September 21, 2022

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

Re: K220607
Trade/Device Name: BD MAX Enteric Viral Panel
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay
Regulatory Class: Class II
Product Code: PCH, OOI
Dated: March 1, 2022
Received: March 2, 2022

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,

for

Noel Gerald
Branch Chief
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)*
K220607

Device Name
BD MAX™ Enteric Viral Panel

Indications for Use *(Describe)*
The BD MAX™ Enteric Viral Panel performed on the BD MAX System, is an automated in vitro diagnostic test for the direct qualitative detection and differentiation of enteric viral pathogens. The BD MAX™ Enteric Viral Panel detects nucleic acids from

- Norovirus GI & GII
- Rotavirus A
- Adenovirus F40/41
- Sapovirus (genogroups I, II, IV, V)
- Human Astrovirus (hAstro)

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/RNA. 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 Norovirus GI & GII, Rotavirus A, Adenovirus F40/41, Sapovirus (genogroups I, II, IV, V), and Astrovirus 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.

510(k) Summary

BD MAX™ Enteric Viral Panel

Summary Preparation Date:

03/01/2022

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 Viral Panel

Common Names:

For the instrument:
Bench-top molecular diagnostics workstation

For the assay:
Gastrointestinal viral panel multiplex nucleic acid-based assay system
Enteric viral panel
Enteric viral nucleic acid test
Enteric viral identification and differentiation system
Enteric assay
Enteric test

Regulatory Information

Regulation section:
21 CFR 866.3990 – Gastrointestinal microorganism multiplex nucleic acid-based assay

Classification:
Class II (Special Controls)

Panel:
Microbiology (83)

Product Code(s):
PCH – Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-Based Assay System
OOI – Real Time Nucleic Acid Amplification System

Predicate Device

BD MAX™ Enteric Viral Panel (K181427)

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

The BD MAX™ Enteric Viral Panel performed on the BD MAX™ System is an automated in vitro diagnostic test for the direct qualitative detection and differentiation of enteric viral pathogens. The BD MAX™ Enteric Viral Panel detects nucleic acids from

- Norovirus GI & GII
- Rotavirus A
- Adenovirus F40/41
- Sapovirus (genogroups I, II, IV, V)
- Human Astrovirus (hAstro)

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/RNA. The test utilizes fluorogenic gene-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 Norovirus GI & GII, Rotavirus A, Adenovirus F40/41, Sapovirus (genogroups I, II, IV, V) and hAstro 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 Viral Panel is performed on the BD MAX™ System

Device Description

The BD MAX™ Enteric Viral Panel assay 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, nucleic acid 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 nucleic acid 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 Viral 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 Viral Panel assay is designed for use with unpreserved or Cary-Blair preserved stool samples. Unpreserved samples are placed in a BD MAX sample buffer tube (SBT) using the provided 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 the provided 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. Last, before analysis on the BD MAX™ System, samples collected/stored with the FecalSwab™ system are vortexed and then pipetted (25 µl) into a BD MAX™ SBT.

Once specimens (Unpreserved, Cary-Blair, or FecalSwab Cary-Blair) are placed into a BD MAX™ SBT, the test principles are as described in K181427. For all specimen types the SBTs are vortexed and then loaded into the BD MAX™ System along with the Unitized Reagent Strips, Master Mixes, Extraction Tubes, and PCR Cartridges. No further operator intervention is necessary, and the following automated procedures occur. The target viruses are lysed, and nucleic acid 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/RNA 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/RNA 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 amplicons of the viral targets (Norovirus GI & GII, Rotavirus A, Adenovirus F40/41, Sapovirus [genogroups I, II, IV, V], and Astrovirus) and the Sample Processing Control amplicons in four 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 cDNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The BD MAX™ System monitors these signals at each cycle and interprets the data at the end of the program to report the final results. The assay includes a Sample Processing Control, which monitors the integrity of the reagents as well as the process steps involved in DNA/RNA extraction, amplification and detection, and checks for the presence of potential assay inhibitors.

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 of EVP to Predicate Device

Item	Predicate - BD MAX Enteric Viral Panel (K181427)	Proposed - BD MAX Enteric Viral Panel with Copan FecalSwab Collection, Preservation, and Transport System
Intended Use	The BD MAX™ Enteric Viral Panel performed on the BD MAX™ System is an automated in vitro diagnostic test for the direct qualitative detection and differentiation of enteric viral pathogens. The BD MAX™ Enteric Viral Panel detects nucleic acids from • Norovirus GI & GII • Rotavirus A • Adenovirus F40/41 • Sapovirus (genogroups I, II, IV, V) • Human Astrovirus (hAstro) 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/RNA. The test utilizes fluorogenic gene-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 Norovirus GI & GII, Rotavirus A, Adenovirus F40/41, Sapovirus (genogroups I, II, IV, V) and hAstro 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
Organisms Detected	• Norovirus GI & GII • Rotavirus A • Adenovirus F40/41 • Sapovirus (genogroups I, II, IV, V) • Human Astrovirus (hAstro)	Same
Specimen Type	Unpreserved stool or Cary-Blair preserved stool	Same

Item	Predicate - BD MAX Enteric Viral Panel (K181427)	Proposed - BD MAX Enteric Viral Panel with Copan FecalSwab Collection, Preservation, and Transport System
Assay Format	Amplification: PCR Detection: Fluorogenic target-specific hybridization	Same
Mode of Detection	Presence of • *RdRp and VP1 g*enes specific for Norovirus GI & GII • non-coding sequence after *nsp-3* gene specific for Rotavirus A • *hexon* gene specific for Adenovirus F40/41 • *RdRp* and *VP1* genes specific to Sapovirus (genogroups I, II, IV, V) • *RdRp* gene specific to Human Astrovirus (hAstro)	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
Preservation Buffer Formulation	• Cary-Blair: Sodium Chloride Calcium Chloride Phosphate Buffer Thioglycolic Acid Sodium Salt Phenol Red Agar Water • Unpreserved: Not Applicable	• Cary-Blair: Same • Unpreserved: Same • FecalSwab: Sodium Chloride Calcium Chloride Phosphate Buffer L-Cysteine Agar Water
Preservation Buffer Container	• Cary-Blair: Plastic Container w/Lid prefilled 15 ml of media. • Unpreserved: Not Applicable	• Cary-Blair: Same • Unpreserved: Same • FecalSwab: Plastic Container w/Lid prefilled 2 ml of media
Transfer Tool to Preservation Buffer	• Cary-Blair: Plastic Paddle • Unpreserved: Not Applicable	• Cary-Blair: Same • Unpreserved: Same • FecalSwab: Flocked Swab
Transport Method to SBT Tube	• Cary-Blair: 5 µL Transport Loop • Unpreserved: 5 µL Transport Loop	• Cary-Blair: Same • Unpreserved: Same • FecalSwab: 25 µL Pipette
Sterile	• Cary-Blair: Not Applicable • Unpreserved: Not Applicable	• Cary-Blair: Same • Unpreserved: Same • FecalSwab: Yes, Irradiation

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 Viral Panel assay:

- A study to confirm equivalent analytical sensitivity with the FecalSwab by the limiting dilution LoD model was performed. 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 organisms were added. A representative strain for each of the BD MAX™ Enteric Viral Panel targets was tested.

  For the BD MAX™ Enteric Viral Panel, quantified viral stocks were used for LoD serial dilution testing of Rotavirus A strain Va70, Adenovirus Type F41, and Astrovirus Type 4. Positive stools diluted to a working solution were used to generate the LoD dilutions for Norovirus GII and Sapovirus GI. Norovirus and Sapovirus are not culturable in their native state. The whole organism strains selected were based on availability in clinical specimens. One viral stock or positive stool was tested for each of the above viruses. Testing was performed with BD MAX EVP reagents, three lots of FecalSwab (four FecalSwab replicates per reagent lot, two SBTs per FecalSwab), and one lot of Cary-Blair preserved specimen medium. A five-fold serial dilution (titration), resulting in a total of five dilutions, was performed for each of the 5 assay targets and tested in both sample types (Cary-Blair and FecalSwab). Sample Buffer Tubes (SBT) were created by pipetting 25 µL from FecalSwab or looping 5 µL loop from Cary-Blair, totaling 24 SBTs each. The SBTs were tested on the BD MAX™ System.

  Limiting dilutions of specimens prepared using the FecalSwab specimen exhibited drop-out rates at similar analyte concentrations to the current Cary-Blair Specimen Collection specimen when tested using the BD MAX™ Enteric Viral Panel assay on the BD MAX™ System. All FecalSwab™ break points were within one five-fold concentration when compared to Para-Pak® (Table 2). There was no indication that the new FecalSwab specimen type negatively impacted the analytical sensitivity of the BD MAX™ Enteric Viral Panel.

Table 2: Number of Positive Samples for the BD MAX™ Enteric Viral Panel

Organism	Norovirus		Adenovirus		Rotavirus		Astrovirus		Sapovirus	
Collection Type	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®	FecalSwab™	Para-Pak®
Conc 1	23/24[a]	24/24	23/24[1]	24/24	23/24[1]	23/24[1]	24/24	24/24	24/24	22/23[a,b]
Conc 2	22/24	23/24	15/24	13/24	23/24	24/24	23/24	24/24	24/24	24/24
Conc 3	11/24	15/24	6/24	1/24	16/24	9/24	24/24	23/24	21/24	18/24
Conc 4	4/24	4/24	0/24	1/24	3/24	5/24	11/24	11/24	12/24	4/24
Conc 5	1/24	1/24	0/24	0/24	2/24	0/24	5/24	2/24	2/24	1/24

a Several of the targets did not exhibit 100% positivity at the highest target concentration tested (Norovirus (FecalSwab), Sapovirus (Cary-Blair), Adenovirus (FecalSwab), and Rotavirus (FecalSwab and Cary-Blair). No additional concentrations were tested because the break point identified for each target was lower than the highest concentration tested.

b One specimen received an Indeterminate (IND) assay result, and the sample was designated for repeat testing. After completion of the study, it was determined that the repeat test was performed using the incorrect SBT; therefore, this replicate was excluded from the data analysis, resulting in 23 valid replicates at this condition.

- 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 Viral Panel assay stability claims. For each organism tested across the BD MAX™ Enteric Viral Panel assay, 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 up to 120 hours (5 days) at 2 - 8 °C or for up to 48 hours at 2 - 25 °C, and sample buffer tube inoculated with FecalSwab specimen can be stored at 2 - 8 °C for a maximum of 120 hours (5 days) or at 2 - 25 °C for a maximum 48 hours (2 days).

- 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 Viral Panel.

  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™ Viral Panel. Six (6) different users prepared two (2) different FecalSwab™ specimens from each of the five (5) panel members: (one (1) negative panel member, three (3) low-positive panel members, and one (1) moderate-positive panel member). The targets were selected to represent each of the PCR Master Mix formulations of the BD MAX Enteric Viral Panel. Norovirus was included because it is the most prevalent target of those in its Master Mix; Astrovirus was selected to represent the second master mix targets because it is the only target in the master mix that can be cultured. 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.

  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 3).

Table 3: User Variability Study Results

Target	Panel Member	Acceptance Criteria	Assay Results	Overall Result
Norovirus	Low Positive	≥ 95% POS	100% POS	Pass
	Moderate Pos	100% POS	100% POS	
	Negative	100% NEG	100% NEG	
Astrovirus	Low Positive	≥ 95% POS	100% POS	
	Moderate Pos	100% POS	100% POS	
	Negative	100% NEG	100% NEG	

The data demonstrate that expected assay results are obtained when FecalSwab stool specimens were prepared by multiple users.

- The performance of the BD FecalSwab™ Collection, Transport and Preservation System when tested with the BD MAX™ Enteric Viral Panel was evaluated in a multicenter clinical study by comparing the results obtained for specimens using Cary-Blair Para-Pak® preserved stool samples to those using the 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 gastroenteritis, enteritis, or colitis from eight (8) geographically diverse clinical centers where specimens were collected as part of routine patient care. At these locations, a portion of the unpreserved stool samples were transferred into both Cary-Blair Para-Pak® collection vials and FecalSwab™ devices. Subsequently, the unpreserved stool sample, the inoculated Cary-Blair collection vial, and the inoculated FecalSwab™ device were shipped to a centralized testing laboratory and tested with the BD MAX™ Enteric Viral Panel. A total of 594 prospective specimens and 211 retrospective specimens were enrolled in the clinical evaluation. Three (3) prospective specimens were excluded from the data analysis due to specimen exclusion criteria. Table 4 describes the 802 (591 prospective and 211 retrospective) compliant specimens enrolled by patient age, sex, and specimen type. Ten (10) additional prospective samples were excluded from the data analysis due to Sample Buffer Tube or instrument level exclusion criteria. The final data analysis included 581 compliant prospective and 211 compliant retrospective subjects for Norovirus GI & GII, Rotavirus A, Adenovirus F40/41, Sapovirus (genogroups I, II, IV, V), and Human Astrovirus (hAstro) targets.

Table 4: 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 = 591	47.0 (22.7)	49.0	<1	95	Male: 44.8%
Unknown Age: 0					Female: 55.2%
Known Age: 591					Unknown: 0.0%
Retrospective Total N = 211	42.0 (24.4)	46.0	<1	88	Male: 41.2%
Unknown Age: 59					Female: 53.1%
Known Age: 152					Unknown: 5.7%
Overall Total N = 802	46.0 (23.1)	49.0	<1	95	Male: 43.9%
Unknown Age: 59					Female: 54.6%
Known Age: 743					Unknown: 1.5%

Positive percent agreement (PPA), negative percent agreement (NPA), and corresponding 95% confidence intervals for Norovirus, Rotavirus, Adenovirus, Sapovirus, and Astrovirus are calculated and presented in Table 5 through Table 9.

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Viral Panel identified 87.0% and 99.6% of the prospectively collected Norovirus positive and negative specimens, respectively, and 99.0% and 94.3% of the retrospectively collected Norovirus positive and negative specimens, respectively (refer to Table 5).

Table 5: Norovirus PPA and NPA of the BD MAX™ Enteric Viral Panel – FecalSwab™ Compared to Cary-Blair Preserved

Norovirus		**Cary-Blair**		**Total**
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	
Prospective	Positive	20	2	22
	Negative	3	554	557
	Total	23	556	579
PPA: 87.0% (67.9%, 95.5%) NPA: 99.6% (98.7%, 99.9%)				
Retrospective	Positive	104	6	110
	Negative	1	100	101
	Total	105	106	211
PPA: 99.0% (94.8%, 99.8%) NPA: 94.3% (88.2%, 97.4%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Viral Panel identified 100.0% and 100.0% of the prospectively collected Rotavirus positive and negative specimens, respectively, and 84.8% and 98.2% of the retrospectively collected Rotavirus positive and negative specimens, respectively (refer to Table 6).

Table 6: Rotavirus PPA and NPA of the BD MAX™ Enteric Viral Panel – FecalSwab™ Compared to Cary-Blair Preserved

Rotavirus		**Cary-Blair**		**Total**
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	
Prospective	Positive	3	0	3
	Negative	0	576	576
	Total	3	576	579
PPA: 100.0% (43.9%, 100.0%) NPA: 100.0% (99.3%, 100.0%)				
Retrospective	Positive	39	3	42
	Negative	7	162	169
	Total	46	165	211
PPA: 84.8% (71.8%, 92.4%) NPA: 98.2% (94.8%, 99.4%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Viral Panel identified 100.0% and 99.5% of the prospectively collected Adenovirus positive and negative specimens, respectively, and 100.0% and 99.0% of the retrospectively collected Adenovirus positive and negative specimens, respectively (refer to Table 7).

Table 7: Adenovirus PPA and NPA of the BD MAX™ Enteric Viral Panel – FecalSwab™ Compared to Cary-Blair Preserved

Adenovirus		**Cary-Blair**		**Total**
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	
Prospective	Positive	1	3	4
	Negative	0	575	575
	Total	1	578	579
PPA: 100.0% (20.7%, 100.0%) NPA: 99.5% (98.5%, 99.8%)				
Retrospective	Positive	9	2	11
	Negative	0	200	200
	Total	9	202	211
PPA: 100.0% (70.1%, 100.0%) NPA: 99.0% (96.5%, 99.7%)				

In addition, due to the small number of Adenovirus positive specimens in the study, contrived specimens were evaluated. The BD FecalSwab™ Collection, Transport and Preservation System on the BD MAX™ Enteric Viral Panel identified 100.0% of the Adenovirus contrived positive and negative specimens, when compared to expected results (refer to Table 8).

Table 8: Adenovirus Contrived FecalSwab™ Specimen Results

Adenovirus	**Expected Result**		
FecalSwab	**Positive**	**Negative**	**Total**
Positive	52	0	52
Negative	0	53	53
Total	52	53	105
PPA: 100.0% (93.1%, 100.0%) NPA: 100.0% (93.2%, 100.0%)			

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Viral Panel identified 50.0% and 99.3% of the prospectively collected Sapovirus positive and negative specimens, respectively, and 100.0% (refer to Table 9).

Table 9: Sapovirus PPA and NPA of the BD MAX™ Enteric Viral Panel – FecalSwab™ Compared to Cary-Blair Preserved

Sapovirus		**Cary-Blair**		**Total**
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	
Prospective	Positive	1	4	5
	Negative	1	574	575
	Total	2	578	580
PPA: 50.0% (9.5%, 90.5%) NPA: 99.3% (98.2%, 99.7%)				
Retrospective	Positive	22	4	26
	Negative	0	185	185
	Total	22	189	211
PPA: 100.0% (85.1%, 100.0%) NPA: 97.9% (94.7%, 99.2%)				

For the BD FecalSwab™ Collection, Transport and Preservation System, the BD MAX™ Enteric Viral Panel identified 100.0% and 99.3% of the prospectively collected Astrovirus positive and negative specimens, respectively, and 96.3% and 96.7% of the retrospectively collected Astrovirus positive and negative specimens, respectively (refer to Table 9).

Table 10: Astrovirus PPA and NPA of the BD MAX™ Enteric Viral Panel – FecalSwab™ Compared to Cary-Blair Preserved

Astrovirus		**Cary-Blair**		**Total**
Specimen Origin	**FecalSwab**	**Positive**	**Negative**	
Prospective	Positive	1	4	5
	Negative	0	575	575
	Total	1	579	580
PPA: 100.0% (20.7%, 100.0%) NPA: 99.3% (98.2%, 99.7%)				
Retrospective	Positive	26	6	32
	Negative	1	178	179
	Total	27	184	211
PPA: 96.3% (81.7%, 99.3%) NPA: 96.7% (93.1%, 98.5%)				