



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

**I Background Information:**

**A 510(k) Number**

K250358

**B Applicant**

Becton, Dickinson and Company

**C Proprietary and Established Names**

BD Enteric Bacterial Panel for BD COR System, BD Enteric Bacterial Panel plus for BD COR System, and Enteric Bacterial Panel Diluent for BD COR System

**D Regulatory Information**

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

**II Submission/Device Overview:**

**A Purpose for Submission:**

To obtain a substantial equivalence determination for the BD Enteric Bacterial Panel for BD COR System and the BD Enteric Bacterial Panel *plus* for BD COR System.

**B Measurand:**

The BD Enteric Bacterial Panel for BD COR System detects target DNA sequences for:

- *Campylobacter* spp. (*C. jejuni* and *C. coli*)
- *Salmonella* spp.
- *Shigella* spp. / Enteroinvasive *E. coli* (EIEC)

- Shiga toxin 1 (*stx1*) / Shiga toxin 2 (*stx2*) genes (found in Shiga toxin-producing *E. coli* [STEC]) as well as *Shigella dysenteriae*, which can possess a Shiga toxin gene (*stx*) that is identical to the *stx1* gene of STEC.

The BD Extended Enteric Bacterial Panel *plus* for BD COR System detects target DNA sequences for:

- *Campylobacter* spp. (*C. jejuni* and *C. coli*)
- *Salmonella* spp.
- *Shigella* spp. / Enteroinvasive *E. coli* (EIEC)
- Shiga toxin 1 (*stx1*) / Shiga toxin 2 (*stx2*) genes (found in Shiga toxin-producing *E. coli* [STEC]) as well as *Shigella dysenteriae*, which can possess a Shiga toxin gene (*stx*) that is identical to the *stx1* gene of STEC.
- Enterotoxigenic *E. coli* (ETEC) heat-labile enterotoxin (LT)/ heat-stable enterotoxin (ST) genes
- *Plesiomonas shigelloides*
- *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*)
- *Yersinia enterocolitica*

### C Type of Test:

The BD MAX Enteric Bacterial Panel for BD COR System is a qualitative real-time polymerase chain reaction (PCR) assay for the amplification and detection of DNA from *Salmonella* spp., *Shigella* spp., and *Campylobacter* spp., as well as the toxin genes *stx1* and *stx2* found in Shiga toxin-producing *E. coli* (STEC).

The BD MAX Enteric Bacterial Panel *plus* for BD COR System is a qualitative real-time polymerase chain reaction (PCR) assay for the amplification and detection of DNA from *Plesiomonas shigelloides*, *Vibrio* (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*), and *Yersinia enterocolitica*, as well as toxin genes heat-labile enterotoxin (LT)/and heat-stable enterotoxin (ST) genes from Enterotoxigenic *E. coli* (ETEC).

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for Use:

BD Enteric Bacterial Panel for BD COR System

The BD Enteric Bacterial Panel for BD COR System is an automated in vitro diagnostic test for the direct qualitative detection and differentiation of enteric bacterial pathogens. BD Enteric Bacterial Panel for BD COR System detects nucleic acids from:

- *Salmonella* spp.
- *Campylobacter* spp. (*C. jejuni* and *C. coli*)
- *Shigella* spp. / Enteroinvasive *Escherichia coli* (EIEC)

- Shiga toxin 1 (stx1) / Shiga toxin 2 (stx2) genes (found in Shiga toxin-producing *Escherichia coli* [STEC]) as well as *Shigella dysenteriae*, which can possess a Shiga toxin gene (stx) that is identical to the stx1 gene of STEC.

Testing is performed utilizing the BD Fecal Collection and Transport Kit. Unpreserved soft to diarrheal stool specimens from symptomatic patients with suspected acute gastroenteritis, enteritis or colitis are probed using the flocced swab and material is transferred to the BD Fecal Collection and Transport tube containing modified Cary-Blair medium. The test is performed utilizing real-time polymerase chain reaction (PCR) for the amplification of specific sequences of target DNA. The test utilizes fluorogenic sequence-specific hybridization probes for detection of the amplified DNA.

This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of *Salmonella*, *Shigella*/EIEC, *Campylobacter*, and Shiga toxin-producing *E. coli* (STEC). Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive 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.

#### BD Enteric Bacterial Panel plus for BD COR System

BD Enteric Bacterial Panel plus for BD COR System is an automated in vitro diagnostic test for the direct qualitative detection and differentiation of enteric bacterial pathogens.

BD Enteric Bacterial Panel plus for BD COR System detects nucleic acids from:

- *Salmonella* spp.
- *Campylobacter* spp. (*C. jejuni* and *C. coli*)
- *Shigella* spp. / Enteroinvasive *Escherichia coli* (EIEC)
- Shiga toxin 1 (stx1) / Shiga toxin 2 (stx2) genes (found in Shiga toxin-producing *Escherichia coli* [STEC]) as well as *Shigella dysenteriae*, which can possess a Shiga toxin gene (stx) that is identical to the stx1 gene of STEC.
- *Plesiomonas shigelloides*
- *Vibrio* spp (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*)
- Enterotoxigenic *Escherichia coli* (ETEC) heat-labile enterotoxin (LT) / heat-stable enterotoxin (ST) genes
- *Yersinia enterocolitica*

Testing is performed utilizing the BD Fecal Collection and Transport Kit. Unpreserved soft to diarrheal stool specimens from symptomatic patients with suspected acute gastroenteritis,

enteritis or colitis are probed using the flocked swab and material is transferred to the BD Fecal Collection and Transport tube containing modified Cary-Blair medium. The test is performed utilizing real-time polymerase chain reaction (PCR) for the amplification of specific sequences of target DNA. The test utilizes fluorogenic sequence-specific hybridization probes for detection of the amplified DNA.

This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of *Salmonella*, *Shigella*/EIEC, *Campylobacter*, Shiga toxin-producing *E. coli* (STEC), *Plesiomonas shigelloides*, *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*), Enterotoxigenic *Escherichia coli* (ETEC) LT/ST and *Yersinia enterocolitica* infections. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive 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.

#### Enteric Bacterial Panel Diluent for BD COR System

The Enteric Bacterial Panel Diluent for BD COR System is intended to be used in clinical settings according to instructions provided for aliquoting into Molecular Aliquot Tubes by the BD COR System. The Enteric Bacterial Panel Diluent for BD COR System is only for use with BD Fecal Collection and Transport Kit specimens tested on BD COR Systems.

### **C Special Conditions for Use Statement(s):**

Rx - For Prescription Use Only

### **D Special Instrument Requirements:**

Both assays are performed on the BD COR System.

## **IV Device/System Characteristics:**

### **A Device Description:**

The BD Enteric Bacterial Panel for BD COR System (BD EBP for BD COR System) simultaneously detects pathogens responsible for gastroenteritis due to *Salmonella* spp., *Campylobacter* spp. (*C. jejuni* and *C. coli*), *Shigella* spp./EIEC, *stx/stx1/stx2* found in Shiga toxin-producing *E. coli* and in *Shigella dysenteriae*, and an internal Sample Processing Control.

The BD Enteric Bacterial Panel *plus* for BD COR Systems (BD EBP *plus* for BD COR System) additionally detects *Plesiomonas shigelloides*, *Vibrio* (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*), Enterotoxigenic *E. coli* (ETEC) LT/ST, *Yersinia enterocolitica* and an internal Sample Processing Control with a second master mix. The assays automate the testing process and minimize operator intervention from the time the sample is placed onto the BD COR System until results are available.

The BD COR System is comprised of a single BD COR PX System attached to a BD COR MX Analyzer as described in the published decision summaries for K210585 and K224653. Once the specimens are loaded, the BD COR PX System performs the necessary pre-analytical steps such as vortexing, aliquoting into a diluent filled molecular aliquot tube, sorting/grouping of the secondary samples for testing by assay, pre-warming and cooling of the sample (where required), and transport of the sample into the BD COR MX Analyzer, where extraction, amplification and detection take place.

Additionally, the steps of ordering tests on the instrument for specific samples will be managed directly by the user interaction with the Laboratory Information System (LIS), which communicates directly with the instrument.

Once the clinical specimens are received in the laboratory and loaded into the transport racks, the user will not be required to directly handle the specimen again prior to result reporting and removal from the system

## **B Principle of Operation:**

The BD Enteric Bacterial Panel for BD COR System and BD Enteric Bacterial Panel *plus* for BD COR System are designed for use with the BD Fecal Collection and Transport Kit for unpreserved soft to diarrheal stool specimens. Specimens are collected and transported to the testing laboratory using the BD Fecal Collection and Transport Kit under conditions of time and temperature that have been determined to maintain the integrity of the target nucleic acids.

The BD COR MX Analyzer, when combined with the BD COR PX System, is to be used for automated sample preparation, extraction, and purification of nucleic acids from the BD Fecal Collection and Transport Kit, as well as the automated amplification and detection of target nucleic acid sequences by fluorescence-based real-time PCR for simultaneous and differential detection of enteric bacteria pathogens.

The BD Enteric Bacterial Panel for BD COR System and BD Enteric Bacterial Panel *plus* for BD COR System extraction reagents are dried in 96-well microtiter plates that contain binding magnetic affinity beads and Sample Processing Control (SPC). Each well is capable of binding and eluting sample nucleic acids. The SPC monitors the integrity of the reagents, and the process steps involved in DNA extraction, amplification, and detection, as well as for the presence of potential assay inhibitors.

The BD Enteric Bacterial Panel for BD COR System and BD Enteric Bacterial Panel *plus* for BD COR System liquid reagent plate includes Wash, Elution, Neutralization, and Rehydration buffers. The beads together with the bound nucleic acids, are washed and the nucleic acids are eluted by a combination of heat and pH. Eluted DNA is neutralized and transferred to the Amplification reagent to rehydrate the PCR reagents.

The BD Enteric Bacterial Panel for BD COR System contains one master mix that contains the dried PCR reagents for the detection and differentiation of *Salmonella*, *Shigella*/EIEC, *Campylobacter*, and Shiga toxin-producing *E. coli* (STEC), while the BD Enteric Bacterial Panel *plus* for BD COR System has two distinct master mixes. The first BD Enteric Bacterial Panel *plus* for BD COR System master contains the same PCR reagents as the BD COR Enteric Bacterial Panel master mix. The second BD Enteric Bacterial Panel *plus* for BD COR System

master mix well contains the dried PCR reagents for the detection and differentiation of *Plesiomonas shigelloides*, *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*), Enterotoxigenic *E. coli* (ETEC) LT/ST, and *Yersinia enterocolitica*. After reconstitution, the BD COR System dispenses a fixed volume of PCR-ready solution containing extracted nucleic acids into the BD PCR cartridge. Microvalves in the BD PCR cartridge are sealed by the system prior to initiating PCR in order to contain the amplification mixture and prevent evaporation and contamination.

The amplified DNA targets are detected using hydrolysis (TaqMan) probes, labeled at one end with a fluorescent reporter dye (fluorophore), and at the other end with a quencher moiety. Probes labeled with different fluorophores are used to detect the target analytes in different optical channels of the BD COR System. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target DNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'-3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The BD COR System monitors these signals at each cycle of the PCR and interprets the data at the end of the reaction to provide qualitative test results for each analyte (i.e., positive or negative).

## V Substantial Equivalence Information:

### A Predicate Device Name(s):

BD MAX Enteric Bacterial Panel, BD MAX Extended Enteric Bacterial Panel

### B Predicate 510(k) Number(s):

K214122

### C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K250358</u>	<u>K214122</u>
Device Trade Name	BD Enteric Bacterial Panel for BD COR System	BD MAX Enteric Bacterial Panel
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	BD Enteric Bacterial Panel for BD COR System is an automated in vitro diagnostic test for the direct qualitative detection and differentiation of enteric bacterial pathogens. BD Enteric Bacterial Panel for BD COR System detects nucleic acids from:	The BD MAX Enteric Bacterial Panel performed on the BD MAX System is an automated in vitro diagnostic test for the direct qualitative detection and differentiation of enteric bacterial pathogens. The BD MAX Enteric Bacterial Panel detects

	<ul style="list-style-type: none"> <li>• <i>Salmonella</i> spp.</li> <li>• <i>Campylobacter</i> spp. (<i>C. jejuni</i> and <i>C. coli</i>)</li> <li>• <i>Shigella</i> spp. / Enteroinvasive <i>Escherichia coli</i> (EIEC)</li> <li>• Shiga toxin 1 (stx1) / Shiga toxin 2 (stx2) genes (found in Shiga toxin-producing <i>Escherichia coli</i> [STEC]) as well as <i>Shigella dysenteriae</i>, which can possess a Shiga toxin gene (stx) that is identical to the stx1 gene of STEC.</li> </ul> <p>Testing is performed utilizing the BD Fecal Collection and Transport Kit. Unpreserved soft to diarrheal stool specimens from symptomatic patients with suspected acute gastroenteritis, enteritis or colitis are probed using the flocked swab and material is transferred to the BD Fecal Collection and Transport tube containing modified Cary-Blair medium. The test is performed utilizing real-time polymerase chain reaction (PCR) for the amplification of specific sequences of target DNA. The test utilizes fluorogenic sequence-specific hybridization probes for detection of the amplified DNA.</p>	<p>nucleic acids from:</p> <ul style="list-style-type: none"> <li>• <i>Salmonella</i> spp.</li> <li>• <i>Campylobacter</i> spp. (<i>jejuni</i> and <i>coli</i>)</li> <li>• <i>Shigella</i> spp. / Enteroinvasive <i>E. coli</i> (EIEC)</li> <li>• Shiga toxin 1 (stx1) / Shiga toxin 2 (stx2) genes (found in Shiga toxin-producing <i>E. coli</i> [STEC]) as well as <i>Shigella dysenteriae</i>, which can possess a Shiga toxin gene (stx) that is identical to the stx1 gene of STEC.</li> </ul> <p>Testing is performed on unpreserved soft to diarrheal stool specimens or Cary-Blair preserved stool specimens from symptomatic patients with suspected acute gastroenteritis, enteritis, or colitis. The test is performed directly on the specimen, utilizing real-time polymerase chain reaction (PCR) for the amplification of SpaO, a <i>Campylobacter</i> specific <i>tuf</i> gene sequence, <i>ipaH</i> and <i>stx1/stx2</i>. The test utilizes fluorogenic sequence-specific hybridization probes for detection of the amplified DNA.</p> <p>This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological</p>
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	<p>This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of <i>Salmonella</i>, <i>Shigella</i>/EIEC, <i>Campylobacter</i>, and Shiga toxin-producing <i>E. coli</i> (STEC). Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive 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.</p>	<p>information, as an aid in the differential diagnosis of <i>Salmonella</i>, <i>Shigella</i>/EIEC, <i>Campylobacter</i> and Shiga toxin-producing <i>E. coli</i> (STEC) infections. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive 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.</p>
Assay Format	PCR	same
Targets	<ul style="list-style-type: none"> <li>• <i>Salmonella</i> spp.</li> <li>• <i>Campylobacter</i> spp. (<i>C. jejuni</i> and <i>C. coli</i>)</li> <li>• <i>Shigella</i> spp. / Enteroinvasive <i>E. coli</i> (EIEC)</li> <li>• Shiga toxin 1 (stx1) / Shiga toxin 2 (stx2) genes (found in Shiga</li> </ul>	same



	toxin-producing <i>E. coli</i> [STEC]) as well as <i>Shigella dysenteriae</i> , which can possess a Shiga toxin gene (stx) that is identical to the stx1 gene of STEC	
Assay Controls	Sample processing control	same
<b>General Device Characteristic Differences</b>		
Specimen Type	Stool collected with BD Fecal Collection and Transport Kit (200µL pipetted aliquot)	Unpreserved stool, Cary-Blair preserved stool (10µL transfer loop). FecalSwab Cary-Blair (50µL pipetted aliquot)
Instrument	BD COR System	BD MAX System
Sample Buffer	Reformulated	Original
Specimen Stability	Fecal Collection and Transport Kit only: 2-32°C for 48 hours 2-8°C for 120 hours (5 days)	Unpreserved or Cary-Blair preserved: 2-25°C for 24 hours 2-8°C for 120 hours (5 days) FecalSwab?
Sample Stability in Sample Buffer Tube:	2-32°C for 120 hours	2-25°C for 48 hours 2-8°C for 120 hours (5 days)
Reagent Stability Extraction tube or Plate, Master Mix Tube or Plate, Reagent Strip or Wet Plate	2-27°C for 14 months	2-25°C for 18 months

<b>Device &amp; Predicate Device(s):</b>	<u>K250358</u>	<u>K214122</u>
Device Trade Name	BD Enteric Bacterial Panel <i>plus</i> for BD COR System	BD MAX Extended Enteric Bacterial Panel
<b>General Device Characteristic Similarities</b>		
Intended Use/Indications For Use	BD Enteric Bacterial Panel <i>plus</i> for BD COR System is an automated in vitro diagnostic test for the direct qualitative detection and	The BD MAX Extended Enteric Bacterial Panel performed on the BD MAX System, is an automated in vitro

	<p>differentiation of enteric bacterial pathogens.</p> <p>BD Enteric Bacterial Panel <i>plus</i> for BD COR System detects nucleic acids from:</p> <ul style="list-style-type: none"> <li>• <i>Salmonella</i> spp.</li> <li>• <i>Campylobacter</i> spp. (<i>C. jejuni</i> and <i>C. coli</i>)</li> <li>• <i>Shigella</i> spp. / Enteroinvasive <i>Escherichia coli</i> (EIEC)</li> <li>• Shiga toxin 1 (stx1) / Shiga toxin 2 (stx2) genes (found in Shiga toxin-producing <i>Escherichia coli</i> [STEC]) as well as <i>Shigella dysenteriae</i>, which can possess a Shiga toxin gene (stx) that is identical to the stx1 gene of STEC.</li> <li>• <i>Plesiomonas shigelloides</i></li> <li>• <i>Vibrio</i> spp. (<i>V. vulnificus</i>, <i>V. parahaemolyticus</i>, and <i>V. cholerae</i>)</li> <li>• Enterotoxigenic <i>Escherichia coli</i> (ETEC) heat-labile enterotoxin (LT) / heat-stable enterotoxin (ST) genes</li> <li>• <i>Yersinia enterocolitica</i></li> </ul> <p>Testing is performed utilizing the BD Fecal Collection and Transport Kit. Unpreserved soft to diarrheal stool specimens from symptomatic patients with suspected acute gastroenteritis, enteritis</p>	<p>diagnostic test for the direct qualitative detection and differentiation of enteric bacterial pathogens. It is used in conjunction with the BD MAX Enteric Bacterial Panel as an optional Master Mix.</p> <p>The BD MAX Extended Enteric Bacterial Panel detects nucleic acids from:</p> <ul style="list-style-type: none"> <li>• <i>Plesiomonas shigelloides</i></li> <li>• <i>Vibrio</i> (<i>V. vulnificus</i>, <i>V. parahaemolyticus</i>, and <i>V. cholerae</i>)</li> <li>• Enterotoxigenic <i>Escherichia coli</i> (ETEC) heat-labile enterotoxin (LT) / heat-stable enterotoxin (ST) genes</li> <li>• <i>Yersinia enterocolitica</i></li> </ul> <p>Testing is performed on unpreserved soft to diarrheal or Cary-Blair preserved stool specimens from symptomatic patients with suspected acute gastroenteritis, enteritis or colitis. The test is performed directly on the specimen, utilizing real-time polymerase chain reaction (PCR) for the amplification of relevant gene target DNA. The test utilizes fluorogenic gene-specific hybridization probes for the detection of the amplified DNA. This test is intended for</p>
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	<p>or colitis are probed using the flocked swab and material is transferred to the BD Fecal Collection and Transport tube containing modified Cary-Blair medium. The test is performed utilizing real-time polymerase chain reaction (PCR) for the amplification of specific sequences of target DNA. The test utilizes fluorogenic sequence-specific hybridization probes for detection of the amplified DNA.</p> <p>This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of <i>Salmonella</i>, <i>Shigella</i>/EIEC, <i>Campylobacter</i>, Shiga toxin-producing <i>E. coli</i> (STEC), <i>Plesiomonas shigelloides</i>, <i>Vibrio</i> spp. (<i>V. vulnificus</i>, <i>V. parahaemolyticus</i>, and <i>V. cholerae</i>), Enterotoxigenic <i>Escherichia coli</i> (ETEC) LT/ST and <i>Yersinia enterocolitica</i>. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not</p>	<p>use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of <i>Plesiomonas shigelloides</i>, <i>Vibrio</i> (<i>V. vulnificus</i>, <i>V. parahaemolyticus</i>, and <i>V. cholerae</i>) Enterotoxigenic <i>Escherichia coli</i> (ETEC) LT/ST and <i>Yersinia enterocolitica</i> infections. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive 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.</p>
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	rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive 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.	
Assay Format	PCR	same
Assay Controls	Sample processing control	same
<b>General Device Characteristic Differences</b>		
Targets	<ul style="list-style-type: none"> <li>• <i>Salmonella</i> spp.</li> <li>• <i>Campylobacter</i> spp. (<i>C. jejuni</i> and <i>C. coli</i>)</li> <li>• <i>Shigella</i> spp. / Enteroinvasive <i>E. coli</i> (EIEC)</li> <li>• Shiga toxin 1 (stx1) / Shiga toxin 2 (stx2) genes (found in Shiga toxin-producing <i>E. coli</i> [STEC]) as well as <i>Shigella dysenteriae</i>, which can possess a Shiga toxin gene (stx) that is identical to the stx1 gene of STEC.</li> <li>• <i>Plesiomonas shigelloides</i></li> <li>• <i>Vibrio</i> spp. (<i>V. vulnificus</i>, <i>V. parahaemolyticus</i>, and <i>V. cholerae</i>)</li> <li>• Enterotoxigenic <i>Escherichia coli</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Plesiomonas shigelloides</i></li> <li>• <i>Vibrio</i> spp. (<i>V. vulnificus</i>, <i>V. parahaemolyticus</i>, and <i>V. cholerae</i>)</li> <li>• Enterotoxigenic <i>Escherichia coli</i> heat-labile enterotoxin (LT)/ heat-stable enterotoxin (ST) genes</li> <li>• <i>Yersinia enterocolitica</i></li> </ul>

	(ETEC) heat-labile enterotoxin (LT)/ heat-stable enterotoxin (ST) genes • <i>Yersinia enterocolitica</i>	
Specimen Type	Fecal Collection and Transport Kit Cary-Blair (200µL pipetted aliquot)	Unpreserved stool (10µL transfer loop). FecalSwab Cary-Blair (50µL pipetted aliquot)
Instrument	BD COR System	BD MAX System
Sample Buffer	Reformulated	Original
Specimen Stability	Fecal Collection and Transport Kit only: 2-32°C for 48 hours 2-8°C for 120 hours	Unpreserved or FecalSwab Cary-Blair preserved: 2-25°C for 24 hours 2-8°C for 120 hours
Sample Stability in SBT	2-32°C for 120 hours	2-25°C for 48 hours 2-8°C for 120 hours
Reagent Stability in Extraction tube or Plate, Master Mix Tube or Plate, Reagent Strip or Wet Plate	2-27°C for 14 months	2-25°C for 18 months

## VI Standards/Guidance Documents Referenced:

Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens, November 2, 2015.

## VII Performance Characteristics (if/when applicable):

### A Analytical Performance:

#### 1. Precision/Reproducibility:

Since the reagents of the BD Enteric Panel for BD COR System are identical to those contained on the BD Enteric Panel *plus* for BD COR System, analytical and clinical validation studies utilized only the more expansive BD Enteric Panel *plus* for BD COR System.

Within-laboratory precision was evaluated for the BD Enteric Bacterial Panel *plus* for BD COR System at one site with one reagent lot. Testing was performed over 12 days, with 2 runs per day per operator, for a total of 48 runs. Test samples were contrived in negative stool matrix and included panel members at distinct target loads for *Campylobacter jejuni*, Shiga toxin-producing *E. coli* (stx-1a), *Salmonella* Typhimurium, *Shigella sonnei*,

*Plesiomonas shigelloides*, *Yersinia enterocolitica*, *Vibrio parahaemolyticus*, and Enterotoxigenic *E. coli* (sta2). Each panel member was tested in triplicate. The following target concentrations were used for spiking levels of the target organisms contained in each panel member:

- Moderate Positive (MP): 3x LoD
- Low Positive (LP): 2x LoD
- True negative (TN): No target

Precision study results for the BD Enteric Bacterial Panel *plus* assay when performed on the BD COR System are described in Table 1.

**Table 1: BD Enteric Bacterial Panel *plus* for BD COR System Precision Study Results**

Panel	Analyte	Level	Total	Negative	Positive	% Correct	95% LCL	95% UCL
Master Mix 1	<i>Shigella</i>	TN	72	72	0	100.0%	94.9%	100.0%
		LP	72	0	72	100.0%	94.9%	100.0%
		MP	72	0	72	100.0%	94.9%	100.0%
	<i>Salmonella</i>	TN	72	72	0	100.0%	94.9%	100.0%
		LP	72	0	72	100.0%	94.9%	100.0%
		MP	72	0	72	100.0%	94.9%	100.0%
	<i>Campylobacter</i>	TN	72	72	0	100.0%	94.9%	100.0%
		LP	72	0	72	100.0%	94.9%	100.0%
		MP	72	0	72	100.0%	94.9%	100.0%
	STX	TN	72	72	0	100.0%	94.9%	100.0%
		LP	72	0	72	100.0%	94.9%	100.0%
		MP	72	0	72	100.0%	94.9%	100.0%
Master Mix 2	<i>Vibrio</i>	TN	72	72	0	100.0%	94.9%	100.0%
		LP	72	0	72	100.0%	94.9%	100.0%
		MP	72	1	71	98.6%	92.5%	99.8%
	<i>Plesiomonas</i>	TN	72	72	0	100.0%	94.9%	100.0%
		LP	72	1	71	98.6%	92.5%	99.8%
		MP	72	0	72	100.0%	94.9%	100.0%
	<i>Yersinia</i>	TN	72	72	0	100.0%	94.9%	100.0%
		LP	72	0	72	100.0%	94.9%	100.0%
		MP	72	1	71	98.6%	92.5%	99.8%

#### Site to Site Reproducibility:

The site-to-site reproducibility study was performed at three clinical sites (two external and one internal) using one reagent lot. Two operators performed two runs per day, over five distinct days (consecutive or not), for a total of 60 runs. The panels used were the same as described in the Precision study above.

The overall site-to-site reproducibility percent agreements were 100% for the TN for all targets and ranged from 98.9% to 100% for both LP and MP panel members. Results are summarized in Table 2.

Analysis of variance of the Ct score results from valid tests performed on positive panel members (Table 3) within lab (total) yielded overall CV (%) ranging from 1.0%–3.4% for the MP panel member and 1.3%–3.4% for the LP panel member.

**Table 2: BD Enteric Bacterial Panel *plus* for BD COR System Site-to-Site Reproducibility Results**

Target	Level	Total	
		Percent Agreement	95% CI
<i>Shigella</i>	TN	100.0% (90/90)	95.9%, 100.0%
	LP	100.0% (90/90)	95.9%, 100.0%
	MP	100.0% (90/90)	95.9%, 100.0%
<i>Salmonella</i>	TN	100.0% (90/90)	95.9%, 100.0%
	LP	100.0% (90/90)	95.9%, 100.0%
	MP	100.0% (90/90)	95.9%, 100.0%
<i>Campylobacter</i>	TN	100.0% (90/90)	95.9%, 100.0%
	LP	100.0% (90/90)	95.9%, 100.0%
	MP	100.0% (90/90)	95.9%, 100.0%
STX	TN	100.0% (90/90)	95.9%, 100.0%
	LP	100.0% (90/90)	95.9%, 100.0%
	MP	100.0% (90/90)	95.9%, 100.0%
<i>Vibrio</i>	TN	100.0% (90/90)	95.9%, 100.0%
	LP	100.0% (90/90)	95.9%, 100.0%
	MP	98.9% (89/90)	94.0%, 99.8%
<i>Plesiomonas</i>	TN	100.0% (90/90)	95.9%, 100.0%
	LP	98.9% (89/90)	94.0%, 99.8%
	MP	100.0% (90/90)	95.9%, 100.0%
<i>Yersinia</i>	TN	100.0% (90/90)	95.9%, 100.0%
	LP	100.0% (90/90)	95.9%, 100.0%
	MP	98.9% (89/90)	94.0%, 99.8%

**Table 3: Variance Component Analysis for Site-to-Site Reproducibility of the BD Enteric Bacterial Panel *plus* for BD COR System**

Target	Level	Total	Mean Ct	Within Run		Between Run		Between Day		Between Site		Total	
				SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
<i>Shigella</i>	LP	90	30.4	0.37	1.2	0.31	1	0.08	0.3	0.02	0.1	0.48	1.6
	MP	90	29.9	0.34	1.1	0.3	1	0	0	0	0	0.45	1.5
<i>Salmonella</i>	LP	90	31.9	0.46	1.4	0.15	0.5	0.21	0.7	0.06	0.2	0.53	1.7
	MP	90	31.2	0.33	1	0.21	0.7	0.14	0.4	0.13	0.4	0.43	1.4
<i>Campylobacter</i>	LP	90	31.9	0.39	1.2	0.18	0.6	0.03	0.1	0.14	0.4	0.45	1.4
	MP	90	31.3	0.29	0.9	0	0	0.03	0.1	0.23	0.7	0.37	1.2
STX	LP	90	31.8	0.32	1	0.21	0.6	0.13	0.4	0.05	0.1	0.41	1.3
	MP	90	31.2	0.25	0.8	0.11	0.4	0.16	0.5	0	0	0.32	1

<i>Vibrio</i>	LP	90	31.6	0.61	1.9	0	0	0.8	2.5	0.4	1.3	1.08	3.4
	MP	89	30.9	0.36	1.2	0.1	0.3	0.11	0.4	0.07	0.2	0.4	1.3
<i>Plesiomonas</i>	LP	89	28.6	0.38	1.3	0.31	1.1	0.19	0.7	0	0	0.52	1.8
	MP	90	28.4	0.34	1.2	0.5	1.7	0.34	1.2	0	0	0.69	2.4
<i>Yersinia</i>	LP	90	30.2	0.44	1.4	0.2	0.7	0.65	2.1	0	0	0.81	2.7
	MP	89	29.3	0.38	1.3	0	0	0.13	0.4	0.2	0.7	0.45	1.5

The lot-to-lot reproducibility study was performed over 15 testing days (consecutive days were not required) with 2 operators each testing 1 panel across 2 COR runs (2 COR runs per user, 4 COR runs each day of testing) with 3 replicates per panel at 1 internal site using 3 reagent lots. Total 90 replicates/target. The panels used were the same as described in the Precision study above.

The overall lot-to-lot reproducibility percent agreements were 100% for the TN for all targets and ranged from 98.9% to 100% for LP and 97.8% to 100% MP. Results are summarized in Table 4.

**Table 4: Lot-to-Lot Reproducibility Results for BD Enteric Bacterial Panel *plus* for BD COR System**

Analyte	Level	Percent Agreement Total		95% Confidence Interval
<i>Shigella</i>	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	100.0%	90/90	( 95.9% - 100.0% )
	MP	100.0%	90/90	( 95.9% - 100.0% )
<i>Salmonella</i>	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	100.0%	90/90	( 95.9% - 100.0% )
	MP	100.0%	90/90	( 95.9% - 100.0% )
<i>Campylobacter</i>	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	100.0%	90/90	( 95.9% - 100.0% )
	MP	100.0%	90/90	( 95.9% - 100.0% )
STX	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	100.0%	90/90	( 95.9% - 100.0% )
	MP	100.0%	90/90	( 95.9% - 100.0% )
<i>Vibrio</i>	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	98.9%	89/90	( 94.0% - 99.8% )
	MP	97.8%	88/90	( 92.3% - 99.4% )
<i>Plesiomonas</i>	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	98.9%	89/90	( 94.0% - 99.8% )
	MP	100.0%	90/90	( 95.9% - 100.0% )
<i>Yersinia</i>	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	100.0%	90/90	( 95.9% - 100.0% )
	MP	98.9%	89/90	( 94.0% - 99.8% )
ETEC	TN	100.0%	90/90	( 95.9% - 100.0% )
	LP	100.0%	90/90	( 95.9% - 100.0% )
	MP	100.0%	90/90	( 95.9% - 100.0% )



2. Linearity:

Not applicable

3. Analytical Specificity/Interference:

*Analytical Reactivity (Inclusivity)*

A variety of BD Enteric Bacterial Panel *plus* for BD COR System target strains were included in this study. Strain selection criteria included prevalence, serotype, and geographic location, where appropriate. One-hundred and forty-three (143) strains were tested, including strains from public collections and well-characterized clinical isolates. Inclusivity testing included 26 strains of *Salmonella* spp., 17 strains of *Shigella*/EIEC, 18 strains of *Campylobacter* spp., 26 strains of STEC, 8 strains of *Plesiomonas shigelloides*, 10 strains of *Yersinia enterocolitica*, 28 strains of *Vibrio* (cholerae, parahaemolyticus and vulnificus) and 10 strains of ETEC LT/ST. The strains were tested at ~3x LoD of the corresponding strain in Fecal Collection and Transport Kit. The BD Enteric Bacterial Panel *plus* for BD COR System correctly identified 143 of the 143 strains tested upon initial testing.

*Analytical Specificity/Cross-Reactivity*

The BD Enteric Bacterial Panel *plus* for BD COR System was performed on samples containing phylogenetically related microorganisms likely to be found in stool specimens. The bacterial cells, yeasts, viruses, and parasites were tested in the Fecal Collection and Transport tube at  $>1.0 \text{ E}+06$  cells/mL, CFU/mL, genomic DNA cp/mL, or EB/mL, and viruses were tested at  $1.0 \text{ E}+05$  viral particles, TCID<sub>50</sub>/mL or genomic equivalents/mL. Organisms tested are represented in Table 11.

- Most of the bacterial strains, yeast, parasites, and viruses tested produced negative results with the BD Enteric Bacterial Panel *plus* assay.
- No cross-reactivity was observed for STEC, *Shigella*/EIEC, *Yersinia enterocolitica*, *Plesiomonas shigelloides*, and ETEC
- *Campylobacter sputorum* biovar sputorum yielded a positive result for *Campylobacter* spp. during initial testing. However, no positive results were recorded at organism concentrations  $\leq 1.0 \text{ E}+04$  CFU/mL in Fecal Collection and Transport Kit.
- Adenovirus Type 3 yielded a positive result for *Salmonella* spp. during initial testing. However, no positive results were recorded at organism concentrations  $\leq 7.20 \text{ E}+04$  TCID<sub>50</sub>/mL.
- The following 7 *Vibrio* species were detected by the BD Enteric Bacterial Panel *plus*: *V. brasiliensis*, *V. campbellii*, *V. harveyi*, *V. hispanicus*, *V. mimicus*, *V. nereis*, and *V. tubiashii*.
  - Two (2) strains of *V. mimicus* produced positive results with the BD Enteric Bacterial Panel *plus* assay. However, no positive results were recorded at organism concentrations  $\leq 1.0 \text{ E}+04$  cells/mL in Fecal Collection and Transport Kit.

- One (1) strain of *V. hispanicus* produced positive results with the Enteric Bacterial Panel *plus* assay. However, no positive results were recorded at organism concentrations  $\leq 1.0 \text{ E}+03$  cells/mL in Fecal Collection and Transport Kit.
- One (1) strain of *V. campbellii* and *V. tubiashii* produced positive results with the BD Enteric Bacterial Panel *plus* assay. However, no positive results were recorded at organism concentrations  $\leq 1.49 \text{ E}+02$  cells/mL in Fecal Collection and Transport Kit.
- One (1) strain of *V. brasiliensis*, *V. harveyi*, and *V. nereis* produced positive results with the BD Enteric Bacterial Panel *plus* assay. These strains were still cross-reactant at  $1.49 \text{ E}+02$  cells/mL in Fecal Collection and Transport Kit.

**Table 5: Organisms Tested to Determine the BD Enteric Bacterial Panel *plus* Specificity**

Organism	Source	Organism	Source
<i>Abiotrophia defectiva</i>	ATCC 49176	<i>Giardia lamblia</i>	Waterborne P101, H3 Isolate
<i>Acinetobacter baumannii</i>	ATCC 19606	<i>Haemophilus influenzae</i>	ATCC 9007
<i>Acinetobacter lwoffii</i>	ATCC 15309	<i>Hafnia alvei</i>	ATCC 13337
Adenovirus Type 1	Zeptomatrix 0810050CF	<i>Helicobacter fennelliae</i>	ATCC 35683
Adenovirus Type 14	Zeptomatrix 0810108CF	<i>Helicobacter pylori</i>	ATCC 43504
Adenovirus Type 3	Zeptomatrix 0810062CF	Herpes Simplex Virus Type 1	Zeptomatrix 0810005CF
Adenovirus Type 4	Zeptomatrix 0810070CF	<i>Klebsiella oxytoca</i>	ATCC 33496
Adenovirus Type 40	Zeptomatrix 0810084CF	<i>Klebsiella pneumoniae</i> subsp. <i>pneumoniae</i>	ATCC 700603
Adenovirus Type 41	Zeptomatrix 0810085CF	<i>Lactobacillus acidophilus</i>	ATCC 4356
Adenovirus Type 8	Zeptomatrix 0810069CF	<i>Lactobacillus reuteri</i>	ATCC 23272
<i>Aeromonas caviae</i>	ATCC 15468	<i>Lactococcus lactis</i> subsp. <i>lactis</i>	ATCC 11454
<i>Aeromonas hydrophila</i>	ATCC 7966	<i>Listeria monocytogenes</i>	ATCC 15313
<i>Aeromonas schubertii</i>	ATCC 43700	<i>Megasphaera elsdenii</i>	ATCC 25940
<i>Aeromonas veronii</i>	ATCC 35623	<i>Morganella morganii</i> subsp. <i>morganii</i>	ATCC 25830
<i>Alcaligenes faecalis</i> subsp. <i>faecalis</i>	ATCC 8750	Norovirus Group I (recombinant)	Zeptomatrix 0810086CF
<i>Anaerococcus tetradius</i>	ATCC 35098	Norovirus Group II	ZeptoMatrix 0810087CF
<i>Arcobacter butzleri</i>	ATCC 49616	<i>Parabacteroides merdae</i>	ATCC 43184
<i>Arcobacter cryaerophilus</i>	ATCC 43158	<i>Peptoniphilus asaccharolyticus</i>	ATCC 14963
Astrovirus Type 4	Zeptomatrix 0810273CF	<i>Peptostreptococcus anaerobius</i>	ATCC 27337

<i>Bacteroides caccae</i>	ATCC 43185	<i>Porphyromonas asaccharolytica</i>	ATCC 25260
<i>Bacteroides fragilis</i>	ATCC 25285	<i>Prevotella melaninogenica</i>	ATCC 25845
<i>Bacteroides stercoris</i>	ATCC 43183	<i>Proteus mirabilis</i>	ATCC 25933
<i>Bacteroides thetaiomicron</i>	ATCC 29148	<i>Proteus penneri</i>	ATCC 35198
<i>Bacteroides vulgatus</i>	ATCC 8482	<i>Proteus vulgaris</i>	ATCC 6380
<i>Bifidobacterium adolescentis</i>	ATCC 15703	<i>Providencia alcalifaciens</i>	ATCC 9886
<i>Bifidobacterium bifidum</i>	ATCC 29521	<i>Pseudomonas aeruginosa</i>	ATCC 27853
<i>Bifidobacterium longum</i> subsp. <i>longum</i>	ATCC 15707	Rotavirus	ZeptoMetrix 0810041CF
<i>Campylobacter hyointestinalis</i>	CCUG 24180	<i>Ruminococcus bromii</i>	ATCC 27255
<i>Campylobacter sputorum</i> biovar <i>sputorum</i>	CCUG 9728	<i>Serratia fonticola</i>	ATCC 29844
<i>Cedecea davisae</i>	ATCC 33431	<i>Serratia liquefaciens</i>	ATCC 27592
<i>Citrobacter freundii</i>	ATCC 8090	<i>Serratia marcescens</i> subsp. <i>marcescens</i>	ATCC 13880
<i>Citrobacter koseri</i>	ATCC 27028	<i>Shewanella algae</i>	ATCC 51192
<i>Citrobacter sedlakii</i>	ATCC 51115	<i>Shimwellia blattae</i>	ATCC 29907
<i>Clostridium difficile</i>	ATCC 43598	<i>Staphylococcus aureus</i> subsp. <i>aureus</i>	ATCC 43300
<i>Clostridium difficile</i>	ATCC 700057	<i>Staphylococcus epidermidis</i>	ATCC 14990
<i>Clostridium histolyticum</i>	ATCC 19401	<i>Stenotrophomonas maltophilia</i>	ATCC 13637
<i>Clostridium novyi</i>	ATCC 19402	<i>Streptococcus agalactiae</i>	ATCC 13813
<i>Clostridium perfringens</i>	ATCC 13124	<i>Streptococcus intermedius</i>	ATCC 27335
<i>Clostridium ramosum</i>	ATCC 25582	<i>Streptococcus pyogenes</i>	ATCC 19615
<i>Clostridium septicum</i>	ATCC 12464	<i>Streptococcus salivarius</i> subsp. <i>salivarius</i>	ATCC 7073
<i>Clostridium sordellii</i>	ATCC 9714	<i>Streptococcus suis</i>	ATCC 43765
<i>Clostridium tetani</i>	ATCC 19406	<i>Trichomonas vaginalis</i>	ATCC 30001
<i>Collinsella aerofaciens</i>	ATCC 25986	<i>Veillonella parvula</i>	ATCC 10790
<i>Cryptosporidium parvum</i>	Waterborne P102M, Iowa isolate	<i>Vibrio alginolyticus</i>	CCUG 16324
<i>Cytomegalovirus</i>	Zeptomatrix 0810003CF	<i>Vibrio brasiliensis</i>	CCUG 48644
<i>Desulfovibrio piger</i>	ATCC 29098	<i>Vibrio campbellii</i>	CCUG 16330
<i>Edwardsiella tarda</i>	ATCC 15947	<i>Vibrio harveyi</i>	CCUG 23159

<i>Enterobacter aerogenes</i>	ATCC 13048	<i>Vibrio hispanicus</i>	CCUG 56966T
<i>Enterobacter cloacae subsp. cloacae</i>	ATCC 35030	<i>Vibrio mimicus</i>	CCUG 39638
<i>Enterococcus faecalis</i>	ATCC 29212	<i>Vibrio mimicus</i>	CCUG 48106
<i>Enterococcus faecium</i>	ATCC 700221	<i>Vibrio natriegens</i>	CCUG 70547
<i>Escherichia fergusonii</i>	ATCC 35469	<i>Vibrio nereis</i>	CCUG 28585
<i>Escherichia hermannii</i>	ATCC 33650	<i>Vibrio tubiashii</i>	CCUG 38428
<i>Escherichia vulneris</i>	ATCC 33821	<i>Yersinia bercovieri</i>	CCUG 26329T
<i>Fusobacterium varium</i>	ATCC 8501	<i>Yersinia frederiksenii</i>	CCUG 11293T
<i>Gemella morbillorum</i>	ATCC 27824	<i>Yersinia intermedia</i>	CCUG 26583
		<i>Yersinia kristensenii</i>	CCUG 46842

### Interfering Substances

Twenty-six biological and chemical substances that may occasionally be present in stool specimens were evaluated for potential interference with the BD Enteric Bacterial Panel *plus* for BD COR System. Eight of these substances were antibiotics tested together as a pool with each antibiotic at a concentration that may be found in a stool sample. Of the 26 substances tested, one demonstrated interference. Anti-Fungal cream was found to interfere at levels above 25%. Results demonstrated no reportable interference with any other substance tested. Table 6 lists all tested substances and the concentrations at which no interference was observed. In addition, microorganisms that may be endogenously present in stool specimens were evaluated for potential interference with the BD Enteric Bacterial Panel *plus* for BD COR System. Fourteen microorganisms were tested at high concentration ( $> 2.00 \times 10^6$  CFU/mL of stool). Table 7 lists all microorganisms tested and the concentrations at which no interference was observed.

**Table 6: Exogenous and Endogenous Substances Tested for Interference**

Substance	Concentration in Stool Where Interference Not Observed	Substance	Concentration in Stool Where Interference Not Observed
Fecal Fats	7.0 mg/mL	Ex-Lax	14.0 mg/mL
Human DNA	21.9 µg/mL	Pepto Bismol	59.0 mg/mL
Mucus	12.5 mg/mL	Amoxicillin trihydrate	64.0 mg/mL
Whole Human Blood	50%	Metronidazole	60.8 mg/mL
Hydrocortisone	15%	Tetracycline HCl	16.0 mg/mL
Moist Towelettes	3 mm <sup>2</sup> (in FCT)	Ceftriaxone	15.8 mg/mL
Mineral Oil	50%	Sulfamethoxazole	80.0 mg/mL
Preparation H	50%	Trimethoprim	16.0 mg/mL
Nystatin Antifungal	25%	Erythromycin	14.0 mg/mL
Polysporin	50%	Ciprofloxacin	5.4 mg/mL
Spermicidal Lubricant	50%	Tums	31.0 mg/mL
Penaten/Zinc oxide	25%	Naproxen	81.0 mg/mL
Vagisil	50%	Imodium	2.5 mg/mL

<sup>a</sup>Substance displayed interference when tested at a higher concentration.

<sup>b</sup>Substances tested together as a pool.

**Table 7: Microorganisms Tested for Interference**

Microorganism	Concentration in Stool Where Interference Not Observed	Microorganism	Concentration in Stool Where Interference Not Observed
Master Mix 1			
Salmonella Typhimurium	>2.00 E+06 CFU/mL	Vibrio parahaemolyticus	>2.00 E+06 CFU/mL
Campylobacter jejuni		Bacteroides fragilis	
Shigella sonnei		Proteus vulgaris	
Plesiomonas shigelloides		Enterobacter aerogenes	
Yersinia enterocolitica		Enterobacter cloacae	
E. coli (sta2)		Bacteroides vulgatus <sup>a</sup>	
Klebsiella pneumoniae		E. coli (stx1/stx2)	
Master Mix 2			
Salmonella Typhimurium	>2.00 E+06 CFU/mL	Vibrio parahaemolyticus	>2.00 E+06 CFU/mL
Campylobacter jejuni		Bacteroides fragilis	
Shigella sonnei		Proteus vulgaris	
Plesiomonas shigelloides		Enterobacter aerogenes	
Yersinia enterocolitica		Enterobacter cloacae	
E. coli (sta2)		Bacteroides vulgatus <sup>a</sup>	>2.00 E+05 CFU/mL
Klebsiella pneumoniae	E. coli (stx1/stx2)		

<sup>a</sup>Microorganism displayed interference when tested at a higher concentration.

#### *Mixed Infection/Competitive Interference*

The mixed infection/competitive interference study was designed to evaluate the ability of the BD Enteric Bacterial Panel *plus* for BD COR System to detect low positive results in the presence of other targets at high concentrations. The study was performed utilizing two target groups on a per master mix basis. For target group one, four organisms (*Salmonella* Typhimurium, *Campylobacter jejuni*, *Shigella sonnei*, and *E. coli (stx1-a)*) were individually prepared at ~2x their respective LoD in negative background stool matrix to serve as a low target. A high target mix comprised of the organisms representative of the other three BD Enteric Bacterial Panel *plus* for BD COR System analytes was added to the sample at concentrations of  $\geq 1$  E+06 CFU/mL. All four low target organisms were successfully detected by the BD Enteric Bacterial Panel *plus* for BD COR System when combined with their respective simulated high target concentration mixed infection preparations. For target group two, four organisms (*Yersinia enterocolitica*, *Plesiomonas shigelloides*, *E. coli (sta2)*, and *Vibrio parahaemolyticus*) were individually prepared at ~2x their respective LoD in negative background stool matrix to serve as a low target. A high target mix comprised of the organisms representative of the other three BD Enteric Bacterial Panel *plus* analytes was added to the sample at concentrations of  $\geq 1$  E+06 units/mL. Successful detection of all low target concentrations was achieved in the presence of *Yersinia enterocolitica* ( $\geq 1$  E+04 CFU/mL) and *Vibrio parahaemolyticus* ( $\geq 1$  E+05 cells/mL).

#### 4. Assay Reportable Range:

Not applicable

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

*Specimen Stability*

A specimen stability study was conducted to demonstrate stability of organisms targeted by the BD Enteric Bacterial Panel *plus* for BD COR System using contrived samples prepared at 3X LoD concentrations in BD Fecal Collection and Transport Kit (FCT) preserved stool matrix as well as post-transfer to sample buffer tubes (SBTs) containing BD EBP/EBP *plus* sample buffer. Results from the stability study support the sample handling and storage claims described in the device labeling.

*External Controls*

A study was conducted to verify use of the Microbiologics Helix Elite Extended Enteric Bacterial Verification Panel as an External Positive Control with the BD Enteric Bacterial Panel *plus* for BD COR system. Uninoculated BD Fecal Collection and Transport Kit tubes were used to verify their use as an External Negative Control. The results demonstrate that the addition of three lyophilized pellets of Microbiologics Helix Elite Extended Enteric Bacterial Verification Panel to a BD Fecal Collection and Transport Kit can be utilized as an External Positive Control for the BD Enteric Bacterial and Enteric. Bacterial Panel *plus* Panels for BD COR system. Uninoculated BD Fecal Collection and Transport Kit tubes can be used as an External Negative Control with the BD Enteric Bacterial and Enteric Bacterial Panel *plus* Panels for BD COR system.

6. Detection Limit:

The Limit of Detection (LoD) of the BD Enteric Bacterial Panel *plus* for BD COR System for target analytes in the BD Fecal Collection and Transport Kit was determined as follows: A microbial suspension was prepared from each of two representative strains of the target organisms detected by the BD Enteric Bacterial Panel *plus* for BD COR System. Each target organism was quantified prior to testing. Positive specimens were prepared by inoculating pooled stool in BD Fecal Collection and Transport Kit with multiple concentrations of each representative strain. Each matrix suspension was tested with at least 20 replicates per concentration using at least 3 BD COR Systems and 3 different lots of the BD Enteric Bacterial Panel *plus* for BD COR System. Determined LoDs were then confirmed with additional replicates. The LoD, defined as the lowest concentration at which at least 95% of all replicates tested positive, ranged from 116 to 10,705 units/mL (Table 8).

**Table 8: Limit of Detection of the BD Enteric Bacterial Panel *plus* Assay**

Organism/Strain ID	Catalog Number	Limit of Detection (CFU/mL in FCT) <sup>a</sup>
<i>Salmonella</i> Typhimurium	ATCC 14028	923
<i>Salmonella enteritidis</i>	ATCC 13076	2769
<i>Shigella sonnei</i>	ATCC 9390	242

<i>Shigella flexneri</i>	ATCC 700930	242
<i>Campylobacter jejuni</i>	ATCC 43429	153
<i>Campylobacter coli</i>	ATCC 43134	116
<i>E. coli</i> (STEC; stx1a)	ATCC 43890	1077
<i>E. coli</i> (STEC; stx2a)	ATCC 43889	344
<i>Plesiomonas shigelloides</i>	ATCC 14029	8269
<i>Plesiomonas shigelloides</i>	ATCC 14030	936
<i>Yersinia enterocolitica</i>	ATCC 9610	2385
<i>Yersinia enterocolitica</i>	ATCC 49397	265
<i>E. coli</i> (ETEC; stx2)	ATCC 43896	361
<i>E. coli</i> (ETEC; sta1, sta2, eltA)	ATCC 35401	121
<i>Vibrio parahaemolyticus</i>	ATCC 17802	207
<i>Vibrio cholerae</i>	ATCC 14033	149
<i>Vibrio vulnificus</i>	ATCC 27562	10705

<sup>a</sup>LoD concentrations are expressed in CFU/mL, except for *Vibrio*, which is expressed in cells/mL.

7. Assay Cut-Off:

Not applicable

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Not applicable

2. Matrix Comparison:

Not applicable

**C Clinical Studies:**

Clinical performance characteristics of the BD Enteric Bacterial Panel *plus* for BD COR System was determined in a multi-site investigational study. The study involved a total of six geographically diverse clinical collection centers where stool specimens were collected as part of routine patient care. Remnant stools were de-identified and enrolled prospectively into the study and tested with BD Enteric Bacterial Panel *plus* for BD COR System.

Specimens were obtained from pediatric or adult patients suspected of acute bacterial gastroenteritis, enteritis, or colitis, for which diagnostic tests had been ordered by a healthcare provider. Three sites performed BD Enteric Bacterial Panel *plus* for BD COR System testing and/or comparator method testing. Retrospective specimens from a previous study and obtained from specimen vendors were also evaluated. The performance of the BD Enteric Bacterial Panel *plus* for BD COR System was evaluated in comparison to an FDA-cleared PCR assay for most analytes. For *Campylobacter* spp., Shiga toxin (stx/stx1/stx2), *Vibrio* spp., *Yersinia enterocolitica*, and ETEC performance was compared to a composite comparator method utilizing three different FDA-cleared PCR tests.

## Study Methods

PPA and NPA were estimated with 95% two-sided confidence interval. Point estimates of 90% agreement with lower bound at 85% for highest prevalence targets.

### *Discrepant Testing*

Results between the BD Enteric Bacterial Panel *plus* for BD COR System assay and the reference method were evaluated to determine if specimen results were concordant or discrepant. If discrepant testing was indicated, an aliquot from the unpreserved parent specimen was prepared and shipped to an external site on dry ice or frozen ice packs and stored until it was tested. Specimens were tested according to the Instructions for Use. Only the result of the discrepant analyte was considered.

### *Repeat Testing*

Specimens were required to be repeated if a non-reportable result was obtained, or an external positive or negative control had failed to produce the expected result(s). Other situations where repeat testing may have been performed include, but are not limited to, instrument malfunctions, testing level noncompliance, or no valid testing result for either the comparator or evaluator.

In order to be as efficient as possible with the specimens collected, specimens that did not have an evaluable pair of results for both the investigational device and reference method due to non-compliance at the testing level were aliquoted and retested during a period from April 2024 through July 2024. Specimens originally collected during the period of November 2022 through July 2023 were tested on both the investigational assay and reference assay even if one method had a valid result. This was to ensure that the specimens were tested under similar conditions. Any valid results from repeated specimens from that period, without a corresponding, comparable result were made non-evaluable. Specimens originally tested from April 2024 through July 2024 were only repeated for the method(s) where no valid result was obtained due to non-compliance.

## Clinical Performance for Target Analytes

### *Salmonella spp.*

In comparison to a single comparator, the BD EBP for BD COR System detected 94.7% and 99.4% of the *Salmonella* spp. prospective positive and negative specimens, respectively, and 98.3% and 98.5% of the retrospective positive and negative specimens, respectively (refer to Table 9).

**Table 9: *Salmonella* spp. – BD Enteric Bacterial Panel *plus* Clinical Performance**

<i>Salmonella</i> spp.		Comparator		Total	
Specimen		BD COR	Positive		Negative
Prospective	Combined Fresh + Frozen	Positive	36	8 <sup>a</sup>	44
		Negative	2 <sup>b</sup>	1434	1436
		Total:	38	1442	1480
		PPA:	94.7%	(82.7% - 98.5%)	
		NPA:	99.4%	(98.9% - 99.7%)	
Retrospective	Frozen	Positive	58	2 <sup>c</sup>	60



		Negative	1 <sup>d</sup>	135	136
		Total:	59	137	196
		PPA:	98.3%	(91.0% - 99.7%)	
		NPA:	98.5%	(94.8% - 99.6%)	

<sup>a</sup>*Salmonella* was detected in 1 of the 8 FP specimens when tested with an independent molecular method.

<sup>b</sup>*Salmonella* was not detected in 1 of 2 FN specimens when tested with an independent molecular method.

<sup>a</sup>*Salmonella* was not detected in both FP specimens when tested with an independent molecular method.

<sup>a</sup>*Salmonella* was not detected in the FN specimen when tested with an independent molecular method.

### ***Campylobacter* spp. (*C. jejuni* and *C. coli*)**

In comparison to a composite comparator, the BD EBP for BD COR System identified 100% and 99.4% of the *Campylobacter jejuni* and *C. coli* prospective positive and negative specimens, respectively, and 100% of the retrospective positive and negative specimens (Table 10) when compared to a two out of three composite comparator method.

**Table 10: *Campylobacter* (*C. jejuni* and *C. coli*) - BD Enteric Bacterial Panel *plus* Clinical Performance**

<i>Campylobacter</i>			Composite Comparator		Total
Specimen		BD COR	Positive	Negative	
Prospective	Combined Fresh + Frozen	Positive	32	3 <sup>a</sup>	35
		Negative	0 <sup>b</sup>	463 <sup>c</sup>	463
		Total:	32	466	498
		PPA:	100.0%	(89.3% - 100.0%)	
		NPA:	99.4%	(98.1% - 99.8%)	
Retrospective	Frozen	Positive	67	0	67
		Negative	0	73 <sup>c</sup>	73
		Total:	67	73	140
		PPA:	100.0%	(94.6% - 100.0%)	
		NPA:	100.0%	(95.0% - 100.0%)	

<sup>a</sup>*Campylobacter* was detected in all 3 FP specimens with one of the three comparator methods.

<sup>b</sup>One specimen negative for *Campylobacter* with BD Enteric Bacterial Panel but positive with the single FDA-cleared comparator was excluded because the parent tube was no longer available and complete composite comparator testing could not be obtained.

<sup>c</sup>The sample size for NPA is smaller for *Campylobacter* spp. (*C. jejuni* and *C. coli*) as only a portion of the specimens with a negative result in BD Enteric Bacterial Panel and with the single FDA-cleared comparator was tested with the complete composite comparator in the prospective and retrospective studies.

### ***Shigella* spp. / EIEC**

In comparison to a single comparator, the BD EBP for BD COR System detected 80.0% and 100% of the *Shigella* spp. / EIEC prospective positive and negative specimens, respectively, and 94.4% and 98.8% of the retrospective positive and negative specimens, respectively (Table 11).

**Table 11: *Shigella* spp. / EIEC – BD Enteric Bacterial Panel *plus* Clinical Performance**

<i>Shigella</i>			Comparator		Total
Specimen		BD COR	Positive	Negative	
Prospective	Combined Fresh	Positive	12	0	12
		Negative	3 <sup>a</sup>	1464	1467

Retrospective	Frozen	Total:	15	1464	1479
		PPA:	80.0%	(54.8% - 93.0%)	
		NPA:	100.0%	(99.7% - 100.0%)	
		Positive	34	2 <sup>b</sup>	36
		Negative	2 <sup>c</sup>	158	160
		Total:	36	160	196
		PPA:	94.4%	(81.9% - 98.5%)	
		NPA:	98.8%	(95.6% - 99.7%)	

<sup>a</sup>*Shigella* spp./EIEC was not detected in the 3 FN specimens when tested with an independent molecular method.

<sup>b</sup>*Shigella* spp./EIEC was not detected in both FP specimens when tested with an independent molecular method.

<sup>c</sup>*Shigella* spp./EIEC was not detected in 1 of the 2 FN specimens when tested with an independent molecular method.

### Shiga toxin-producing *E. coli* (stx/stx1/stx2 genes)

In comparison to a composite comparator, the BD EBP for BD COR System detected 100% and 99.8% of the Shiga toxin (stx/stx1/stx2 genes) prospective positive and negative specimens, respectively, and 100% of the retrospective positive and negative specimens (Table 12).

**Table 12: Shiga toxin-producing *E. coli* (stx/stx1/stx2 genes) – BD Enteric Bacterial Panel plus Composite Comparator Clinical Performance**

Shiga toxin-producing <i>E. coli</i>		Composite Comparator		Total	
Specimen		BD COR	Positive		Negative
Prospective	Combined Fresh + Frozen	Positive	10 <sup>a</sup>	1	11
		Negative	0	489 <sup>b</sup>	489
		Total:	10	490	500
		PPA:	100.0%	(72.3% - 100.0%)	
		NPA:	99.8%	(98.9% - 100.0%)	
Retrospective	Frozen	Positive	9	0	9
		Negative	0	130 <sup>b</sup>	130
		Total:	9	130	139
		PPA:	100.0%	(70.1% - 100.0%)	
		NPA:	100.0%	(97.1% - 100.0%)	

<sup>a</sup>One specimen positive for Shiga toxin with BD EBP plus and the single FDA-cleared comparator was excluded because the parent tube was no longer available and complete composite comparator testing could not be obtained.

<sup>b</sup>The sample size for NPA is smaller for Shiga toxin as only a portion of the specimens with a negative result with BD EBP plus and with the single FDA-cleared comparator was tested with the complete composite comparator in the prospective and retrospective studies.

As Shiga toxin (stx/stx1/stx2 genes) prevalence was low, an evaluation of contrived specimens was performed to supplement the data collected in the study (Table 13).

**Table 13: Shiga toxin-producing *E. coli* (stx/stx1/stx2 genes) – Contrived Specimen Performance**

Shiga toxins	Expected Result		Total
	Positive	Negative	
Positive	50	0	50

Negative	0	250	250
Total:	50	250	300
PPA:	100.0%	(92.9% -	100.0%)
NPA:	100.0%	(98.5% -	100.0%)

### ***Plesiomonas shigelloides***

In comparison to a single comparator, the BD EBP for BD COR System detected 66.7% and 100% of the *Plesiomonas shigelloides* prospective positive and negative specimens, respectively, and 100% of the retrospective positive and negative specimens (Table 14).

**Table 14: *Plesiomonas shigelloides* – BD Enteric Bacterial Panel *plus* Clinical Performance**

<i>Plesiomonas shigelloides</i>		Comparator		Total	
Specimen	BD COR	Positive	Negative		
Prospective	Combined Fresh + Frozen	Positive	2	0	2
		Negative	1 <sup>a</sup>	1484	1485
		Total:	3	1484	1487
		PPA:	66.7%	(20.8% - 93.9%)	
		NPA:	100.0%	(99.7% - 100.0%)	
Retrospective	Frozen	Positive	2	0	2
		Negative	0	195	195
		Total:	2	195	197
		PPA:	100.0%	(34.2% - 100.0%)	
		NPA:	100.0%	(98.1% - 100.0%)	

<sup>a</sup>One specimen could not be tested with an independent molecular method.

As *Plesiomonas shigelloides* prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study (Table 15).

**Table 15: *Plesiomonas shigelloides* – Contrived Specimens Results**

<i>Plesiomonas shigelloides</i>	Expected Result		Total
	Positive	Negative	
Positive	50	0	50
Negative	0	250	250
Total:	50	250	300
PPA:	100.0%	(92.9% -	100.0%)
NPA:	100.0%	(98.5% -	100.0%)

### ***Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*)**

In comparison to a composite comparator, the BD EBP for BD COR System identified 100% of the *Vibrio* spp. prospective positive and negative specimens, and 100% of the retrospective negative specimens (Table 16).

**Table 16: *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*) – BD Enteric Bacterial Panel *plus* Clinical Performance**

<i>Vibrio</i> spp.		Composite Comparator		Total	
Specimen	BD COR	Positive	Negative		
Prospective	Combined Fresh + Frozen	Positive	2	0	2
		Negative	0	501 <sup>a</sup>	501
		Total:	2	501	503
		PPA:	100.0%	(34.2% - 100.0%)	
		NPA:	100.0%	(99.2% - 100.0%)	
Retrospective	Frozen	Positive	0	0	0
		Negative	0	140	140
		Total:	0	140	140
		NPA:	100.0%	(97.3% - 100.0%)	

<sup>a</sup>The sample size for NPA is smaller for *Vibrio* spp. as only a portion of the specimens with a negative result with BD EBP *plus* and with the single FDA-cleared comparator was tested with the complete composite comparator in the prospective and retrospective studies.

As *Vibrio* spp. prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study (Table 17).

**Table 17: *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*) – Contrived Specimens Results**

<i>Vibrio</i> spp.	Expected Result		Total
	Positive	Negative	
Positive	48	0	48
Negative	2	250	252
Total:	50	250	300
PPA:	96.0%	(86.5% - 98.9%)	
NPA:	100.0%	(98.5% - 100.0%)	

#### **ETEC (Heat-Labile Enterotoxin (LT) / Heat-Stable Enterotoxin (ST) Genes)**

In comparison to a composite comparator, the BD EBP for BD COR System identified 70.6% and 99.8% of the ETEC prospective positive and negative specimens, respectively, and 100% and 99.2% of the retrospective positive and negative specimens, respectively (Table 18).

**Table 18: ETEC (Heat-Labile Enterotoxin (LT) / Heat-Stable Enterotoxin (ST) Genes) – BD Enteric Bacterial Panel *plus* Composite Comparator Clinical Performance**

ETEC		Composite Comparator		Total	
Specimen	BD COR	Positive	Negative		
Prospective	Fresh	Positive	9	1 <sup>a</sup>	10
		Negative	1 <sup>b</sup>	240 <sup>c</sup>	241
		Total:	10	241	251

		PPA:	90.0%	(59.6% - 98.2%)	
		NPA:	99.6%	(97.7% - 99.9%)	
Prospective	Frozen	Positive	3	0	3
		Negative	4 <sup>d</sup>	246 <sup>c</sup>	250
		Total:	7	246	253
		PPA:	42.9%	(15.8% - 75.0%)	
		NPA:	100.0%	(98.5% - 100.0%)	
Retrospective	Frozen	Positive	13	1 <sup>b</sup>	14
		Negative	0	246 <sup>c</sup>	246
		Total:	13	247	260
		PPA:	100.0%	(77.2% - 100.0%)	
		NPA:	99.6%	(97.7% - 99.9%)	

<sup>a</sup>ETEC was detected in the FP specimen with one of the three comparator methods in the prospective and retrospective studies.

<sup>b</sup>ETEC was not detected in the FN specimen with one of the three comparator methods.

<sup>c</sup>The sample size for NPA is smaller for ETEC as only a portion of the specimens with a negative result with COR EBP plus and with the single FDA-cleared comparator was tested with the complete composite comparator in the prospective and retrospective studies.

<sup>d</sup>ETEC was not detected in all 4 FN specimens with one of the three comparator methods.

As ETEC prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study (Table 19).

**Table 19: ETEC (Heat-Labile Enterotoxin (LT) / Heat-Stable Enterotoxin (ST) Genes) – Contrived Specimens Results**

ETEC	Expected Result		Total
	Positive	Negative	
Positive	50	0	50
Negative	0	250	250
Total:	50	250	300
PPA:	100.0%	(92.9% - 100.0%)	
NPA:	100.0%	(98.5% - 100.0%)	

### ***Yersinia enterocolitica***

In comparison to a composite comparator, the BD EBP for BD COR System identified 100% of the *Y. enterocolitica* prospective positive and negative specimens, and 100% of the retrospective positive and negative specimens (Table 20).

**Table 20: *Yersinia enterocolitica* – BD Enteric Bacterial Panel *plus* Clinical Performance**

<i>Yersinia enterocolitica</i>		Composite Comparator			Total
Specimen		BD COR	Positive	Negative	
Prospective	Combined Fresh + Frozen	Positive	4	0	4
		Negative	0 <sup>a</sup>	497 <sup>b</sup>	497
		Total:	4	497	501
		PPA:	100.0%	(51.0% - 100.0%)	
		NPA:	100.0%	(99.2% - 100.0%)	
Retrospective	Frozen	Positive	2	0	2

	Negative	0	138 <sup>b</sup>	138
	Total:	2	138	140
	PPA:	100.0%	(34.2% - 100.0%)	
	NPA:	100.0%	(97.3% - 100.0%)	

<sup>a</sup>One specimen negative for *Yersinia enterocolitica* with BD EBP plus and positive with the single FDA-cleared comparator was excluded because two comparators of the composite comparator disagreed and the specimen for the tiebreaker was non-compliant. One specimen negative for *Y. enterocolitica* with BD EBP plus and positive with the single FDA-cleared comparator was excluded because two comparators of the composite disagreed, and the tiebreaker gave a final non-reportable result.

<sup>b</sup>The sample size for NPA is smaller for *Yersinia enterocolitica* as only a portion of the specimens with a negative result with COR EBP plus and with the single FDA-cleared comparator was tested with the composite comparator in the prospective and retrospective studies.

As *Yersinia enterocolitica* prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study (Table 21).

**Table 21: *Yersinia enterocolitica* – Contrived Specimens Results**

<i>Yersinia enterocolitica</i>	Expected Result		Total
	Positive	Negative	
Positive	50	0	50
Negative	0	250	250
Total:	50	250	300
PPA:	100.0%	(92.9% - 100.0%)	
NPA:	100.0%	(98.5% - 100.0%)	

### **Non-Reportable Results for BD Enteric Bacterial Panel for BD COR System and BD Enteric Bacterial Panel *plus* for BD COR System**

Non-reportable results were defined as results obtained while assessing the BD Enteric Bacterial Panel *plus* for BD COR System targets with the BD Enteric Bacterial Panel *plus* assay on BD COR System which resulted in a sample processing control or system failure. A failure may also occur when the External Control produces an unexpected result such as an External Positive Control that produces a negative result or an External Negative Control that produces a positive result.

For non-reportable rate calculations, the specimen and the BD Enteric Bacterial Panel for BD COR System and BD Enteric Bacterial Panel *plus* for BD COR System must be compliant to qualify the data included in the calculation for the denominator of the UNR/IND/INC rate. A UNR is counted in the numerator only if it is specimen compliant, BD Enteric Bacterial Panel for BD COR System and BD Enteric Bacterial Panel *plus* for BD COR System compliant, and External Controls yield expected results. External Controls are not considered for IND/INC numerator calculations. Non-reportable rates with BD Enteric Bacterial Panel for BD COR System and BD Enteric Bacterial Panel *plus* for BD COR System are shown in Table 22 and Table 23, respectively.

**Table 22: Summary of BD Enteric Bacterial Panel for BD COR System Total Non-Reportable Rate for Combined Targets**

Combined EBP <i>plus</i> Targets	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total UNR+IND+INC Rate	
Specimen Origin	Initial (95% CI)	Final <sup>a</sup> (95% CI)	Initial (95% CI)	Final <sup>a</sup> (95% CI)	Initial (95% CI)	Final <sup>a</sup> (95% CI)	Initial (95% CI)	Final <sup>a</sup> (95% CI)
Prospective	3.1%	1.6%	0.1%	0.0%	0.1%	0.0%	3.3%	1.6%
	47/1537	24/1514	1/1537	0/1514	2/1537	0/1514	50/1537	24/1514
	(2.3%, 4.0%)	(1.1%, 2.3%)	(0.0%, 0.4%)	(0.0%, 0.2%)	(0.0%, 0.5%)	(0.0%, 0.2%)	(2.5%, 4.3%)	(1.1%, 2.3%)
Retrospective	3.0%	2.0%	0.0%	0.0%	0.0%	0.0%	3.0%	2.0%
	6/200	4/200	0/200	0/200	0/200	0/200	6/200	4/200
	(1.4%, 6.4%)	(0.8%, 5.0%)	(0.0%, 1.9%)	(0.0%, 1.9%)	(0.0%, 1.9%)	(0.0%, 1.9%)	(1.4%, 6.4%)	(0.8%, 5.0%)

<sup>a</sup>The final rate is calculated with valid repeats only.

**Table 23: Summary of BD Enteric Bacterial Panel *plus* for BD COR System Total Non-Reportable Rate for Combined Targets**

Combined EBP <i>plus</i> Targets	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total UNR+IND+INC Rate	
Specimen Origin	Initial (95% CI)	Final <sup>a</sup> (95% CI)	Initial (95% CI)	Final <sup>a</sup> (95% CI)	Initial (95% CI)	Final <sup>a</sup> (95% CI)	Initial (95% CI)	Final <sup>a</sup> (95% CI)
Prospective	4.9%	1.8%	10.0%	0.0%	10.0%	0.0%	5.1%	1.8%
	76/1537	28/1514	1/1537	0/1514	2/1537	0/1514	79/1537	28/1514
	(4.0%, 6.1%)	(1.3%, 2.6%)	(0.0%, 0.4%)	(0.0%, 0.2%)	(0.0%, 0.5%)	(0.0%, 0.2%)	(4.1%, 6.4%)	(1.3%, 2.6%)
Retrospective	4.5%	3.0%	0.0%	0.0%	0.0%	0.0%	4.5%	3.0%
	9/200	6/200	0/200	0/200	0/200	0/200	9/200	6/200
	(2.4%, 8.3%)	(1.4%, 6.4%)	(0.0%, 1.9%)	(0.0%, 1.9%)	(0.0%, 1.9%)	(0.0%, 1.9%)	(2.4%, 8.3%)	(1.4%, 6.4%)

<sup>a</sup>The final rate is calculated with valid repeats only.

#### D Clinical Cut-Off:

Not applicable

#### E Expected Values/Reference Range:

A total of 1682 prospective remnant specimens and 235 retrospectively collected specimens to total of 1,917 specimens were included in this study. Of these, 110 specimens did not meet inclusion/exclusion criteria, had inadequate source documentation, specimen handling errors, or were outside of stability leaving a total of 1807 specimens compliant for testing. After exclusion of specimens due to testing non-compliance (79) and final non-reportable results, a total of 1493 prospective and 200 retrospective specimens were evaluable with the BD Enteric Bacterial Panel *plus* for BD COR System and the comparator method with at least one target included into the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) calculations.

The number and percentage of positive cases per target, as determined by the BD EBP *plus* for BD COR System, are presented in Table 24 below.

**Table 24: Positivity Rate Among Prospective Specimens for BD EBP *plus* Targets by Collection Site**

Collection Site	<i>Salmonella</i>	<i>Campylobacter</i>	Shigella /EIEC	Shiga toxin	<i>Plesiomonas shigelloides</i>	<i>Vibrio</i>	ETEC	<i>Yersinia enterocolitica</i>
1	4.9% (4/81)	3.7% (3/81)	0.0% (0/81)	4.9% (4/82)	1.2% (1/83)	0.0% (0/83)	0.0% (0/83)	0.0% (0/83)
2	4.7% (12/258)	2.7% (7/259)	0.0% (0/258)	0.8% (2/259)	0.0% (0/262)	0.8% (2/262)	0.8% (2/262)	0.0% (0/262)
3	4.4% (2/45)	0.0% (0/45)	0.0% (0/45)	2.2% (1/45)	2.2% (1/46)	0.0% (0/46)	2.2% (1/46)	0.0% (0/46)
4	0.8% (4/483)	0.4% (2/483)	0.8% (4/483)	0.4% (2/484)	0.0% (0/486)	0.0% (0/486)	0.4% (2/486)	0.4% (2/486)
5	1.3% (3/226)	1.8% (4/226)	0.0% (0/226)	0.4% (1/226)	0.0% (0/227)	0.0% (0/227)	0.0% (0/227)	0.4% (1/227)
6	4.8% (19/396)	4.8% (19/396)	2.0% (8/395)	0.5% (2/396)	0.0% (0/392)	0.0% (0/392)	2.0% (8/393)	0.3% (1/392)
Subtotal	3.0% (44/1,489)	2.3% (35/1,490)	0.8% (12/1,488)	0.8% (12/1,492)	0.1% (2/1,496)	0.1% (2/1,496)	0.9% (13/1,497)	0.3% (4/1,496)

## 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.