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

July 28, 2022

Re: K214122
Trade/Device Name: BD MAX Enteric Bacterial Panel, BD MAX Extended Enteric Bacterial Panel
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay
Regulatory Class: Class II
Product Code: PCI, PCH, OOI
Dated: December 22, 2021
Received: December 30, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K214122

Device Name
BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel

Indications for Use *(Describe)*

BD MAX™ Enteric Bacterial Panel

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.* (*jejuni* and *coli*)
- *Shigella spp.* / Enteroinvasive *E. coli* (EIEC)
- Shiga toxin 1 (*stx*1) / Shiga toxin 2 (*stx*2) 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.

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-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.

BD MAX™ Extended Enteric Bacterial Panel

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.

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.

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.

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510(k) Summary

BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel

Summary Preparation Date:

12/22/2021

Submitted by:

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

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

Proprietary Names:

For the instrument:

BD MAX™ System

For the assay:

BD MAX™ Enteric Bacterial Panel
BD MAX™ Extended Enteric Bacterial Panel

Common Names:

For the instrument:

Bench-top molecular diagnostics workstation

For the assay:

Gastrointestinal Bacterial Panel Multiplex Nucleic Acid-Based Assay System
Enteric Bacterial Panel
Enteric Bacterial Nucleic Acid Test
Enteric Bacterial identification and differentiation system
Enteric assay
Enteric test

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

Predicate Device

BD MAX™ Enteric Bacterial Panel (K140111)
BD MAX™ Extended Enteric Bacterial Panel (K170308)

Device Establishment

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
Registration Number: 1119779

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.

Intended Use

BD MAX™ Enteric Bacterial Panel

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. (*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 *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-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.

BD MAX™ Extended Enteric Bacterial Panel

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.

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.

Special Conditions for Use Statement: For Prescription Use Only

Special Instrument Requirements: BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel are performed on the BD MAX™ System

Device Description

The BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assays along with the BD MAX System are comprised of an instrument with associated hardware and accessories, disposable microfluidic cartridges, master mixes, unitized reagent strips, and extraction reagents. The instrument automates sample preparation including target lysis, DNA extraction and concentration, reagent rehydration, target nucleic acid amplification and detection using real-time PCR. The assay includes a Sample Processing Control (SPC) that is present in the Extraction Tube. The SPC monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances. The BD MAX™ System software automatically interprets test results. For the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel, a test result may be called as POS, NEG or UNR (Unresolved) based on the amplification status of the targets and of the Sample Processing Control. IND (Indeterminate) or INC (Incomplete) results are due to BD MAX™ System failure.

Test Principle

The BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assays are designed for use with unpreserved or Cary-Blair preserved stool samples. Unpreserved samples are placed in a BD MAX sample buffer tube (SBT) with a 10 µL transfer loop for analysis on the BD Max System. The current Cary-Blair preserved specimen claim utilizes a plastic paddle (scoop) to place a stool sample into 15 ml of Cary-Blair media for transport before being placed into a SBT with a 10 µL transfer loop prior to analysis on the BD Max System.

To use the FecalSwab Collection, Transport, and Preservation System, the operator transfers fecal material from an unpreserved stool specimen to the vial of FecalSwab transport medium using the nylon flocked specimen collection swab. The FecalSwab transport medium tube is filled with 2 ml of a semi-solid modified Cary-Blair medium that is designed to maintain the viability of enteric pathogenic bacteria during transit to the testing laboratory. Last, before analysis on the BD MAX system, samples collected/stored with the FecalSwab system are vortexed and then pipetted (50 µl) into a BD MAX™ sample buffer tube (SBT).

Once specimens (Unpreserved, Cary-Blair, or FecalSwab Cary-Blair) are placed into a BD MAX SBT, the test principles are as described in K140111 and K170308. For all specimen types the SBTs are vortexed and then loaded into the BD MAX system along with the Unitized Reagent Strips, Master Mix, Extraction Tubes, and PCR Cartridges. No further operator intervention is necessary, and the following automated procedures occur. The microbial cells are lysed and DNA

is extracted using a combination of lytic and extraction reagents at elevated temperatures. Nucleic acids released from the target organisms are captured on magnetic affinity beads. 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 Master Mix Tube to rehydrate the PCR reagents. After reconstitution, the BD MAX System dispenses a fixed volume of PCR-ready solution containing the extracted nucleic acids into the PCR Cartridge. Microvalves in the 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 MAX System. The probes are used to detect amplicons for enteric bacterial targets and the Sample Processing Control in five different optical channels of the BD MAX 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 amount of fluorescence detected in the optical channels used for the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assays are directly proportional to the quantity of the corresponding probe that is hydrolyzed. The BD MAX 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). The assay includes a Sample Processing Control, which monitors the integrity of the reagents as well as the process steps involved in DNA extraction, amplification and detection, and checks for the presence of potential assay inhibitor.

Substantial Equivalence[1]

Table 1 and Table 2 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 of BD MAX™ Enteric Bacterial Panel to Predicate Device

Item	Predicate - BD MAX™ Enteric Bacterial Panel (K140111)	Submitted Device - BD MAX™ Enteric Bacterial Panel with FecalSwab Collection, Preservation, and Transport System
Intended Use	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. (*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. 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-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.	Same

Item	Predicate - BD MAX™ Enteric Bacterial Panel (K140111)	Submitted Device - BD MAX™ Enteric Bacterial Panel with FecalSwab Collection, Preservation, and Transport 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
Specimen Type	Unpreserved stool or Cary-Blair preserved stool	Same
Assay Format	Amplification: PCR Detection: Fluorogenic target-specific hybridization	Same
Mode of Detection	Presence of • *tuf* gene specific for *Campylobacter* • *SpaO* gene specific for *Salmonella* • *ipaH* gene specific for *Shigella* • *stx1a* and *stx2a* genes specific to Shiga-toxin producing organisms	Same
Interpretation of Test Results	Automated (BD MAX™ System diagnostic software)	Same
Analysis Platform	BD MAX™ System	Same
PCR Sample Preparation	Automated by the BD MAX™ System	Same
Detection Probes	TaqMan® Probe	Same
Assay Controls	Sample Processing Control (SPC)	Same
Cary-Blair Buffer Formulation	-Sodium Chloride -Calcium Chloride -Phosphate Buffer -Thioglycolic Acid Sodium Salt -Phenol Red -Agar -Water	-Chloride salts -Sodium salts -Phosphate buffer -L-Cysteine -Agar -Water
Cary-Blair Buffer Container	Plastic Container w/Lid prefilled 15 ml of media	Plastic Container w/Lid prefilled 2 ml of media

Item	Predicate - BD MAX™ Enteric Bacterial Panel (K140111)	Submitted Device - BD MAX™ Enteric Bacterial Panel with FecalSwab Collection, Preservation, and Transport System
Specimen Transfer Tool (unpreserved to Cary-Blair)	Plastic Paddle	Flocked Swab
Transport Method to SBT Tube	10 µL Transport Loop	50 µL Pipette
Sterility of FecalSwab	Not Applicable	Yes, Irradiation (FecalSwab)

Table 2: Comparison of BD MAX™ Extended Enteric Bacterial Panel to Predicate Device

Item	Predicate - BD MAX Extended Enteric Bacterial Panel (K170308)	Proposed - BD MAX Extended Enteric Bacterial Panel with FecalSwab Collection, Preservation, and Transport System
Intended Use	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. 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	Same

Item	Predicate - BD MAX Extended Enteric Bacterial Panel (K170308)	Proposed - BD MAX Extended Enteric Bacterial Panel with FecalSwab Collection, Preservation, and Transport System
	by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.	
Organisms Detected	• *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*	Same
Specimen Type	Unpreserved stool or Cary-Blair preserved stool	Same
Assay Format	Amplification: PCR Detection: Fluorogenic target-specific hybridization	Same
Mode of Detection	Presence of • Undefined gene suspected to be implicated in Fe^{3+} transport for *Plesiomonas shigelloides* • *atpA* gene specific for *Vibrio* • *eltA* gene specific for *Enterotoxigenic Escherichia coli* • *invA* gene for *Yersinia enterocolitica*	Same
Interpretation of Test Results	Automated (BD MAX™ System diagnostic software)	Same
Analysis Platform	BD MAX™ System	Same
PCR Sample Preparation	Automated by the BD MAX™ System	Same
Detection Probes	TaqMan® Probe	Same
Assay Controls	Sample Processing Control (SPC)	Same
Cary-Blair Buffer Formulation	Sodium Chloride Calcium Chloride Phosphate Buffer Thioglycolic Acid Sodium Salt Phenol Red Agar Water	-Chloride salts -Sodium salts -Phosphate buffer -L-Cysteine -Agar -Water

Item	Predicate - BD MAX Extended Enteric Bacterial Panel (K170308)	Proposed - BD MAX Extended Enteric Bacterial Panel with FecalSwab Collection, Preservation, and Transport System
Cary-Blair Buffer Container	Plastic Container w/Lid prefilled 15 ml of media	Plastic Container w/Lid prefilled 2 ml of media
Transfer Tool	Plastic Paddle	Nylon Flocked Swab
Transport Method to SBT Tube	Transport Loop	Pipette
Sterility of FecalSwab	Not Applicable	Yes, Irradiation (FecalSwab)

Performance Evaluation

Four studies were conducted to demonstrate the substantial equivalence between the current predicate specimen collection (Cary-Blair) and the additional specimen collection (FecalSwab) for use in the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assays:

- Confirmation of equivalent analytical sensitivity with the Copan FecalSwab™ preserved stool specimen (FecalSwab) compared to the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel from a Cary-Blair Para-Pak® stool sample was performed by the limiting dilution LoD model. Acceptable performance was demonstrated when the detection break points between the FecalSwab and Cary-Blair Para-Pak® specimen types were within one five-fold dilution of each other. Break point is defined as the highest concentration where the positivity rate is <95% (<23/24). To achieve this comparison, a negative stool pool was prepared and divided into five aliquots, to which serially diluted multiplex organism mix was added. The organism mix contained a representative strain for each of the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel targets. The organism mixes contain one species from all claimed genera.

  For the BD MAX™ Enteric Bacterial Panel the organism mix was prepared by combining the following targets in PBS: *Salmonella typhimurium* (ATCC 14028), *Shigella sonnei* (ATCC 9290), *Campylobacter jejuni* (ATCC 43429), and *Escherichia coli stx1* (ATCC 43890). For the BD MAX™ Extended Enteric Bacterial Panel the organism mix was prepared by combining the following targets in PBS: *Plesiomonas shigelloides* (ATCC 14029), *V. parahaemolyticus* (ATCC 178020), *Y. enterocolitica* (ATCC 9610), and *Escherichia coli* ETEC (ATCC 35401). The diluted BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel mixtures were spiked into aliquots of the stool pool. Three separate lots of FecalSwabs and one lot of scaled volume Cary-Blair were inoculated with each of the serially diluted stool samples. A 0.5 McFarland turbidity suspension was prepared for each organism. This suspension was diluted in PBS to create concentration 1 (Conc 1). Five additional concentrations (Conc 2-6) were prepared by performing 5-fold serial dilutions from Conc 1.

  Limiting dilutions of specimens for each organism prepared using the FecalSwab™ and Para-Pak® exhibited drop-out rates at similar levels when tested with the BD MAX™ Enteric Bacterial Panel and the BD MAX™ Extended Enteric Bacterial Panel Assays on the BD MAX™ System. All FecalSwab™ break points were within one five-fold concentration when compared to Para-Pak® (Table 3). There was no indication that the FecalSwab™ collection device negatively impacted the analytical sensitivity of the BD MAX™ Enteric Bacterial Panel or BD MAX™ Extended Enteric Bacterial Panel.

Table 3: Number of Positive Samples for the BD MAX™ Enteric Bacterial Panel

Enteric Bacterial Panel								
Organism	*S. typhimurium*		*E. coli stx1*		*C. jejuni*		*S. sonnei*	
Collection Type	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®
Conc 1	24/24	24/24	24/24	24/24	24/24	24/24	24/24	24/24
Conc 2	24/24	24/24	24/24	24/24	24/24	24/24	24/24	24/24
Conc 3	22/24	16/24	24/24	23/24	24/24	24/24	24/24	23/24
Conc 4	8/24	6/24	16/24	9/24	23/24	22/24	20/24	21/24
Conc 5	3/24	7/24	3/24	6/24	14/24	13/24	13/24	15/24
Conc 6	0/24	0/24	0/24	0/24	3/24	3/24	3/24	4/24
Extended Enteric Bacterial Panel								
Organism	*P. shigelloides*		*Y. enterocolitica*		*V. parahaemolyticus*		*E. coli ETEC*	
Collection Type	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®
Conc 1	24/24	23/23*	24/24	23/23*	24/24	23/23*	24/24	23/23*
Conc 2	24/24	24/24	24/24	24/24	24/24	24/24	24/24	24/24
Conc 3	24/24	17/24	24/24	17/24	24/24	18/24	24/24	18/24
Conc 4	14/24	9/24	10/24	10/24	7/24	3/24	13/24	7/24
Conc 5	3/24	6/24	2/24	1/24	1/24	0/24	6/24	4/24
Conc 6	0/24	0/24	1/24	2/24	0/24	0/24	1/24	1/24

*One non-reportable sample was not retested, and 23 replicates were accepted for the highest concentration.

- Specimen Stability of stool specimen collected with the FecalSwab was tested against all target organisms. The results showed that specimen stability of FecalSwab meets the current BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assay stability claims. For each organism tested across both the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assays, a detection ≥ 95% occurred at all the target stability time points claimed in the package insert. Therefore, stool preserved with FecalSwab can be stored for 24 hours (1 days) at 25 ± 2 °C and 120 hours (5 days) at 2 - 8 °C, and sample buffer tube inoculated with FecalSwab specimen can be stored for 48 hours (2 days) at 25 ± 2 °C and 120 hours (5 days) at 2 - 8 °C.

- A user variability study was performed using the FecalSwab since there are differences in workflow (unpreserved sample to preservation media to SBT) between the FecalSwab and Cary-Blair Para-Pak® specimen collection. The data demonstrate that expected assay results are obtained when FecalSwab stool specimens were prepared by multiple users and shows that the difference in workflow between Cary-Blair Para-Pak® and FecalSwab specimen collection has no effect on the ability of the user to place the sample into the SBT for the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assays.

  The user variability study was performed to confirm that the preparation of the FecalSwab™ by different users does not induce variability in the expected results for the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel assays. Six (6) different users prepared two (2) different FecalSwab™ specimens from each of the five (5) panel members provided (one (1) negative panel member, three (3) low-positive panel members, and one (1)

moderate-positive panel member;). Once the FecalSwab™ specimens were prepared by various users, all subsequent steps, including the transfer to SBTs from each FecalSwab™, were performed by a single experienced BD MAX™ user. *Campylobacter jejuni* was used for BD MAX™ Enteric Bacterial Panel assay because it is the most prevalent Enteric Bacterial Panel target and has the lowest LoD from Enteric Bacterial Panel targets. ETEC ST/LT was used for BD MAX™ Extended Enteric Bacterial Panel assay because it is the most prevalent Extended Enteric Bacterial target and has the second lowest LoD from Extended Enteric Bacterial targets.

Acceptance criteria were: 100% negative results for the twelve (12) negative samples, ≥95% positive results for the thirty-six (36) low-positive samples, and 100% positive for the twelve (12) moderate-positive samples. All conditions met acceptance criteria (Table 4)

Table 4. Acceptance criteria for user variability

Target	Panel Member	Acceptance Criteria	Assay Results	Results
***Campylobacter jejuni* and ETEC**	Moderate-Positive	100% POS	100% POS	Pass
	Low-Positive	≥95% POS	100% POS	
Negative samples	Negative	100% NEG	100% NEG	

Results met all acceptance criteria. The data demonstrate that expected assay results are obtained when the FecalSwab™ fecal specimens were prepared by multiple users.

- The performance of the BD FecalSwab™ Collection, Transport and Preservation System when tested with the BD MAX™ Enteric Bacterial Panel and BD MAX™ Extended Enteric Bacterial Panel was evaluated in a comparison study by comparing the results obtained for specimens using Cary-Blair Para-Pak® preserved stool samples to those using the BD FecalSwab™ Collection, Transport and Preservation System. Both the BD FecalSwab™ and Copan FecalSwab™ are identical other than branding and were incorporated into the performance evaluation. Unpreserved stool samples were collected from pediatric and adult patients suspected of acute bacterial gastroenteritis, enteritis, or colitis from eight (8) geographically diverse clinical centers where specimens were collected as part of routine patient care. At these locations, the fresh, unpreserved stool samples were transferred into both Cary-Blair Para-Pak® collection vials and BD FecalSwab™ devices. All samples were subsequently shipped to a centralized testing laboratory and tested with the BD MAX™ Enteric Bacterial panel. A total

of 621 prospective specimens and 295 retrospective specimens were enrolled in the clinical evaluation where three (3) prospective samples were excluded from the data analysis due to subject exclusion criteria. Table 5 describes the 913 (618 prospective and 295 retrospective) compliant specimens enrolled by patient age, sex, and specimen type. Sixteen (16) additional prospective samples were excluded from the data analysis due to specimen or instrument level exclusion criteria. The final data analysis included 897 compliant subjects for *Campylobacter*, *Salmonella*, *Shigella* spp. / Enteroinvasive *E. coli* (EIEC), Shiga toxin producing *E. coli* (STEC), *Plesiomonas shigelloides*, Vibrio (*V. vulnificus, V. parahaemolyticus V. cholerae*), Enterotoxigenic *E. coli* (ETEC) LT/ST, and *Yersinia enterocolitica* targets.

Table 5: Compliant Clinical Trial Enrollment Summary by Age, Sex, and Specimen Type

Specimen Type	Mean Age in years (SD)	Median Age in years	Min Age in years	Max Age in years	Sex of Total N
Prospective Total N = 618	47.1 (22.4)	49.0	<1	95	Male: 44.8%
Unknown Age: 0					Female: 55.2%
Known Age: 618					Unknown: 0.0%
Retrospective Total N = 295	37.2 (20.8)	33.5	<1	86	Male: 30.5%
Unknown Age: 149					Female: 24.1%
Known Age: 146					Unknown: 45.4%
Overall Total N = 913	45.2 (22.4)	47.0	<1	95	Male: 40.2%
Unknown Age: 149					Female: 45.1%
Known Age: 764					Unknown: 14.7%

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 100.0% and 99.8% of the *Campylobacter* spp. prospective positive and negative specimens, respectively, and 100.0% and 97.1% of the retrospective positive and negative specimens, respectively (Table 6).

Table 6: *Campylobacter* spp. PPA and NPA of the BD MAX™ Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

***Campylobacter* spp.**		**Cary-Blair**		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	9	1	10
	Negative	0	585	585
	Total	9	586	595
PPA: 100.0% (70.1%, 100.0%) NPA: 99.8% (99.0%, 100.0%)				
Retrospective	Positive	88	6	94
	Negative	0	200	200
	Total	88	206	294
PPA: 100.0% (95.8%, 100.0%) NPA: 97.1% (93.8%, 98.7%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 100.0% of the *Salmonella* spp. prospective positive and negative specimens, and 93.3% and 95.9% of the retrospective positive and negative specimens, respectively (Table 7).

Table 7: *Salmonella* spp. PPA and NPA of the BD MAX™ Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

***Salmonella* spp.**		**Cary-Blair**		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	4	0	4
	Negative	0	591	591
	Total	4	591	595
PPA: 100.0% (51.0%, 100.0%) NPA: 100.0% (99.4%, 100.0%)				
Retrospective	Positive	70	9	79
	Negative	5	210	215
	Total	75	219	294
PPA: 93.3% (85.3%, 97.1%) NPA: 95.9% (92.4%, 97.8%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 100% of the *Shigella* spp. prospective positive and negative specimens, and 98.1% and 99.6% of the retrospective positive and negative specimens, respectively (Table 8).

Table 8: *Shigella* spp. PPA and NPA of the BD MAX™ Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

***Shigella* spp.**		**Cary-Blair**		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	7	0	7
	Negative	0	588	588
	Total	7	588	595
PPA: 100.0% (64.6%, 100.0%) NPA: 100.0% (99.4%, 100.0%)				
Retrospective	Positive	52	1	53
	Negative	1	240	241
	Total	53	241	294
PPA: 98.1% (90.1%, 99.7%) NPA: 99.6% (97.7%, 99.9%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 100.0% and 99.5% of the *stx1*/*stx2* (STX) prospective positive and negative specimens, respectively, and 92.9% and 100.0% of the retrospective positive and negative specimens, respectively (Table 9.

Table 9: *stx1*/*stx2* (STX) PPA and NPA of the BD MAX™ Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

STX		**Cary-Blair**		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	1	3	4
	Negative	0	591	591
	Total	1	594	595
PPA: 100.0% (20.7%, 100.0%) NPA: 99.5% (98.5%, 99.8%)				
Retrospective	Positive	13	0	13
	Negative	1	281	282
	Total	14	281	295
PPA: 92.9% (68.5%, 98.7%) NPA: 100.0% (98.7%, 100.0%)				

In addition, due to the small number of *stx1/stx2* (STX) positive specimens in the study, contrived specimens were evaluated. The BD FecalSwab™ Collection, Transport and Preservation System on the BD MAX™ Enteric Bacterial Panel identified 100% of the *stx1/stx2* (STX) contrived positive and negative specimens, when compared to expected results (Table 10).

Table 10: STX Contrived FecalSwab™ Specimen Results

STX	Expected Results			
Contrived	Positive	53	0	53
	Negative	0	53	53
	Total	53	53	106
PPA: 100.0% (93.2%, 100.0%) NPA: 100.0% (93.2%, 100.0%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 100.0% and 99.0% of the *Plesiomonas shigelloides* prospective positive and negative specimens, respectively, and 33.3% and 100.0% of the retrospective positive and negative specimens, respectively (Table 11).

Table 11: *Plesiomonas shigelloides* PPA and NPA of the BD MAX™ Extended Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

Plesiomonas shigelloides		**Cary-Blair**		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	2	6	8
	Negative	0	586	586
	Total	2	592	594
PPA: 100.0% (34.2%, 100.0%) NPA: 99.0% (97.8%, 99.5%)				
Retrospective	Positive	1	0	1
	Negative	2	291	293
	Total	3	291	294
PPA: 33.3% (6.1%, 79.2%) NPA: 100.0% (98.7%, 100.0%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 99.7% of the *Vibrio* spp. prospective negative specimens (zero prospective positives specimens were analyzed), and 100.0% of the retrospective positive and negative specimens (Table 12).

Table 12: *Vibrio* spp. PPA and NPA of the BD MAX™ Extended Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

Vibrio		**Cary-Blair**		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	0	2	2
	Negative	0	592	592
	Total	0	594	594
PPA: Not Available NPA: 99.7% (98.8%, 99.9%)				
Retrospective	Positive	4	0	4
	Negative	0	290	290
	Total	4	290	294
PPA: 100.0% (51.0%, 100.0%) NPA: 100.0% (98.7%, 100.0%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 100.0% of the ETEC prospective positive and negative specimens, and 100.0% and 99.6%-of the retrospective positive and negative specimens, respectively (Table 13).

Table 13: ETEC PPA and NPA of the BD MAX™ Extended Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

ETEC		Cary-Blair		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	2	0	2
	Negative	0	592	592
	Total	2	592	594
PPA: 100.0% (34.2%, 100.0%) NPA: 100.0% (99.4%, 100.0%)				
Retrospective	Positive	14	1	15
	Negative	0	279	279
	Total	14	280	294
PPA: 100.0% (78.5%, 100.0%) NPA: 99.6% (98.0%, 99.9%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Bacterial Panel identified 100.0% of the *Yersinia enterocolitica* prospective negative specimens (zero prospective positive specimens were analyzed), and 100.0% and 99.0% of the retrospective positive and negative specimens, respectively (Table 14).

Table 14: *Yersinia enterocolitica* PPA and NPA of the BD MAX™ Extended Enteric Bacterial Panel - FecalSwab™ Compared to Cary-Blair

Yersinia enterocolitica		Cary-Blair		
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	**Total**
Prospective	Positive	0	0	0
	Negative	1	593	594
	Total	1	593	594
PPA: 0.0% (0.0%, 79.3%) NPA: 100.0% (99.4%, 100.0%)				
Retrospective	Positive	4	3	7
	Negative	0	287	287
	Total	4	290	294
PPA: 100.0% (51.0%, 100.0%) NPA: 99.0% (97.0%, 99.6%)				

Additional contrived specimens were evaluated due to low prevalence of the targets in the study. The BD FecalSwab™ Collection, Transport and Preservation System on the BD MAX™ Extended Enteric Bacterial Panel identified 100.0% of the *Plesiomonas shigelloides* contrived positive and negative specimens, when compared to expected results (Table 15).

Table 15: *Plesiomonas shigelloides* Contrived FecalSwab™ Specimen Results

Plesiomonas shigelloides	Expected Results			
Contrived	Positive	53	0	53
	Negative	0	53	53
	Total	53	53	106
PPA: 100.0% (93.2%, 100.0%) NPA: 100.0% (93.2%, 100.0%)				

The BD FecalSwab™ Collection, Transport and Preservation System on the BD MAX™ Extended Enteric Bacterial Panel identified 98.1% and 100.0% of the positive and negative *Vibrio* contrived positive and negative specimens, respectively, when compared to expected results (Table 16).

Table 16: *Vibrio* Contrived FecalSwab™ Specimen Results

***Vibrio* ssp.**	**Expected Results**			
Contrived	Positive	52	0	52
	Negative	1	53	54
	Total	53	53	106
PPA: 98.1% (90.1%, 99.7%) NPA: 100.0% (93.2%, 100.0%)				

The BD FecalSwab™ Collection, Transport and Preservation System on the BD MAX™ Extended Enteric Bacterial Panel identified 100.0% of the ETEC contrived positive and negative specimens, when compared to expected results (Table 17).

Table 17: ETEC Contrived FecalSwab™ Specimen Results

ETEC	**Expected Results**			
Contrived	Positive	53	0	53
	Negative	0	53	53
	Total	53	53	106
PPA: 100.0% (93.2%, 100.0%) NPA: 100.0% (93.2%, 100.0%)				

The BD FecalSwab™ Collection, Transport and Preservation System on the BD MAX™ Extended Enteric Bacterial Panel identified 98.1% and 100.0% of the positive and negative *Yersinia enterocolitica* contrived positive and negative specimens, respectively, when compared to expected results (Table 18).

Table 18: *Yersinia enterocolitica* Contrived FecalSwab™ Specimen Results

Yersinia enterocolitica	**Expected Results**			
Contrived	Positive	52	0	52
	Negative	1	53	54
	Total	53	53	106
PPA: 98.1% (90.1%, 99.7%) NPA: 100.0% (93.2%, 100.0%)				