *In Vitro* Diagnostic Use Only. For Prescription Use Only. Positive results do not rule out co-infection with organisms not included in the BioCode GPP. The agent detected may not be the definite cause of the disease. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease. Concomitant culture is necessary for organism recovery and further typing of bacterial agents. This device is not intended to monitor or guide treatment for *C. difficile* infection. Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for Adenovirus 40/41, *Campylobacter*, *E. coli* O157, *Shigella*/EIEC, *Yersinia enterocolitica*, and *Giardia lamblia* were established additionally with retrospective clinical specimens. Performance characteristics for *Entamoeba histolytica*, *Giardia lamblia*, *Yersinia enterocolitica* and *Vibrio* (*V. parahaemolyticus*, *V. vulnificus*, and *V. cholerae*) were established primarily using contrived clinical specimens.	BioCode Gastrointestinal Pathogen Panel (GPP). The agent detected may not be the cause of patient illness. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease. Concomitant culture is necessary for organism recovery and further typing of bacterial agents. This device is not intended to monitor or guide treatment for *C. difficile* infection. Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for *Campylobacter spp.*, *E. coli* O157, *Shigella/*EIEC, *Yersinia enterocolitica,* and Adenovirus 40/41 were established primarily with retrospective clinical specimens. Performance characteristics for *Entamoeba histolytica,* and *Vibrio* spp. *(V. parahaemolyticus, V. vulnificus,* and *Vibrio cholerae)* were established primarily using contrived clinical specimens.
Sample Type	Same	Unpreserved stool and stool in Cary-

Similarities		
		Blair medium
Control	Same	Externally sourced
Instrument	Same	BioCode MDx 3000
Assay Methodology	Same	Multiplex PCR and probe hybridization followed by fluorescence detection and decoding of barcoded magnetic beads (BMB) that are coupled to biotinylated products with streptavidin conjugate
Test Interpretation	Same	Automated test interpretation and report generation.
Calibrators	Same	Internal Calibration

Differences		
Item	**New Device: Applied BioCode Gastrointestinal Pathogen Panel (GPP) K190585**	**Applied BioCode Gastrointestinal Pathogen Panel (GPP) K180041**
Sample Extraction	Roche MagNA Pure 96	bioMérieux NucliSENSE easyMAG
Time to Result	Approximately 4 hours	Approximately 5 hours

K. Standard/Guidance Document Referenced (if applicable):

Not applicable.

L. Test Principle:

The BioCode Gastrointestinal Pathogen Panel (GPP) is an automated system that integrates PCR amplification, target capture, signal generation and optical detection for multiple gastrointestinal pathogens from a single stool specimen. Stool specimens are processed, and nucleic acids are extracted with the bioMérieux NucliSENSE easyMAG or Roche MagNA Pure 96 automated systems. Once the PCR plate is set up and sealed, all other operations are automated.

M. Performance Characteristics:

1. Analytical performance:

a. Reproducibility:

A study was performed to assess the Reproducibility of the BioCode GPP using samples extracted with the MagNA Pure 96. This study was designed to assess intra-assay (within run), inter-assay (run-to-run), day-to-day and instrument-to-instrument (operator-to-operator) reproducibility. One lot of reagents was assayed at Applied BioCode on 3 instruments by 3 operators, 2 runs per day per operator for 5 days (total of 30 runs). The reproducibility panel consisted of 7 contrived samples (sample 7 is a negative control) extracted in triplicate and each assayed in singlet. The samples consisted of combinations of 12 representative targets at 1.5x LoD (Low) and 3x LoD (Medium). Results from the study are shown in Table 1 below.

Table 1: Reproducibility of BioCode GPP with MagNA Pure 96 Extractions- Qualitative results.

Organism Tested	Target Probe	Concentration Tested	Expected Results	% Agreement with Expected Result			
				Instrument 1 Operator 1	Instrument 2 Operator 2	Instrument 3 Operator 3	All Instruments/ Operators
Campylobacter jejuni spp. *jejuni* ATCC 33292	Campy	Medium Positive 3xLoD 1.05×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 5.25×10^2 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Clostridium difficile (toxinotype III; Nap1) Zeptometrix 0801619cf	tcdB	Medium Positive 3xLoD 1.25×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 6.23×10^2 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Enteroaggregative *E. coli* O92:H33 (EAEC) STEC TW04440	EAEC	Medium Positive 3xLoD 2.10×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 1.05×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Enterotoxigenic *E. coli* O78:H11 H10407 (ETEC) ATCC 35401	ST-1a	Medium Positive 3xLoD 8.40×10^2 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 4.20×10^2 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not	150/150	150/150	150/150	450/450

Organism Tested	Target Probe	Concentration Tested	Expected Results	% Agreement with Expected Result			
				Instrument 1 Operator 1	Instrument 2 Operator 2	Instrument 3 Operator 3	All Instruments/ Operators
			Detected	(100%)	(100%)	(100%)	(100%)
Salmonella enterica ssp. *enterica* ATCC 14028	Salm	Medium Positive 3xLoD 3.30×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 1.65×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Shiga-like toxin producing *E. coli* (STEC) ATCC BAA-2217	stx2	Medium Positive 3xLoD 3.75×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 1.88×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Shigella sonnei ATCC 29930	Shig	Medium Positive 3xLoD 6.60×10^2 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 3.30×10^2 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Vibrio parahaemolyticus ATCC 17802	V. para	Medium Positive 3xLoD 1.95×10^1 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 9.75×10^0 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Yersinia enterocolitica ATCC 23715	Y.ent	Medium Positive 3xLoD 2.25×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 1.13×10^3 CFU/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Cryptosporidium Parvum waterborne P102	Crypto	Medium Positive 3xLoD 9.30×10^3 oocysts/mL	Detected	30/30 (100%)	30/30 (100%)	29/30 (97%)	89/90 (99%)
		Low Positive	Detected	30/30	30/30	29/30	89/90

Organism Tested	Target Probe	Concentration Tested	Expected Results	% Agreement with Expected Result			
				Instrument 1 Operator 1	Instrument 2 Operator 2	Instrument 3 Operator 3	All Instruments/ Operators
		1.5xLoD 4.65 x 10^3 oocysts/mL		(100%)	(100%)	(97%)	(99%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Giardia intestinalis (aka *G. lamblia*) waterborne P101	G.lam	Medium Positive 3xLoD 2.70 x 10^3 cysts/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 1.35 x 10^3 cysts/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)
Rotavirus ATCC VR-2018	Rota	Medium Positive 3xLoD 3.75 x 10^3 $TCID_{50}$/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		Low Positive 1.5xLoD 1.88 x 10^2 $TCID_{50}$/mL	Detected	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
		None	Not Detected	150/150 (100%)	150/150 (100%)	150/150 (100%)	450/450 (100%)

b. Fresh vs. Frozen Study:

Please refer to previously FDA-cleared 510(k) Premarket Notifications, k180041 for Fresh vs. Frozen performance. No additional testing was conducted.

c. Specimen Stability:

Please refer to previously FDA-cleared 510(k) Premarket Notifications, k180041 for Specimen Stability performance. No additional testing was conducted.

d. Limit of detection:

A study was performed to assess the performance of the BioCode GPP on the BioCode MDx 3000 at the Limit of Detection (LoD) for both unpreserved Stool and Cary-Blair specimens. In this study the GI Panel was tested with quantified bacteria, virus or parasite stocks (except norovirus which used clinical samples). For initial screening, four replicates of each concentration (near LoD for the predicate) in negative stool and Cary-Blair were extracted on the easyMAG and MagNA Pure 96 Systems and tested in singlet with the BioCode GPP on the BioCode MDx 3000 system. The LoD was confirmed by extracting 20 replicates of

each sample type/extraction method and testing each in singlet for a total of 20 replicates at or near presumptive LoD. LoD for each stock was defined as the lowest concentration with ≥95% detection of 20 replicates (19 out of 20). Results are shown in the Tables below.

Table 2: Limit of Detection Summary of Unpreserved Stool Extracted with the easyMAG and MagNA Pure 96 and Assayed with BioCode GPP.

Strain	Source	EasyMAG		MagNA Pure 96	
		Unpreserved Stool LoD	Detection	Unpreserved Stool LoD	Detection
Campylobacter coli	ATCC 33559	2.81 x 10^1 CFU/mL	19/20	2.81 x 10^1 CFU/mL	20/20
Campylobacter jejuni spp. jejuni	ATCC 33292	3.50 x 10^2 CFU/mL	19/20	3.50 x10^2 CFU/mL	19/20
Clostridium difficile (toxinotype 0)	ATCC 9689	9.50 x 10^1 CFU/mL	20/20	9.50 x 10^1 CFU/mL	20/20
Clostridium difficile (toxinotype III; Nap1)	Zeptometrix 0801619cf	4.15 x 10^2 CFU/mL	20/20	4.15 x10^2 CFU/mL	20/20
Enteroaggregative *E. coli* O92:H33 (EAEC)	STEC TW04440	7.00 x 10^2 CFU/mL	20/20	7.00 x10^2 CFU/mL	20/20
Enteroinvasive *E. coli* O29:NM (EIEC)	ATCC 43892	3.60 x 10^2 CFU/mL	20/20	1.80 x10^2 CFU/mL	20/20
Enterotoxigenic *E. coli* O78:H11 H10407 (ETEC)	ATCC 35401	2.80 x 10^2 CFU/mL	20/20	2.80 x10^2 CFU/mL	20/20
Salmonella bongori	SGSC 4900	1.40 x 10^3 CFU/mL	20/20	1.40 x10^3 CFU/mL	20/20
Salmonella enterica ssp. enterica	ATCC 14028	1.10 x 10^3 CFU/mL	20/20	1.10 x10^3 CFU/mL	20/20
Shiga-like toxin producing *E. coli* (STEC)	ATCC BAA-2217	1.25 x 10^3 CFU/mL	20/20	1.25 x10^3 CFU/mL	20/20
E. coli O157	ATCC 700376	1.65 x 10^3 CFU/mL	20/20	1.65 x10^3 CFU/mL	20/20
Shigella sonnei	ATCC 29930	2.20 x 10^2 CFU/mL	20/20	2.20 x10^2 CFU/mL	20/20
Vibrio cholerae	ATCC 25870	2.45 x 10^2 CFU/mL	20/20	2.45 x10^2 CFU/mL	20/20
Vibrio parahaemolyticus	ATCC 17802	6.50 x 10^0 CFU/mL	20/20	6.50 x10^0 CFU/mL	20/20
Yersinia enterocolitica	ATCC 23715	7.50 x 10^2 CFU/mL	20/20	7.50 x10^2 CFU/mL	20/20
Cryptosporidium parvum	waterborne P102C	3.10 x 10^3 oocysts/mL	20/20	3.10 x10^3 oocysts/mL	20/20

Strain	Source	EasyMAG		MagNA Pure 96	
		Unpreserved Stool LoD	Detection	Unpreserved Stool LoD	Detection
Entamoeba histolytica HB-301:NIH	BEI NR-178	1.55 x 10^{-1} cysts/mL	20/20	1.55 x10^{-1} cysts/mL	20/20
Giardia intestinalis (aka *G. lamblia*)	waterborne P101	9.00 x 10^{2} cysts/mL	20/20	9.00 x10^{2} cysts/mL	20/20
Adenovirus 40 (dugan)	Zeptometrix 0810084	2.00 x 10^{-1} $TCID_{50}$/mL	20/20	1.00 x10^{-1} $TCID_{50}$/mL	20/20
Adenovirus 41 (TAK)	Zeptometrix 0810085	9.4 x 10^{-2} $TCID_{50}$/mL	20/20	4.70 x10^{-2} $TCID_{50}$/mL	20/20
Rotavirus A	ATCC VR-2018	2.5 x 10^{3} $TCID_{50}$/mL	20/20	1.25 x10^{3} $TCID_{50}$/mL	20/20

Table 3: Limit of Detection Summary of Cary-Blair Stool Extracted with the easyMAG and MagNA Pure 96 and Assayed with BioCode GPP.

Strain	Source	EasyMAG		MagNA Pure 96	
		Cary-Blair Stool LoD	Detection	Cary-Blair Stool LoD	Detection
Campylobacter coli	ATCC 33559	5.61 x 10^{1} CFU/mL	20/20	2.81 x 10^{1} CFU/mL	20/20
Campylobacter jejuni spp. jejuni	ATCC 33292	3.50 x10^{2} CFU/mL	20/20	7.00 x10^{2} CFU/mL	20/20
Clostridium difficile (toxinotype 0)	ATCC 9689	9.50 x 10^{1} CFU/mL	20/20	9.50 x 10^{1} CFU/mL	20/20
Clostridium difficile (toxinotype III; Nap1)	Zeptometrix 0801619cf	4.15 x10^{2} CFU/mL	20/20	4.15 x10^{2} CFU/mL	20/20
Enteroaggregative *E. coli* O92:H33 (EAEC)	STEC TW04440	7.00 x10^{2} CFU/mL	20/20	7.00 x10^{2} CFU/mL	20/20
Enteroinvasive *E. coli* O29:NM (EIEC)	ATCC 43892	3.60 x10^{2} CFU/mL	20/20	1.80 x10^{2} CFU/mL	20/20
Enterotoxigenic *E. coli* O78:H11 H10407 (ETEC)	ATCC 35401	2.80 x10^{2} CFU/mL	20/20	2.80 x10^{2} CFU/mL	19/20
Salmonella bongori	SGSC 4900	1.40 x10^{3} CFU/mL	19/20	1.40 x10^{3} CFU/mL	20/20
Salmonella enterica ssp. enterica	ATCC 14028	1.10 x10^{3} CFU/mL	20/20	1.10 x10^{3} CFU/mL	20/20

Strain	Source	EasyMAG		MagNA Pure 96	
		Cary-Blair Stool LoD	Detection	Cary-Blair Stool LoD	Detection
Shiga-like toxin producing *E. coli* (STEC)	ATCC BAA-2217	1.25 x10^3 CFU/mL	20/20	1.25 x10^3 CFU/mL	20/20
E. coli O157	ATCC 700376	3.30 x10^3 CFU/mL	20/20	1.65 x10^3 CFU/mL	20/20
Shigella sonnei	ATCC 29930	2.20 x10^2 CFU/mL	20/20	2.20 x10^2 CFU/mL	20/20
Vibrio cholerae	ATCC 25870	2.45 x10^2 CFU/mL	20/20	2.45 x10^2 CFU/mL	20/20
Vibrio parahaemolyticus	ATCC 17802	6.50 x10^0 CFU/mL	20/20	6.50 x10^0 CFU/mL	20/20
Yersinia enterocolitica	ATCC 23715	7.50 x10^2 CFU/mL	20/20	7.50 x10^2 CFU/mL	20/20
Cryptosporidium parvum	waterborne P102C	3.10 x10^3 oocysts/mL	20/20	3.10 x10^3 oocysts/mL	20/20
Entamoeba histolytica HB-301:NIH	BEI NR-178	1.55 x10^{-1} cysts/mL	20/20	1.55 x10^{-1} cysts/mL	20/20
Giardia intestinalis (aka G. lamblia)	waterborne P101	9.00 x10^2 cysts/mL	20/20	9.00 x10^2 cysts/mL	20/20
Adenovirus 40 (dugan)	Zeptometrix 0810084	2.00 x10^{-1} $TCID_{50}$/mL	20/20	1.00 x10^{-1} $TCID_{50}$/mL	20/20
Adenovirus 41 (TAK)	Zeptometrix 0810085	4.70 x10^{-2} $TCID_{50}$/mL	20/20	4.70 x10^{-2} $TCID_{50}$/mL	20/20
Rotavirus A	ATCC VR-2018	1.25 x10^3 $TCID_{50}$/mL	20/20	1.25 x10^3 $TCID_{50}$/mL	20/20

For Norovirus GI and GII targets, positive clinical specimens were used, and serial dilutions (initial 10- fold dilution series followed by finer dilutions) were performed. Four replicates of each dilution in negative unpreserved stool and Cary-Blair stool were extracted with the easyMAG and MagNA Pure 96 Systems and tested with the BioCode GPP on the BioCode MDx 3000 system. The LoD was confirmed by extracting 20 replicates of each sample type with each extraction method and testing at or near presumptive LoD. For unpreserved stool, LoD with the easyMAG extraction was 2-fold and 8.3-fold lower than the MagNA Pure 96 extraction for Norovirus GI and Norovirus GII, respectively. For Cary-Blair stool, LoD with the easyMAG extraction was less than 2-fold lower than the MagNA Pure 96 extraction for both Norovirus GI and GII. Results are shown in the tables below.

Table 4: Norovirus - Limit of Detection Summary of Unpreserved Stool Extracted with the easyMAG and MagNA Pure 96 and Assayed with BioCode GPP.

Target	Source	Target Probe	EasyMAG		MagNA Pure 96	
			Unpreserved Stool Dilution	Detection	Unpreserved Stool Dilution	Detection
Norovirus GI	Clinical Sample ID#60	NoVG1	1:10,000	20/20	1:5,000	19/20
Norovirus GII	Clinical Sample ID#54	NoVG2	1:250,000	20/20	1:30,000	20/20

Table 5: Norovirus - Limit of Detection Summary of Cary-Blair Stool Extracted with the easyMAG and MagNA Pure 96 and Assayed with BioCode GPP.

Target	Source	Target Probe	EasyMAG		MagNA Pure 96	
			Unpreserved Stool Dilution	Detection	Unpreserved Stool Dilution	Detection
Norovirus GI	Clinical Sample ID#60	NoVG1	1:50,000	20/20	1:80,000	19/20
Norovirus GII	Clinical Sample ID#54	NoVG2	1:100,000	20/20	1:80,000	20/20

e. Analytical Reactivity:

Please refer to previously FDA-cleared 510(k) Premarket Notifications, K180041 for Analytical Reactivity performance. No additional testing was conducted.

f. Analytical Specificity:

Please refer to previously FDA-cleared 510(k) Premarket Notifications, K180041 for Analytical Specificity performance. No additional testing was conducted.

g. Interference:

Please refer to previously FDA-cleared 510(k) Premarket Notifications, K180041 for Potentially Interfering Substances study information and results. No additional testing was conducted.

h. Carry-Over/Cross-Contamination study:

A study was performed to demonstrate the absence of carryover or cross-contamination of the MagNA Pure 96. High-positive samples (*Shigella sonnei*, ATCC 29930 at 5.42 x 10^6 CFU/mL) were tested alternating with no-template control samples in a "checkerboard" pattern. Samples were extracted an alternating pattern of high and low concentration then and assayed individually. The study consisted of

five complete MagNA Pure 96 well runs and assayed on two BioCode MDx 3000 instruments. No evidence of carry-over contamination was observed.

2. Comparison studies:

   a. Method comparison with predicate device:

   Not applicable

   b. Matrix Comparison :

   Not applicable

3. Clinical studies:

A clinical investigational study was performed in which a total of 466 leftover, de-identified archived specimens (275 frozen unpreserved and 191 inoculated Cary-Blair) that were previously characterized as positive from the BioCode Gastrointestinal Pathogen Panel (K180041) clinical study were collected. Fifty-three (53) freshly collected leftover samples were used for *C. difficile* testing. In addition, a total of 120 samples were contrived and tested to determine the performance characteristics for Entamoeba histolytica, Yersinia enterocolitica and Vibrio (V. parahaemolyticus, V. vulnificus, and V. cholerae). Specimens were extracted using the MagNA Pure 96 and the easyMAG and tested with the BioCode Gastrointestinal Pathogen Panel (GPP) on the MDx 3000 system.

Table 6: Demographic Data for Archived Specimens (Frozen Unpreserved and Inoculated Cary-Blair

Archived Samples	
Total Specimen Count	466
Gender	
Male	248/466 (53.22%)
Female	211/466 (45.28%)
Unknown	7/466 (1.50%)
Age Category	
≤ 5 yrs	85/466 (18.24%)
6-21 yrs	91/466 (19.53%)
22-59 yrs	194/466 (41.63%)
60+yrs	89/466 (19.10%)
Unknown	7/466 (1.50%)

Table 7: Demographic Data for Fresh Specimens (Unpreserved)

Fresh Samples	
Total Specimen Count	53
Gender	

Male	9/53 (16.98%)
Female	44/53 (83.02%)
Age Category	
≤ 5 yrs	1/53 (1.89%)
6-21 yrs	5/53 (9.43%)
22-59 yrs	23/53 (43.40%)
60+yrs	24/53 (45.28%)

PPA was calculated as TP / (TP + FN). TP = true positive or positive by both the EasyMAG and the MagNA Pure 96; FN = false negative or negative by the MagNA Pure 96 only. NPA was calculated as TN/(TN + FP). TN = true negative or negative by the EasyMAG and the MagNA Pure 96; FP = false positive or positive by the MagNA Pure 96 only. The exact binomial two-sided 95% confidence interval was calculated. The results stratified by sample type and storage method are presented in the Table below.

Table 8: Summary of Clinical Investigational Study Results (Archived Specimens)

Target	Specimen Type	(n)	Positive Agreement		Negative Agreement	
			PPA (%)	95% CI	NPA (%)	95% CI
Campylobacter spp.[a]	Inoculated Cary-Blair	190	22/23 (95.65)	79.0 – 99.2	164/167 (98.20)	94.9 – 99.4
	Unpreserved (Frozen)	274	27/27 (100)	87.5 - 100	244/247 (98.80)	96.5 – 99.6
	All Archived	464	49/50 (98.0)	89.5 – 99.6	408/414 (98.60)	96.9 – 99.3
Clostridium difficile[b]	Inoculated Cary-Blair	190	10/11 (90.91)	62.3 – 98.4	178/179 (99.44)	96.9 – 99.9
	Unpreserved (Frozen)	274	21/22 (95.45)	78.2 – 99.2	250/252 (99.20)	97.2 – 99.8
	All Archived	464	31/33 (93.94)	80.4 – 98.3	428/431 (99.30)	98.0 – 99.8
E. coli O157	Inoculated Cary-Blair	190	3/3 (100)	43.9 - 100	187/187 (100)	98.0 - 100
	Unpreserved (Frozen)	274	14/14 (100)	78.5 - 100	260/260 (100)	98.5 - 100
	All Archived	464	17/17 (100)	81.6 - 100	447/447 (100)	99.1 - 100
Enteroaggregative *E. coli* (EAEC) [c]	Inoculated Cary-Blair	190	15/17 (88.24)	65.7 – 96.7	171/173 (98.8)	95.9 – 99.7
	Unpreserved (Frozen)	274	29/29 (100)	88.3 - 100	244/245 (99.59)	97.7 – 99.9
	All Archived	464	44/46 (95.65)	85.5 – 98.8	415/418 (99.30)	97.9 -99.8
Enterotoxigenic *E. coli* (ETEC) [d]	Inoculated Cary-Blair	190	3/5 (60.00)	23.1 – 88.2	185/185 (100)	98.0 - 100
	Unpreserved (Frozen)	274	13/13 (100)	77.2 - 100	261/261 (100)	98.5 - 100

Target	Specimen Type	(n)	Positive Agreement		Negative Agreement	
			PPA (%)	95% CI	NPA (%)	95% CI
	All Archived	464	16/18 (88.89)	67.2 – 96.9	446/446 (100)	99.1 - 100
Shiga toxin-producing *E. coli* (STEC) [e]	Inoculated Cary-Blair	190	12/13 (92.31)	66.7 – 98.6	177/177 (100)	97.9 - 100
	Unpreserved (Frozen)	274	29/30 (96.67)	83.3 – 99.4	243/244 (99.60)	97.7 – 99.9
	All Archived	464	41/43 (95.35)	84.5 – 98.7	420/421 (99.80)	98.7 - 100
Salmonella spp.[f]	Inoculated Cary-Blair	190	17/17 (100)	81.6 - 100	169/173 (97.70)	94.2 – 99.1
	Unpreserved (Fresh)	274	25/27 (92.59)	76.6 – 97.9	246/247 (99.60)	97.7 – 99.9
	All Archived	464	42/44 (95.45)	84.9 – 98.7	415/420 (98.80)	97.2 – 99.5
Shigella/ EIEC [g]	Inoculated Cary-Blair	190	9/9 (100)	70.1 - 100	181/181 (100)	97.9 - 100
	Unpreserved (Frozen)	274	20/22 (90.91)	72.2 – 97.5	252/252 (100)	98.5 - 100
	All Archived	464	29/31 (93.55)	79.3 – 98.2	433/433 (100)	99.1 - 100
Vibrio parahaemolyticus [h]	Inoculated Cary-Blair	190	1/1 (100)	20.7 - 100	189/189 (100)	98.0 - 100
	Unpreserved (Frozen)	274	1/1 (100)	20.7 - 100	272/273 (99.6)	98.0 – 99.9
	All Archived	464	2/2 (100)	34.2 – 100	461/462 (99.8)	99.8 - 100
Vibrio spp. (not *parahaemolyticus*)[i]	Inoculated Cary-Blair	190	N/A	N/A	190/190 (100)	98.0 - 100
	Unpreserved (Frozen)	274	0/1 (0%)	N/A	273/273 (100)	98.6 – 100
	All Archived	464	0/1 (0%)	N/A	463/463 (100)	99.2 - 100
Yersinia enterocolitica [j]	Inoculated Cary-Blair	190	3/3 (100)	43.9 - 100	187/187 (100)	98.0 - 100
	Unpreserved (Frozen)	274	3/3 (100)	43.9 - 100	269/271 (99.26)	97.3 – 99.8
	All Archived	464	6/6 (100)	61.0 – 100	456/458 (99.6)	98.4- 99.9
Cryptosporidium spp. [k]	Inoculated Cary-Blair	190	11/12 (91.67)	64.6 – 98.5	178/178 (100)	97.9 - 100
	Unpreserved (Frozen)	274	22/24 (91.67)	74.2 – 97.7	248/250 (99.20)	97.1 – 99.8
	All Archived	464	33/36 (91.67)	78.2 – 97.1	426/428 (99.5)	98.3 – 99.9

Target	Specimen Type	(n)	Positive Agreement		Negative Agreement	
			PPA (%)	95% CI	NPA (%)	95% CI
Entamoeba histolytica	Inoculated Cary-Blair	190	N/A	N/A	190/190 (100)	98.0 - 100
	Unpreserved (Frozen)	274	N/A	N/A	274/274 (100)	98.6 - 100
	All Archived	464	N/A	N/A	464/464 (100)	99.2 - 100
Giardia lamblia [l]	Inoculated Cary-Blair	190	3/3 (100)	43.90 - 100	187/187 (100)	98.0 - 100
	Unpreserved (Frozen)	274	14/14 (100)	78.5 - 100	255/260 (98.1)	95.6 – 99.2
	All Archived	464	17/17 (100)	81.6 - 100	442/447 (98.9)	97.4 – 99.5
Adenovirus 40/41 [m]	Inoculated Cary-Blair	190	7/10 (70.00)	39.7 – 89.2	177/180 (98.32)	95.2 – 99.4
	Unpreserved (Frozen)	274	11/14 (78.60)	52.4 – 92.4	252/260 (96.90)	94.0 – 98.4
	All Archived	464	18/24 (75.00)	55.1 – 88.0	429/440 (97.5)	95.6 – 98.6
Norovirus (GI/GII) [n]	Inoculated Cary-Blair	190	19/19 (100)	83.2 - 100	168/171 (98.20)	95.0 – 99.4
	Unpreserved (Frozen)	274	21/22 (95.45)	78.2 – 99.2	248/252 (98.40)	96.0 – 99.4
	All Archived	464	40/41 (97.6)	87.4 – 96.6	416/423 (98.3)	96.6 – 99.2
Rotavirus A [o]	Inoculated Cary-Blair	190	12/13 (92.31)	66.7 – 98.6	176/177 (99.44)	96.9 – 99.9
	Unpreserved (Frozen)	274	15/15 (100)	79.6 - 100	255/259 (98.5)	96.1 – 99.4
	All Archived	464	27/28 (96.43)	82.3 – 99.4	431/436 (98.9)	97.3 – 99.5

Performance of archived specimens were also compared to the historical comparator method result from the BioCode Gastrointestinal Pathogen Panel (K180041) clinical study. Results are shown in Table 9 below.

Table 9: Performance Compared to Historical Reference results. (Stratified by sample type and extraction method). N=290 samples. 1 Invalid for EasyMAG (Cary-Blair sample); 3 Invalid for MP96 (1 Cary-Blair, 2 Unpreserved).

Target	Specimen Type	EasyMAG		MagNa Pure 96	
		Positive Agreement	Negative Agreement	Positive Agreement	Negative Agreement
		PPA (%)	NPA (%)	PPA (%)	NPA (%)
Campylobacter spp.	Inoculated Cary-Blair	3/3 (100%)	135/140 (96%)	3/3 (100%)	134/140 (96%)
	Unpreserved	1/1 (100%)	139/145 (96%)	1/1 (100%)	135/143 (94%)
	All Archived	4/4 (100%)	274/285 (96%)	4/4 (100%)	269/283 (95%)
Clostridium difficile	Inoculated Cary-Blair	9/12 (75%)	131/131 (100%)	9/12 (75%)	131/131 (100%)
	Unpreserved	12/13 (92%)	131/133 (98%)	12/13 (92%)	127/131 (97%)
	All Archived	21/25 (84%)	262/264 (99%)	21/25 (84%)	258/262 (98%)
E. coli O157	Inoculated Cary-Blair	1/1 (100%)	141/142 (99%)	0/1 (N/A)	141/142 (99%)
	Unpreserved	0/0 (N/A)	144/146 (99%)	0/0 (N/A)	142/144 (99%)
	All Archived	1/1 (100%)	285/288 (99%)	0/1 (N/A)	283/286 (99%)
Enteroaggregative *E. coli* (EAEC)	Inoculated Cary-Blair	14/14 (100%)	128/129 (99%)	13/14 (93%)	127/129 (98%)
	Unpreserved	13/14 (93%)	131/132 (99%)	13/14 (93%)	130/131 (99%)
	All Archived	27/28 (96%)	259/261 (99%)	26/28 (93%)	257/260 (99%)
Enterotoxigenic E. coli (ETEC)	Inoculated Cary-Blair	3/6 (50%)	137/137 (100%)	3/6 (50%)	137/137 (100%)
	Unpreserved	6/7 (86%)	139/139 (100%)	6/7 (86%)	138/138 (100%)
	All Archived	9/13 (69%)	276/276 (100%)	9/13 (69%)	275/275 (100%)
Shiga toxin-producing *E. coli* (STEC)	Inoculated Cary-Blair	1/3 (33%)	139/140 (99%)	1/3 (33%)	139/140 (99%)
	Unpreserved	0/0 (N/A)	144/146 (99%)	0/0 (N/A)	142/144 (99%)
	All Archived	1/3 (33%)	283/286 (99%)	1/3 (33%)	281/284 (99%)

Target	Specimen Type	EasyMAG		MagNa Pure 96	
		Positive Agreement	Negative Agreement	Positive Agreement	Negative Agreement
		PPA (%)	NPA (%)	PPA (%)	NPA (%)
Salmonella spp.	Inoculated Cary-Blair	8/10 (80%)	129/133 (97%)	9/10 (90%)	126/133 (95%)
	Unpreserved	10/10 (100%)	132/136 (97%)	10/10 (100%)	131/134 (98%)
	All Archived	18/20 (90%)	261/269 (97%)	19/20 (95%)	257/267 (96%)
Shigella/ EIEC	Inoculated Cary-Blair	3/3 (100%)	134/140 (96%)	3/3 (100%)	134/140 (96%)
	Unpreserved	2/2 (100%)	136/144 (94%)	2/2 (100%)	135/142 (95%)
	All Archived	5/5 (100%)	270/284 (95%)	5/5 (100%)	269/282 (95%)
Vibrio parahaemolyticus	Inoculated Cary-Blair	0/0 (N/A)	142/143 (99%)	0/0 (N/A)	142/143 (99%)
	Unpreserved	0/0 (N/A)	145/146 (99%)	0/0 (N/A)	143/144 (99%)
	All Archived	0/0 (N/A)	287/289 (99%)	0/0 (N/A)	285/287 (99%)
Vibrio spp. (not *parahaemolyticus*)	Inoculated Cary-Blair	0/0 (N/A)	143/143 (100%)	0/0 (N/A)	143/143 (100%)
	Unpreserved	0/0 (N/A)	146/146 (100%)	0/0 (N/A)	144/144 (100%)
	All Archived	0/0 (N/A)	289/289 (100%)	0/0 (N/A)	287/287 (100%)
Yersinia enterocolitica	Inoculated Cary-Blair	0/0 (N/A)	141/143 (99%)	0/0 (N/A)	141/143 (99%)
	Unpreserved	0/0 (N/A)	146/146 (100%)	0/0 (N/A)	144/144 (100%)
	All Archived	0/0 (N/A)	287/289 (99%)	0/0 (N/A)	285/287 (99%)
Cryptosporidium spp.	Inoculated Cary-Blair	3/4 (75%)	139/139 (100%)	2/4 (50%)	139/139 (100%)
	Unpreserved	3/4 (75%)	142/142 (100%)	3/4 (75%)	140/140 (100%)
	All Archived	6/8 (75%)	281/281 (100%)	5/8 (63%)	279/279 (100%)
Entamoeba histolytica	Inoculated Cary-Blair	0/0 (N/A)	143/143 (100%)	0/0 (N/A)	143/143 (100%)
	Unpreserved	0/0 (N/A)	146/146 (100%)	0/0 (N/A)	144/144 (100%)
	All Archived	0/0 (N/A)	289/289 (100%)	0/0 (N/A)	287/287 (100%)

Target	Specimen Type	EasyMAG		MagNa Pure 96	
		Positive Agreement	Negative Agreement	Positive Agreement	Negative Agreement
		PPA (%)	NPA (%)	PPA (%)	NPA (%)
Giardia lamblia	Inoculated Cary-Blair	1/1 (100%)	141/142 (99%)	1/1 (100%)	141/142 (99%)
	Unpreserved	1/1 (100%)	142/145 (98%)	1/1 (100%)	140/143 (98%)
	All Archived	2/2 (100%)	283/287 (99%)	2/2 (100%)	281/285 (99%)
Adenovirus 40/41	Inoculated Cary-Blair	½ (50%)	142/142 (100%)	1/2 (50%)	138/141 (98%)
	Unpreserved	5/6 (83%)	137/140 (98%)	5/6 (83%)	134/138 (97%)
	All Archived	6/8 (75%)	279/282 (99%)	6/8 (75%)	272/279 (97%)
Norovirus (GI/GII)	Inoculated Cary-Blair	19/19 (100%)	124/124 (100%)	19/19 (100%)	122/124 (98%)
	Unpreserved	19/19 (100%)	125/127 (98%)	19/19 (100%)	124/125 (99%)
	All Archived	38/38 (100%)	249/251 (99%)	38/38 (100%)	246/249 (99%)
Rotavirus A	Inoculated Cary-Blair	11/11 (100%)	130/132 (98%)	11/11 (100%)	132/133 (99%)
	Unpreserved	9/9 (100%)	135/137 (99%)	9/9 (100%)	130/135 (96%)
	All Archived	20/20 (100%)	264/269 (99%)	20/20 (100%)	262/268 (98%)

N. Instrument Name:

BioCode MDx 3000 instrument

O. System Descriptions:

1. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   No

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes

3. Specimen Identification:

   Specimen identity is provided by barcode magnetic beads.

4. Specimen Sampling and Handling:

   After extraction with the easyMAG or MagNA Pure 96 system and loading samples into a 96well formatted plate, the BioCode MDx 3000 processes all RT-PCR steps automatically.

5. Calibration:

   Optical calibration of the MDx 3000 is performed twice a year by Applied BioCode. No calibration kit is available.

6. Quality Control:

   Each laboratory should establish its own Quality Control ranges and frequency of QC testing based on applicable local laws, regulations and good laboratory practices. The BioCode Gastrointestinal Pathogen Panel (GPP) uses an internal control (bacteriophage MS2) which is added to each sample during pre- treatment. The internal control monitors the efficiency of the extraction, reverse transcription, amplification and detection stages of the assay. Positive results may be reported in the absence of RNA IC detection. The BioCode Gastrointestinal Pathogen Panel (GPP) software will suppress negative results for any wells with invalid RNA IC results.

P. Other Supportive Instrument Performance Characteristics Data Not Covered in the "Performance Characteristics" Section above:

Not applicable.

Q. Proposed Labeling:

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

R. Conclusion:

The submitted information in this premarket notification is sufficient to support a substantial equivalence decision for the BioCode Gastrointestinal Pathogen Panel (GPP).