October 31, 2025

Becton, Dickinson and Company
Joseph Basore
Senior Staff Regulatory Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K250358
Trade/Device Name: 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
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay
Regulatory Class: Class II
Product Code: PCI
Dated: February 7, 2025
Received: February 7, 2025

Dear Joseph Basore:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bryan M. Grabias -S
2025.10.31 12:11:41
-04'00'

Bryan Grabias, Ph.D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250358

Device Name
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

Indications for Use *(Describe)*
BD Enteric Bacterial Panel for BD COR™ System

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 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, 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. 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

BD Enteric Bacterial Panel for BD COR™ System and BD Enteric Bacterial Panel *plus* for BD COR™ System

Summary Preparation Date:

10/1/2025

Submitted by:

BD Integrated Diagnostic Solutions
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

Joseph Basore, Ph.D., RAC
Senior Staff Regulatory Affairs Specialist
Tel: 616-301-4068
Email: Joseph.Basore@bd.com

Proprietary Names:

For the instrument: BD COR™ System

For the assay: BD Enteric Bacterial Panel for BD COR™ System and BD Enteric Bacterial Panel *plus* for BD COR™ System

Common Names:

For the instrument: High-throughput molecular system

For the assay: Gastrointestinal Bacterial Panel Multiplex Nucleic Acid-Based Assay
Enteric Bacterial Panel
Enteric Bacterial Nucleic Acid Test
Enteric Bacterial identification and differentiation system
Enteric assay
Enteric Test
BD EBP *plus* for BD COR™ System
BD EBP for BD COR™ System

Regulatory Information

Regulation section: 21 CFR 866.3990 – Gastrointestinal Bacterial Panel Multiplex Nucleic Acid-Based Assay System

Classification: Class II (Special Controls)

Panel: Microbiology (83)

Product Code(s):

PCI	Gastrointestinal Bacterial Panel Multiplex Nucleic Acid-Based Assay System
PCH	Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-Based Assay System
OOI	Real Time Nucleic Acid Amplification System

Performance Standards

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.

Predicate Device

BD MAX™ Enteric Bacterial Panel (K170308, K214122) and BD MAX™ Extended Enteric Bacterial Panel (K170308, K214122)

Device Establishment

Registration Number: 1119779

Intended Use

BD Enteric Bacterial Panel for BD COR™ System

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 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*, 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*, and Shiga toxin-producing *E. coli* (STEC), *Plesiomonas shigelloides*, *Vibrio* (*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.

Special Conditions for Use Statement: For Prescription Use Only

Special Instrument Requirements: BD COR™ System

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 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.

Test Principle

The BD EBP for BD COR™ System and BD EBP *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 EBP for BD COR™ System and BD EBP *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 tube 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 EBP for BD COR™ System and BD EBP *plus* for BD COR™ System liquid reagent plate includes Wash, Rehydration, Elution and Neutralization buffers. The beads (described

above), together with the bound nucleic acids, are washed and the nucleic acids are eluted by a combination of heat and pH. When performed on BD COR™ MX, there is an additional buffer to rehydrate the dried extraction mix. Eluted DNA is neutralized and transferred to the Amplification reagent (described below) to rehydrate the PCR reagents.

The BD EBP 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 EBP *plus* for BD COR™ System has two distinct master mixes. The first BD EBP *plus* for BD COR™ System master contains the same PCR reagents as the BD COR™ EBP master mix. The second BD EBP *plus* for BD COR™ System master mix well contains the dried PCR reagents for the detection and differentiation for *Plesiomonas shigelloides, Vibrio* (*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 thus 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).

Substantial Equivalence[1]

Table 1 provides the similarities and differences between the submitted device and the legally marketed predicate device.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1: Comparison to Predicate Device

Item	Predicate: BD MAX EBP (K140111, K214122)	Proposed: BD Enteric Bacterial Panel for BD COR™ System	Predicate: BD MAX xEBP (K170308, K214122)	Proposed BD Enteric Bacterial Panel *plus* for BD COR™ System
Intended Use/Indications for Use Statement	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 nucleic acids from: - *Salmonella* spp. - *Campylobacter* spp. (C. *jejuni and C. coli*) - *Shigella* spp. / Enteroinvasive *Escherichia coli* (EIEC) - Shiga toxin 1 (*stx*1) / Shiga toxin 2 (*stx*2) 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 *stx*1 gene of STEC. 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 *Campylobacter* specific *tuf* gene sequence, *ipaH* and *stx*1/*stx*2. The test utilizes fluorogenic sequence-	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. The BD COR™ Enteric Bacterial Panel detects nucleic acids from: - *Salmonella* spp. - *Campylobacter* spp. (*C. jejuni* and *C. coli*) - *Shigella* spp. / Enteroinvasive *Escherichia coli* (EIEC) - Shiga toxin 1 (*stx*1) / Shiga toxin 2 (*stx*2) 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 *stx*1 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 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	The BD MAX™ Extended 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. It is used in conjunction with the BD MAX™ Enteric Bacterial Panel as an optional Master Mix. The BD MAX™ Extended Enteric Bacterial Panel detects nucleic acids from: - *Plesiomonas shigelloides* - *Vibrio* (*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 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.	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 (*stx*1) / Shiga toxin 2 (*stx*2) 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 *stx*1 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

Item	Predicate: BD MAX EBP (K140111, K214122)	Proposed: BD Enteric Bacterial Panel for BD COR™ System	Predicate: BD MAX xEBP (K170308, K214122)	Proposed BD Enteric Bacterial Panel *plus* for BD COR™ System
	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) 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.	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	This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of *Plesiomonas shigelloides*, *Vibrio (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.	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* (*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.
Specimen Type	Unpreserved stool (10 µL transfer loop), Cary-Blair preserved stool (10 µL transfer loop), FecalSwab Cary-Blair (50 µL pipetted aliquot)	FCT Cary-Blair (200µL pipetted aliquot)	Unpreserved stool (10 µL transfer loop), Cary-Blair preserved stool (10 µL transfer loop), FecalSwab Cary-Blair (50 µL pipetted aliquot)	FCT Cary-Blair (200µL pipetted aliquot)
Assay Format	PCR	Same	Same	Same

Item	Predicate: BD MAX EBP (K140111, K214122)	Proposed: BD Enteric Bacterial Panel for BD COR™ System	Predicate: BD MAX xEBP (K170308, K214122)	Proposed BD Enteric Bacterial Panel *plus* for BD COR™ System
Organisms Detected	• *Salmonella* spp. • *Campylobacter* spp. *(jejuni* and coli) • *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.	Same	• *Salmonella* spp.* • *Campylobacter* spp. (*jejuni* and *coli*) * • *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. * • *Plesiomonas shigelloides* • *Vibrio* (*V. vulnificus, V. parahaemolyticus,* and *V. cholerae*) • Enterotoxigenic *Escherichia coli* (ETEC) heat-labile enterotoxin (LT)/ heat-stable enterotoxin (ST) genes • *Yersinia enterocolitica* *The BD MAX xEBP assay must be used in conjunction with the BD MAX EBP assay and therefore when the assay is run all eight targets are tested.	Same
Analysis Platform	BD MAX System (Automated)	BD COR System (Automated)	BD MAX System (Automated)	BD COR System (Automated)
Assay Controls	Sample Processing Control	Same	Sample Processing Control	Same
Sample Buffer	Original	Reformulated to reduce potential environmental impact	Original	Reformulated to reduce potential environmental impact

Item	Predicate: BD MAX EBP (K140111, K214122)	Proposed: BD Enteric Bacterial Panel for BD COR™ System	Predicate: BD MAX xEBP (K170308, K214122)	Proposed BD Enteric Bacterial Panel *plus* for BD COR™ System
Specimen Stability: Unpreserved or Cary-Blair Preserved (including FCT)	2-25 ºC for 24 hours 2-8 ºC for 120 hours (5 days)	FCT Only 2-32 ºC for 48 hours (punctured or unpunctured) 2-8 ºC for 120 hours (5 days)	2-25 ºC for 24 hours 2-8 ºC for 120 hours (5 days)	FCT Only 2-32 ºC for 48 hours (punctured or unpunctured) 2-8 ºC for 120 hours (5 days)
Sample Stability: In SBT (regardless of if cap is punctured or unpunctured)	2-25 ºC for 48 hours 2-8 ºC for 120 hours (5 days)	2-32 ºC for 120 hours (5 days)	2-25 ºC for 48 hours 2-8 ºC for 120 hours (5 days)	2-32 ºC for 120 hours (5 days)
Reagent Stability Extraction Tube or Plate, Master Mix Tube or Plate, Reagent Strip or Wet Plate	2-25 ºC for 18 months	2-27 ºC for 14 months	2-25 ºC for 18 months	2-27 ºC for 14 months
Reagent Stability: Enteric Bacterial Panel Diluent for BD COR™	N/A	2-27 ºC for 14 months	N/A	2-27 ºC for 14 months
Reagent Stability: Open pouch for Tx and MM	2-25 ºC for 31 days	N/A	2-25 ºC for 31 days	N/A
Reagent Stability: Tx, MM, Wet Plate, In Use (On Board COR)	N/A	Up to 32ºC for 5 days	N/A	Up to 32 ºC for 5 days
Reagent Stability: Enteric Bacterial Panel Diluent for BD COR™ (On Board COR)	N/A	Up to 32 ºC for 45 days	N/A	Up to 32 ºC for 45 days

Storage and Stability

Specimen Collection and Transport

In order to obtain an adequate specimen, the procedure for specimen collection must be followed closely. Immediately after collection, transfer the unpreserved liquid or soft stool specimen into the BD Fecal Collection and Transport Kit device according to the manufacturer's instructions. Transport and test the BD Fecal Collection and Transport System specimen as soon as possible within the conditions given in Table 2.

Note: The clinical performance study stored unpreserved stool at -70°C or 2-8°C prior to transferring to the BD Fecal Collection and Transport Kit device. The time between unpreserved stool collection and testing the BD Fecal Collection and Transport Kit device on the BD COR™ System did not extend beyond 120 hours when stored at 2-8°C. Please follow your institution's rules and protocols regarding sample storage validation for other temperatures.

Table 2: Storage and Stability of Stool Specimens Placed in the BD Fecal Collection and Transport System

Specimen Stability	Transport and/or Storage Time/Temperature
Stool specimen in BD Fecal Collection and Transport System	Up to 120 hours at 2–8 °C or Up to 48 hours at 2–32 °C[a]
BD COR™ Molecular Aliquot Tube	Up to 120 hours at 2–32 °C[a]

[a] Inclusive of pierced and non-pierced durations.

Reagent Stability

BD EBP for BD COR™ System and BD EBP *plus* for BD COR™ System are stable at 2–27 °C through the stated expiration date. Do not use kits or kit components that have passed their stated expiration date(s).

BD EBP for BD COR™ System and BD EBP *plus* for BD COR™ System Master Mixes and Extraction plates are provided in sealed pouches with a desiccant. Once the pouch is opened, both plates should be placed into the BD COR™ MX Analyzer. The plates must be used within 5 days or until printed expiration, whichever is first (Table 3). Once the Enteric Bacterial Panel Bulk Diluent bottle is opened, it should be placed on board and must be used within 45 days or until printed expiration, whichever is first.

Table 3: BD EBP and BD EBP *plus* Assay Reagent Stability on Board the BD COR™ System

Reagent	Temperature	Stability
Master Mix Plates	Up to 32 °C	Up to 5 days
Extraction Plates	Up to 32 °C	Up to 5 days
Liquid Reagent Plates	Up to 32 °C	Up to 5 days
BD Enteric Bacterial Panel Diluent for BD COR™ (Bottle)	Up to 32 °C	Up to 45 days

Analytical Performance

Configuration Equivalence

An analytical equivalence study was performed on low positive specimens for all BD EBP for BD COR™ System targets when processed with BD EBP for BD COR™ System or BD EBP *plus* for BD COR™ System. All BD EBP for BD COR™ System targets were equivalent at both 2x and 5x LoD when tested in either BD EBP for BD COR™ System or BD EBP *plus* for BD COR™ System configuration. All targets demonstrated ≥95% positivity and negativity in both configurations. In addition, the 90% confidence intervals for the difference in mean Ct.Score between BD EBP for BD COR™ System and BD EBP *plus* for BD COR™ System were contained within the interval of [-6% of the reference mean, +6% of the reference mean]. This data demonstrates that the BD EBP for BD COR™ System and BD EBP *plus* for BD COR™ System configurations perform equivalently for the four BD EBP for BD COR™ System targets. Therefore, the BD EBP *plus* for BD COR™ System was used as the representative assay in the clinical study and many of the analytical performance studies (Table 4).

Table 4: Assay Used in Analytical V&V Studies

Analytical V&V Study	Assay Used in V&V Study
Limit of Detection (LoD)	BD EBP *plus* only
Reproducibility and Precision	BD EBP *plus* only
Specimen Stability	BD EBP *plus* only
Interfering Substances	BD EBP *plus* only
Mixed Infection	BD EBP *plus* only
Carry Over Contamination	BD EBP and BD EBP *plus*
Environmental Tolerance	BD EBP *plus* only
Freeze Thaw Stability	BD EBP *plus* only
Inclusivity	BD EBP *plus* only
Configuration Equivalency	BD EBP and BD EBP *plus*
Cross-Reactivity	BD EBP *plus* only
External Controls	BD EBP *plus* only
Reagent Stability	BD EBP and EBP *plus*
Clinical Study	BD EBP *plus* only

Analytical Sensitivity

The analytical sensitivity/Limit of Detection (LoD) of the BD EBP *plus* for BD COR™ System in the BD Fecal Collection and Transport Kit was determined as follows: Individual microbial suspensions were prepared from at least two (2) representative strains of the target organisms detected by the BD EBP *plus* for BD COR™ System. Each target organism was quantified prior to testing. Positive specimens were prepared by inoculating pooled stool in the 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 EBP *plus* for BD COR™ System. Determined LoDs were then confirmed with additional replicates. Analytical sensitivity (LoD), defined as the lowest concentration at which at least 95% of all replicates tested positive, ranged from 116 to 10,705 units/mL depending on the target organism. (Table 5).

Table 5: Limit of Detection of the BD EBP plus Assay

Organism/Strain ID	Catalog Number	Limit of Detection (CFU/mL in FCT)
Salmonella Typhimurium	ATCC® 14028	923
Salmonella enteritidis	ATCC® 13076	2,769
Shigella sonnei	ATCC® 9290	242
Shigella flexneri	ATCC® 700930	242
Campylobacter jejuni	ATCC® 43429	153
Campylobacter coli	ATCC® 43134	116
*Escherichia col*i (STEC; stx1a)	ATCC® 43890	1,077
Escherichia coli (STEC; stx2a)	ATCC® 43889	344
Plesiomonas shigelloides	ATCC® 14029	8,269
Plesiomonas shigelloides	ATCC® 14030	936
Yersinia enterocolitica	ATCC® 9610	2,385
Yersinia enterocolitica	ATCC® 49397	265
Escherichia coli (ETEC; sta2)	ATCC® 43896	361
Escherichia coli (ETEC; sta1, sta2, eltA)	ATCC® 35401	121
Vibrio parahaemolyticus[a]	ATCC® 17802	207
Vibrio cholerae[a]	ATCC® 14033	149
Vibrio vulnificus[a]	ATCC® 27562	10,705

[a]*Vibrio* should be expressed as cells/mL.

Analytical Reactivity (Inclusivity)

A variety of BD EBP *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 FCT. The BD EBP *plus* for BD COR™ System correctly identified 143 of the 143 strains tested upon initial testing.

Analytical Specificity/Cross-Reactivity

The BD EBP *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 > 1E+06 cells/mL, CFU/mL, genomic DNA cp/mL, or EB/mL, and viruses were tested at 1E+05 viral particles, $TCID_{50}$/mL or genomic equivalents/mL. Organisms tested are represented in Table 6.

- Most of the bacterial strains, yeast, parasites, and viruses tested produced negative results with the BD EBP *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 ≤1.0E+04 CFU/mL in FCT.
- Adenovirus Type 3 yielded a positive result for *Salmonella* spp. during initial testing. However, no positive results were recorded at ≤ 7.20E+04 TCID50/mL.
- The following 7 Vibrio species were detected by the BD EBP 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 EBP *plus* assay. However, no positive results were recorded at ≤1.0E+04 cells/mL in FCT.
    - One (1) strain of *V. hispanicus* produced positive results with the BD EBP *plus* assay. However, no positive results were recorded at ≤1.0E+03 cells/mL in FCT.

- One (1) strain of *V. campbellii* and *V. tubiashii* produced positive results with the BD EBP *plus* assay. However, no positive results were recorded at ≤1.49E+02 cells/mL in FCT.

- One (1) strain of *V. brasiliensis*, *V. harveyi*, and *V. nereis* produced positive results with the BD EBP *plus* assay. These strains were still cross-reactant at 1.49E+02 cells/mL in FCT.

Table 6: Organisms Tested in BD EBP *plus* Assay to Determine Analytical Specificity

Organism	Source
Abiotrophia defectiva	ATCC® 49176
Acinetobacter baumannii	ATCC® 19606
Acinetobacter lwoffii	ATCC® 15309
Adenovirus Type 1	Zeptometrix® 0810050CF
Adenovirus Type 14	Zeptometrix® 0810108CF
Adenovirus Type 3	Zeptometrix® 0810062CF
Adenovirus Type 4	Zeptometrix® 0810070CF
Adenovirus Type 40	Zeptometrix® 0810084CF
Adenovirus Type 41	Zeptometrix® 0810085CF
Adenovirus Type 8	Zeptometrix® 0810069CF
Aeromonas caviae	ATCC® 15468
Aeromonas hydrophila	ATCC® 7966
Aeromonas schubertii	ATCC® 43700
Aeromonas veronii	ATCC® 35623
Alcaligenes faecalis subsp. *faecalis*	ATCC® 8750
Anaerococcus tetradius	ATCC® 35098
Arcobacter butzleri	ATCC® 49616
Arcobacter cryaerophilus	ATCC® 43158
Astrovirus Type 4	Zeptometrix® 0810273CF
Bacteroides caccae	ATCC® 43185
Bacteroides fragilis	ATCC® 25285
Bacteroides stercoris	ATCC® 43183
Bacteroides thetaiomicron	ATCC® 29148
Bacteroides vulgatus	ATCC® 8482
Bifidobacterium adolescentis	ATCC® 15703
Bifidobacterium bifidum	ATCC® 29521
Bifidobacterium longum subsp. *longum*	ATCC® 15707
Campylobacter hyointestinalis	CCUG 24180
Campylobacter sputorum biovar *sputorum*	CCUG 9728
Cedecea davisae	ATCC® 33431
Citrobacter freundii	ATCC® 8090
Citrobacter koseri	ATCC® 27028
Citrobacter sedlakii	ATCC® 51115

Organism	Source
Clostridium difficile	ATCC® 43598
Clostridium difficile	ATCC® 700057
Clostridium histolyticum	ATCC® 19401
Clostridium novyi	ATCC® 19402
Clostridium perfringens	ATCC® 13124
Clostridium ramosum	ATCC® 25582
Clostridium septicum	ATCC® 12464
Clostridium sordellii	ATCC® 9714
Clostridium tetani	ATCC® 19406
Collinsella aerofaciens	ATCC® 25986
Cryptosporidium parvum	Iowa
Cytomegalovirus	Zeptometrix® 0810003CF
Desulfovibrio piger	ATCC® 29098
Edwardsiella tarda	ATCC® 15947
Enterobacter aerogenes	ATCC® 13048
Enterobacter cloacae subsp. *cloacae*	ATCC® 35030
Enterococcus faecalis	ATCC® 29212
Enterococcus faecium	ATCC® 700221
Escherichia fergusonii	ATCC® 35469
Escherichia hermannii	ATCC® 33650
Escherichia vulneris	ATCC® 33821
Fusobacterium varium	ATCC® 8501
Gemella morbillorum	ATCC® 27824
Giardia lamblia	H3
Haemophilus influenzae	ATCC® 9007
Hafnia alvei	ATCC® 13337
Helicobacter fennelliae	ATCC® 35683
Helicobacter pylori	ATCC® 43504
Herpes Simplex Virus Type 1	Zeptometrix 0810005CF
Klebsiella oxytoca	ATCC® 33496
Klebsiella pneumoniae subsp. *pneumoniae*	ATCC® 700603
Lactobacillus acidophilus	ATCC® 4356
Lactobacillus reuteri	ATCC® 23272
Lactococcus lactis subsp. *lactis*	ATCC® 11454
Listeria monocytogenes	ATCC® 15313
Megasphaera elsdenii	ATCC® 25940
Morganella morganii subsp. *morganii*	ATCC® 25830
Norovirus Group I (recombinant)	Zeptometrix® 0810086CF
Norovirus Group II	ZeptoMetrix® 0810087CF
Parabacteroides merdae	ATCC® 43184
Peptoniphilus asaccharolyticus	ATCC® 14963
Peptostreptococcus anaerobius	ATCC® 27337
Porphyromonas asaccharolytica	ATCC® 25260

Organism	Source
Prevotella melaninogenica	ATCC® 25845
Proteus mirabilis	ATCC® 25933
Proteus penneri	ATCC® 35198
Proteus vulgaris	ATCC® 6380
Providencia alcalifaciens	ATCC® 9886
Pseudomonas aeruginosa	ATCC® 27853
Rotavirus	ZeptoMetrix® 0810041CF
Ruminococcus bromii	ATCC® 27255
Serratia fonticola	ATCC® 29844
Serratia liquefaciens	ATCC® 27592
Serratia marcescens subsp. *marcescens*	ATCC® 13880
Shewanella algae	ATCC® 51192
Shimwellia blattae	ATCC® 29907
Staphylococcus aureus subsp. *aureus*	ATCC® 43300
Staphylococcus epidermidis	ATCC® 14990
Stenotrophomonas maltophilia	ATCC® 13637
Streptococcus agalactiae	ATCC® 13813
Streptococcus intermedius	ATCC® 27335
Streptococcus pyogenes	ATCC® 19615
Streptococcus salivarius subsp. *salivarius*	ATCC® 7073
Streptococcus suis	ATCC® 43765
Trichomonas vaginalis	ATCC® 30001
Veillonella parvula	ATCC® 10790
Vibrio alginolyticus	CCUG 16324
Vibrio brasiliensis	CCUG 48644
Vibrio campbellii	CCUG 16330
Vibrio harveyi	CCUG 23159
Vibrio hispanicus	CCUG 56966T
Vibrio mimicus	CCUG 39638
Vibrio mimicus	CCUG 48106
Vibrio natriegens	CCUG 70547
Vibrio nereis	CCUG 28585
Vibrio tubiashii	CCUG 38428
Yersinia bercovieri	CCUG 26329T
Yersinia frederiksenii	CCUG 11293T
Yersinia intermedia	CCUG 26583
Yersinia kristensenii	CCUG 46842

Interfering Substances

Twenty-six (26) biological and chemical substances that may occasionally be present in stool specimens were evaluated for potential interference with the BD EBP *plus* for BD COR™ System. Eight (8) 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 (1) demonstrated interference. Anti-Fungal cream was found to interfere at levels above 25%. Results demonstrated no reportable interference with any other substance tested. Table 7 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 EBP *plus* for BD COR™ System. Fourteen (14) microorganisms were tested at high concentration (> 2.00E+06 CFU/mL of stool). Results demonstrated no reportable interference with any microorganism tested. Table 8 lists all microorganisms tested and the concentrations at which no interference was observed.

Table 7: 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	47.0 mg/mL
Human DNA	21.9 ug/mL	Pepto Bismol	59.0 mg/mL
Mucus	12.5 mg/mL	Amoxicillin trihydrate[b]	64.0 mg/mL
Whole Human Blood	50%	Metronidazole[b]	60.8 mg/mL
Hydrocortisone	15%	Tetracycline HCl[b]	16.0 mg/mL
Moist Towelettes	3 mm^2 (in FCT)	Ceftriaxone[b]	15.8 mg/mL
Mineral Oil	50%	Sulfamethoxazole[b]	80.0 mg/mL
Preparation H	50%	Trimethoprim[b]	16.0 mg/mL
Nystatin Anti fungal[a]	25%	Erythromycin[b]	14.0 mg/mL
Polysporin	50%	Ciprofloxacin[b]	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

[a]Substance displayed interference when tested at a higher concentration.

[b]Substances tested together as a pool.

Table 8: 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	>2.00E+06 CFU/mL	*Vibrio parahaemolyticus*	>2.00E+06 CFU/mL
Campylobacter jejuni		*Bacteroides fragilis*	
Shigella sonnei		*Proteus vulgaris*	
Escherichia coli (stx1/stx2)		*Bacteroides vulgatusa*	
Plesiomonas shigelloides		*Enterobacter aerogenes*	
Yersinia enterocolitica		*Enterobacter cloacae*	
Escherichia coli (sta2)		*Klebsiella pneumoniae*	
Master Mix 2			
Salmonella Typhimurium	>2.00E+06 CFU/mL	*Vibrio parahaemolyticus*	>2.00E+06 CFU/mL
Campylobacter jejuni		*Bacteroides fragilis*	
Shigella sonnei		*Proteus vulgaris*	
Escherichia coli (stx1/stx2)[a]	2.00E+05 CFU/mL	*Bacteroides vulgatusa*	2.00E+05 CFU/mL
Plesiomonas shigelloides	>2.00E+06 CFU/mL	*Enterobacter aerogenes*	>2.00E+06 CFU/mL
Yersinia enterocolitica		*Enterobacter cloacae*	
Escherichia coli (sta2)		*Klebsiella pneumoniae*	

[a]Microorganism displayed interference when tested at a higher concentration.

Mixed Infection/Competitive Interference

The mixed infection and competitive interference study was designed to evaluate the ability of the BD EBP *plus* for BD COR™ System to detect low-positive results in the presence of other targets at high concentrations. The study was conducted using two target groups, each assessed per master mix. For target group one, four sets were prepared, each containing four organisms: *Salmonella typhimurium*, *Campylobacter jejuni*, *Shigella sonnei*, and *Escherichia coli* (stx1-a). Within each set, three of the four targets were prepared at approximately twice their respective limits of detection (LoD), while one target was prepared at a high concentration (≥1E+06 CFU/mL), all in a negative background stool matrix. For target group two, four sets were similarly prepared, each containing four organisms: *Yersinia*

enterocolitica, *Plesiomonas shigelloides*, *Escherichia coli* (sta2), and *Vibrio parahaemolyticus*. As with target group one, three of the four targets in each set were prepared at ~2x their respective LoDs, and one target was prepared at a high concentration (≥1E+06 CFU/mL), in a negative stool matrix. All target organisms across both groups were successfully detected by the BD EBP *plus* for BD COR™ System when combined with their respective simulated high-concentration mixed infection preparations. These results demonstrate the system's robustness and reliability in detecting low-level targets in the presence of high-concentration co-infections.

Precision

Within-laboratory precision was evaluated for the BD EBP *plus* for BD COR™ System at one site with one reagent lot. Testing was performed over 12 days, with 2 runs per day per technologist (2 technologists), 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 *Escherichia coli* (stx-1a), *Salmonella typhimurium*, *Shigella sonne*i, *Plesiomonas shigelloides*, *Yersinia enterocolitica*, *Vibrio parahaemolyticus*, and Enterotoxigenic *Escherichia coli (*sta2*).* Each panel member was tested in duplicate. 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 EBP *plus* assay when performed on the BD COR™ System are described in Table 9.

Table 9: Overall Precision Study Results Using One Lot of BD EBP plus for BD COR™ System (Percent Agreement with Expected Results)

Assay Panel	Analyte	Level	N Total	N Negative	N Positive	% Correct	95% LCL	95% UCL
Master Mix 1	*Shigella*	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	0	72	100.00%	94.90%	100.00%
		MP	72	0	72	100.00%	94.90%	100.00%
	Salmonella	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	0	72	100.00%	94.90%	100.00%
		MP	72	0	72	100.00%	94.90%	100.00%
	Campylobacter	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	0	72	100.00%	94.90%	100.00%
		MP	72	0	72	100.00%	94.90%	100.00%

Assay Panel	Analyte	Level	N Total	N Negative	N Positive	% Correct	95% LCL	95% UCL
Master Mix 2	STX	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	0	72	100.00%	94.90%	100.00%
		MP	72	0	72	100.00%	94.90%	100.00%
	Vibrio	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	0	72	100.00%	94.90%	100.00%
		MP	72	1	71	98.60%	92.50%	99.80%
	Plesiomonas	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	1	71	98.60%	92.50%	99.80%
		MP	72	0	72	100.00%	94.90%	100.00%
	Yersinia	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	0	72	100.00%	94.90%	100.00%
		MP	72	1	71	98.60%	92.50%	99.80%
	ETEC	TN	72	72	0	100.00%	94.90%	100.00%
		LP	72	0	72	100.00%	94.90%	100.00%
		MP	72	0	72	100.00%	94.90%	100.00%

Reproducibility

The site-to-site reproducibility study was performed at three (3) clinical sites (2 external and 1 internal) using one (1) reagent lot. Two (2) technologists performed two (2) runs per day, over 5 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. Results are summarized in Table 10.

Analysis of variance of the Ct score results from valid tests performed on positive panel members (see Table 11) within lab (total) yielded overall CV (%) ranging from 1.0%–3.4% for MP and 1.3%–3.4% for LP.

Table 10: Overall Percent Agreement for Site-to-Site Reproducibility

		Total	
Target	**Category**	**Percent Agreement**	**95% CI**
Shigella	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)
	Low Positive (LP)	100.0% (90/90)	(95.9%, 100.0%)
	Moderate Positive (MP)	100.0% (90/90)	(95.9%, 100.0%)
Salmonella	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)
	Low Positive (LP)	100.0% (90/90)	(95.9%, 100.0%)
	Moderate Positive (MP)	100.0% (90/90)	(95.9%, 100.0%)
Campylobacter	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)

		Total	
Target	**Category**	**Percent Agreement**	**95% CI**
	Low Positive (LP)	100.0% (90/90)	(95.9%, 100.0%)
	Moderate Positive (MP)	100.0% (90/90)	(95.9%, 100.0%)
STX	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)
	Low Positive (LP)	100.0% (90/90)	(95.9%, 100.0%)
	Moderate Positive (MP)	100.0% (90/90)	(95.9%, 100.0%)
Vibrio	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)
	Low Positive (LP)	100.0% (90/90)	(95.9%, 100.0%)
	Moderate Positive (MP)	98.9% (89/90)	(94.0%, 99.8%)
Plesiomonas	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)
	Low Positive (LP)	98.9% (89/90)	(94.0%, 99.8%)
	Moderate Positive (MP)	100.0% (90/90)	(95.9%, 100.0%)
Yersinia	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)
	Low Positive (LP)	100.0% (90/90)	(95.9%, 100.0%)
	Moderate Positive (MP)	98.9% (89/90)	(94.0%, 99.8%)
ETEC	True Negative (TN)[a]	100.0% (90/90)	(95.9%, 100.0%)
	Low Positive (LP)	100.0% (90/90)	(95.9%, 100.0%)
	Moderate Positive (MP)	100.0% (90/90)	(95.9%, 100.0%)

[a] For the True Negative Category, the reported agreement indicates percent of negative results.

Table 11: Variance Component Analysis for Site-to-Site Reproducibility

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

					Within Run		Between Run		Between Day		Between Site		Total	
Target	**PCR Metric**	**Category**	**N**	**Mean**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Vibrio	Ct Score	Low Positive (LP)	90	31.6	0.61	1.9	0	0	0.8	2.5	0.4	1.3	1.08	3.4
		Moderate Positive (MP)	89	30.9	0.36	1.2	0.1	0.3	0.11	0.4	0.07	0.2	0.4	1.3
Plesiomonas	Ct Score	Low Positive (LP)	89	28.6	0.38	1.3	0.31	1.1	0.19	0.7	0	0	0.52	1.8
		Moderate Positive (MP)	90	28.4	0.34	1.2	0.5	1.7	0.34	1.2	0	0	0.69	2.4
Yersinia	Ct Score	Low Positive (LP)	90	30.2	0.44	1.4	0.2	0.7	0.65	2.1	0	0	0.81	2.7
		Moderate Positive (MP)	89	29.3	0.38	1.3	0	0	0.13	0.4	0.2	0.7	0.45	1.5
ETEC	Ct Score	Low Positive (LP)	90	31.4	0.46	1.5	0.24	0.8	0.2	0.6	0	0	0.56	1.8
		Moderate Positive (MP)	90	30.9	0.54	1.7	0.28	0.9	0.86	2.8	0	0	1.05	3.4

The lot-to-lot reproducibility study was performed at one internal clinical site using three (3) reagent lots. Two (2) technologists performed two (2) runs per day, over 5 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 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 12.

Table 12: Overall Percent Agreement for Lot-to-Lot Reproducibility

		Percent Agreement	Confidence Intervals	
Analyte	**Level**	**Total**	**95% LCL**	**95% UCL**
Shigella	TN	100.0% (90/90)	95.90%	100.00%
	LP	100.0% (90/90)	95.90%	100.00%
	MP	100.0% (90/90)	95.90%	100.00%
Salmonella	TN	100.0% (90/90)	95.90%	100.00%
	LP	100.0% (90/90)	95.90%	100.00%
	MP	100.0% (90/90)	95.90%	100.00%
Campylobacter	TN	100.0% (90/90)	95.90%	100.00%
	LP	100.0% (90/90)	95.90%	100.00%
	MP	100.0% (90/90)	95.90%	100.00%
STX	TN	100.0% (90/90)	95.90%	100.00%

		Percent Agreement	Confidence Intervals	
Analyte	**Level**	**Total**	**95% LCL**	**95% UCL**
	LP	100.0% (90/90)	95.90%	100.00%
	MP	100.0% (90/90)	95.90%	100.00%
Vibrio	TN	100.0% (90/90)	95.90%	100.00%
	LP	98.9% (89/90)	94.00%	99.80%
	MP	97.8% (88/90)	92.30%	99.40%
Plesiomonas	TN	100.0% (90/90)	95.90%	100.00%
	LP	98.9% (89/90)	94.00%	99.80%
	MP	100.0% (90/90)	95.90%	100.00%
Yersinia	TN	100.0% (90/90)	95.90%	100.00%
	LP	100.0% (90/90)	95.90%	100.00%
	MP	98.9% (89/90)	94.00%	99.80%
ETEC	TN	100.0% (90/90)	95.90%	100.00%
	LP	100.0% (90/90)	95.90%	100.00%
	MP	100.0% (90/90)	95.90%	100.00%

Cross-Contamination for BD EBP for BD COR™ System

A study was conducted to investigate cross-contamination while processing samples with high microbial load of *Campylobacter jejuni* in the BD EBP assay. High positive samples contained *Campylobacter jejuni* at concentrations of ≥1 E+06 CFU/mL in the Fecal Collection and Transport tube. The negative samples consisted of Fecal Collection and Transport tubes without any target analyte. Twelve (12) replicates of the high positive panel member and 12 replicates of the negative panel member were alternated in the BD COR™ P-Rack and tested across 18 runs, using three BD COR™ Systems or a total of 216 positive and 216 negative samples tested. Of the 216 negative samples tested, two false positive results were obtained (0.93%).

Cross-Contamination for BD EBP *plus* for BD COR™ System

A study was conducted to investigate cross-contamination while processing samples with high microbial load of ETEC in the BD EBP *plus* assay. High positive samples contained ETEC at concentrations of ≥1 E+06 CFU/mL in the Fecal Collection and Transport tube. The negative samples consisted of Fecal Collection and Transport tubes without any target analyte. Twelve (12) replicates of the high positive panel member and 12 replicates of the negative panel member were alternated in the BD COR™ P-Rack and tested across 18 runs, using three BD COR™ Systems for a total of 216 positive and 216 negative samples tested. Of the 216 negative samples tested, no false positive results were obtained.

Clinical Performance

Clinical performance characteristics of the BD EBP for BD COR™ System and BD EBP *plus* for BD COR™ System were determined in a multi-site investigational study. The study involved a total of six (6) 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 the BD EBP *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 healthcare provider. Four sites performed BD EBP *plus* for BD COR™ System testing and/or comparator method testing. Retrospective specimens from a previous BD study and specimen vendors were added. The performance of the BD EBP *plus* for BD COR™ System was evaluated in comparison to a single FDA-cleared high sensitivity PCR assay for *Salmonella* spp., *Shigella* spp./EIEC, and *Plesiomonas shigelloides* and a two out of three composite comparator method for *Campylobacter* spp. (*C. jejuni* and *C. coli*), Shiga toxin (*stx/stx1/stx2* genes), *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae), Yersinia enterocolitica*, and ETEC.

A total of 1,682 prospective remnant specimens were collected and a total of 235 retrospectively collected specimens were also enrolled giving a total of 1,917 specimens included in this study. From them, 110 specimens were excluded due to inclusion/exclusion criteria not met, inadequate source documentation, specimen handling errors, and specimens outside of stability giving a total of 1,807 specimens compliant for testing. After exclusion of specimens due to testing non-compliance (79) and final non-reportable results, a total of 1,493 prospective and 200 retrospective specimens were evaluable with the BD EBP *plus* on the BD COR™ System and comparator assay(s) with at least one target included into the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) calculations.

Table 13 describes the number of compliant prospective specimens enrolled by patient age, gender and specimen type.

Table 14 describes the number of compliant retrospective specimens enrolled by patient age and gender. Table 15 through Table 27 describe the performance characteristics of BD EBP for BD COR™ System and BD EBP *plus* for BD COR™ System that were observed during the clinical study.

Table 13: Demographics Summary for Compliant Prospective Specimens by Specimen Type

Demographic	Characteristics	Frozen N=764	Fresh N=729	Combined N=1,493
Gender	Male	41.4% (316/764)	43.5% (317/729)	42.4% (633/1,493)
	Female	58.6% (448/764)	56.5% (412/729)	57.6% (860/1,493)
	Unknown	0.0% (0/764)	0.0% (0/729)	0.0% (0/1,493)
Age Group	<1 Year	0.8% (6/764)	1.5% (11/729)	1.1% (17/1,493)
	1–4 Years	6.0% (46/764)	5.9% (43/729)	6.0% (89/1,493)
	5–12 Years	11.8% (90/764)	11.4% (83/729)	11.6% (173/1,493)
	13–18 Years	11.4% (87/764)	9.2% (67/729)	10.3% (154/1,493)
	19–65 Years	41.5% (317/764)	41.0% (299/729)	41.3% (616/1,493)
	>65 Years	28.5% (218/764)	31.0% (226/729)	29.7% (444/1,493)

Table 14: Demographics Summary for Compliant Retrospective Specimens

Demographic	Characteristics	Total N=200
Gender	Male	35.0% (70/200)
	Female	32.5% (65/200)
	Unknown	32.5% (65/200)
Age Group	<1 Year	2.0% (4/200)
	1–4 Years	9.0% (18/200)
	5–12 Years	14.0% (28/200)
	13–18 Years	8.0% (16/200)
	19–65 Years	54.5% (109/200)
	> 65 Years	11.0% (22/200)
	Unknown	1.5% (3/200)

The performance of the BD EBP *plus* for BD COR™ System was evaluated for each panel test result using a single FDA-cleared test for *Shigella* spp. / EIEC, *Salmonella* spp., and *Plesiomonas shigelloides*. A composite comparator method consisting of two out of three independent FDA-cleared test methods was used for *Campylobacter* spp. (*C. jejuni* and *C. coli*), Shiga toxin (*stx/stx1/stx2* genes), *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*), *Yersinia enterocolitica*, and ETEC. Any specimen that tested positive by two assays was considered positive, whereas any specimen that tested negative by two assays was considered negative.

Percent Agreement for *Salmonella* spp.

The BD EBP *plus* for BD COR™ System identified 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 15) when compared to a single comparator.

Table 15: *Salmonella* spp. – Overall Performance

***Salmonella* spp.**			**Single Comparator**		**Total**
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	
Prospective	Combined Fresh and Frozen	Positive	36	8[a]	44
		Negative	2[b]	1,434	1,436
		Total	38	1,442	1,480
PPA: 94.7% (82.7%, 98.5%) NPA: 99.4% (98.9%, 99.7%)					
Retrospective	Frozen	Positive	58	2[c]	60
		Negative	1[d]	135	136
		Total	59	137	196
PPA: 98.3% (91.0%, 99.7%) NPA: 98.5% (94.8%, 99.6%)					

[a]*Salmonella* was detected in 1 of the 8 FP specimens when tested with an independent molecular method.
[b]*Salmonella* was not detected in 1 of the 2 FN specimens when tested with an independent molecular method.
[c]*Salmonella* was not detected in both FP specimens when tested with an independent molecular method.
[d]*Salmonella* was not detected in the FN specimen when tested with an independent molecular method.

Percent Agreement for *Campylobacter* spp. (*C. jejuni* and *C. coli*)

The BD EBP *plus* for BD COR™ System identified 100% and 99.4% of the *C. jejuni* and *C. coli* prospective positive and negative specimens, respectively, and 100% of the retrospective positive and negative specimens (refer to Table 16) when compared to a two out of three composite comparator method.

Table 16: *Campylobacter* spp. *(C. jejuni* and *C. coli)* – Overall Performance

***Campylobacter* spp. (*C. jejuni* and *C. coli*)**			**Composite Comparator**		**Total**
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	
	Combined Fresh and Frozen	Positive	32	3[a]	35
Prospective		Negative	0[b]	463	463
		Total	32	466	498
PPA: 100.0% (89.3%, 100.0%) NPA: 99.4% (98.1%, 99.8%)					
		Positive	67	0	67
Retrospective	Frozen	Negative	0	73[c]	73
		Total	67	73	140
PPA: 100.0% (94.6%, 100.0%) NPA: 100.0% (95.0% 100.0%)					

[a] *Campylobacter* was detected in all 3 FP specimens with one of the three comparator methods.

[b] One specimen negative for *Campylobacter* with BD EBP *plus* 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.

[c] 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 EBP *plus* and with the single FDA-cleared comparator was tested with the complete composite comparator in the prospective and retrospective studies.

Percent Agreement for *Shigella* spp. / EIEC

The BD EBP *plus* for BD COR™ System identified 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 (refer to Table 17) when compared to a single comparator.

Table 17: *Shigella* spp. / EIEC – Overall Performance

***Shigella* spp. / EIEC**			**Single Comparator**		
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	**Total**
Prospective	Combined Fresh and Frozen	Positive	12	0	12
		Negative	3[a]	1,464	1,467
		Total	15	1,464	1,479
PPA: 80.0% (54.8%, 93.0%) NPA: 100.0% (99.7%, 100.0%)					
Retrospective	Frozen	Positive	34	2[b]	36
		Negative	2[c]	158	160
		Total	36	160	196
PPA: 94.4% (81.9%, 98.5%) NPA: 98.8% (95.6%, 99.7%)					

[a] *Shigella* spp. / EIEC was not detected in the 3 FN specimens when tested with an independent molecular method.
[b] *Shigella* spp. / EIEC was not detected in both FP specimens when tested with an independent molecular method.
[c] *Shigella* spp. / EIEC was not detected in 1 of the 2 FN specimens when tested with an independent molecular method.

Percent Agreement for Shiga toxins (*stx*/*stx1*/*stx2* genes)

The BD EBP for BD COR™ System identified 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 (refer to Table 10) when compared to a two out of three composite comparator method (refer to Table 18).

As Shiga toxins (*stx*/*stx1*/*stx2* genes) prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study. These were prepared by spiking 5 different strains of Shiga toxin-producing *E. coli* (STEC) in negative stool matrix. Strains were spiked at various clinically relevant loads and randomly distributed among three (3) clinical sites for BD EBP *plus* for BD COR™ System testing. A positive agreement of 100% was obtained across the tested loads. Results are shown in Table 19 when compared to a two out of three composite comparator method.

Table 18: Shiga Toxins (*stx/stx1/stx2* genes) – Overall Performance

Shiga Toxins (*stx*, *stx1*, and *stx2* genes)			Composite Comparator		
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	**Total**
Prospective	Combined Fresh and Frozen	Positive	10[a]	1	11
		Negative	0	489[b]	489
		Total	10	490	500
PPA: 100.0% (72.2%, 100.0%) NPA: 99.8% (98.9%, 100.0%)					
Retrospective	Frozen	Positive	9	0	9
		Negative	0	130[b]	130
		Total	9	130	139
PPA: 100.0% (70.1%, 100.0%) NPA: 100.0% (97.1%, 100.0%)					

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

Table 19: Shiga Toxins (stx/stx1/stx2 genes) – Contrived Specimens Results

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%)			

Percent Agreement for *Plesiomonas shigelloides*

The BD EBP *plus* for BD COR™ System identified 66.7% and 100% of the *Plesiomonas shigelloides* prospective positive and negative specimens, respectively, and 100% of the retrospective positive and negative specimens, respectively (refer to Table 20) when compared to a single comparator.

As *Plesiomonas shigelloides* prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study. These were prepared by spiking 5 different strains of *Plesiomonas shigelloides* in negative stool matrix. Strains were spiked at various

clinically relevant loads and randomly distributed among three (3) clinical sites for BD EBP *plus* for BD COR™ System testing. A positive agreement of 100% was obtained across the tested loads. Results are shown in Table 21.

Table 20: *Plesiomonas shigelloides* – Overall Performance

Plesiomonas shigelloides			**Single Comparator**		
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	**Total**
Prospective	Combined Fresh and Frozen	Positive	2	0	2
		Negative	1[a]	1,484	1,485
		Total	3	1,484	1,487
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%)					

[a] One specimen could not be tested with an independent molecular method.

Table 21: *Plesiomonas shigelloides* – Contrived Specimens Results

Plesiomonas shigelloides	**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%)			

Percent Agreement for *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*)

The BD EBP *plus* for BD COR™ System identified 100% of the *Vibrio* spp. prospective positive and negative specimens, and 100% of the retrospective negative specimens (refer to Table 22) when compared to a two out of three composite comparator method.

As *Vibrio* spp. prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study. These were prepared by spiking 5 different strains of *Vibrio* spp. in negative stool matrix. Strains were spiked at various clinically relevant loads and randomly distributed among three (3) clinical sites for BD EBP *plus* for BD COR™ System testing. A positive agreement of 96.0% was obtained across the tested loads. Results are shown in Table 23.

Table 22: *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*) – Overall Performance

***Vibrio* spp.**			**Comparator**		**Total**
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	
Prospective	Combined Fresh and Frozen	Positive	2	0	2
		Negative	0	501[a]	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[a]	140
		Total	0	140	140
PPA: Not Available NPA: 100.0% (97.3%, 100.0%)					

[a]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.

Table 23: *Vibrio* spp. (*V. vulnificus*, *V. parahaemolyticus*, and *V. cholerae*) – Contrived Specimens Results

***Vibrio* 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%)			

Percent Agreement for ETEC (Heat-Labile Enterotoxin (LT) / Heat-Stable Enterotoxin (ST) Genes)

The BD EBP *plus* 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 (refer to Table 24) when compared to a two out of three composite comparator.

As ETEC prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study. These were prepared by spiking 5 different strains of ETEC in negative stool matrix. Strains were spiked at various clinically relevant loads and

randomly distributed among three (3) clinical sites for BD EBP *plus* for BD COR™ System testing. A positive agreement of 100% was obtained across the tested loads. Results are shown in Table 25.

Table 24: ETEC (Heat-Labile Enterotoxin (LT) / Heat-Stable Enterotoxin (ST) Genes) – Overall Performance

ETEC			Composite Comparator		Total
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	
Prospective	Fresh	Positive	9	1[a]	10
		Negative	1[b]	240[c]	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[d]	246[c]	250
		Total	7	246	253
PPA: 42.9% (15.8%, 75.0%) NPA: 100.0% (98.5%, 100.0%)					
Retrospective	Frozen	Positive	13	1[b]	14
		Negative	0	128[c]	128
		Total	13	129	142
PPA: 100.0% (77.2%, 100.0%) NPA: 99.2% (95.7%, 99.9%)					

[a]ETEC was detected in the FP specimen with one of the three comparator methods in the prospective and retrospective studies.
[b]ETEC was not detected in the FN specimen with one of the three comparator methods.
[c]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.
[d]ETEC was not detected in all 4 FN specimens with one of the three comparator methods.

Table 25: 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%)			

Percent Agreement for *Yersinia enterocolitica*

The BD EBP *plus* for BD COR™ System identified 100% of the *Y. enterocolitica* prospective positive and negative specimens, and 100% of the retrospective positive and negative specimens (refer to Table 26) when compared to a two out of three composite comparator method.

As *Yersinia enterocolitica* prevalence was low, an evaluation of contrived specimens was performed to supplement data collected in the study. These were prepared by spiking 5 different strains of *Yersinia enterocolitica* in negative stool matrix. Strains were spiked at various clinically relevant loads and randomly distributed among three (3) clinical sites for BD EBP *plus* for BD COR™ System testing. A positive agreement of 100% was obtained across the tested loads. Results are shown in Table 27.

Table 26: *Yersinia enterocolitica* – Overall Performance

Yersinia enterocolitica			**Composite Comparator**		**Total**
Specimen Origin	**Specimen Type**	**BD COR™**	**Positive**	**Negative**	
Prospective	Combined Fresh and Frozen	Positive	4	0	4
		Negative	0[a]	497[b]	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[b]	138
		Total	2	138	140
PPA: 100.0% (34.2%, 100.0%) NPA: 100.0% (97.3%, 100.0%)					

[a]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 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.
[b]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.

Table 27: *Yersinia enterocolitica* – Contrived Specimens Results

Yersinia enterocolitica	**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 EBP for BD COR™ System and BD EBP *plus* for BD COR™ System

Non-reportable results were defined as results obtained while assessing the BD EBP *plus* for BD COR™ System targets with the BD EBP *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 EBP for BD COR™ System and BD EBP 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 EBP for BD COR™ System and BD EBP 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 EBP for BD COR™ System and BD EBP plus for BD COR™ System are shown in Table 28 and Table 29, respectively.

Table 28: Summary of BD EBP for BD COR™ System Total Non-Reportable Rate for Combined Targets

Combined EBP Targets	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total UNR+IND+INC Rate	
Specimen Origin	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)
Prospective	3.1% 47/1,537 (2.3%, 4.0%)	1.6% 24/1,514 (1.1%, 2.3%)	0.1% 1/1,537 (0.0%, 0.4%)	0.0% 0/1,514 (0.0%, 0.2%)	0.1% 2/1,537 (0.0%, 0.5%)	0.0% 0/1,514 (0.0%, 0.2%)	3.3% 50/1,537 (2.5%, 4.3%)	1.6% 24/1,514 (1.1%, 2.3%)
Retrospective	3.0% 6/200 (1.4%, 6.4%)	2.0% 4/200 (0.8%, 5.0%)	0.0% 0/200 (0.0%, 1.9%)	0.0% 0/200 (0.0%, 1.9%)	0.0% 0/200 (0.0%, 1.9%)	0.0% 0/200 (0.0%, 1.9%)	3.0% 6/200 (1.4%, 6.4%)	2.0% 4/200 (0.8%, 5.0%)

[a]The final rate is calculated with valid repeats only.

Table 29: Summary of BD EBP *plus* for BD COR™ System Total Non-Reportable Rate for Combined Targets

Combined EBP *plus* Targets	Unresolved Rate		Indeterminate Rate		Incomplete Rate		Total UNR+IND+INC Rate	
Specimen Origin	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)	Initial (95% CI)	Final[a] (95% CI)
Prospective	4.9% 76/1,537 (4.0%, 6.1%)	1.8% 28/1,514 (1.3%, 2.6%)	0.1% 1/1,537 (0.0%, 0.4%)	0.0% 0/1,514 (0.0%, 0.2%)	0.1% 2/1,537 (0.0%, 0.5%)	0.0% 0/1,514 (0.0%, 0.2%)	5.1% 79/1,537 (4.1%, 6.4%)	1.8% 28/1,514 (1.3%, 2.6%)
Retrospective	4.5% 9/200 (2.4%, 8.3%)	3.0% 6/200 (1.4%, 6.4%)	0.0% 0/200 (0.0%, 1.9%)	0.0% 0/200 (0.0%, 1.9%)	0.0% 0/200 (0.0%, 1.9%)	0.0% 0/200 (0.0%, 1.9%)	4.5% 9/200 (2.4%, 8.3%)	3.0% 6/200 (1.4%, 6.4%)

[a]The final rate is calculated with valid repeats only.