November 29, 2018

Becton, Dickinson and Company
Laura Stewart
Staff Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K181427
Trade/Device Name: BD MAX Enteric Viral Panel, BD MAX Instrument
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal microorganism multiplex nucleic acid-based assay
Regulatory Class: Class II
Product Code: PCH, OOI
Dated: May 30, 2018
Received: June 1, 2018

Dear Laura Stewart:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Steven R. Gitterman -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181427

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:

5/30/2018

Submitted by:

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152

Contact:
Laura Stewart
Staff Regulatory Affairs Specialist

Tel: 410-316-4435
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Email: laura.stewart@bd.com

Proprietary Names:
For the instrument:
BD MAX™ System
For the assay:
BD MAX™ Enteric Viral Panel (EVP)

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:
866.3990 – Gastrointestinal microorganism multiplex nucleic acid-based assay.

Classification:
Class II

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
BioFire Diagnostics FilmArray Gastrointestinal (GI) Panel [510(k) K143005]

Device Establishment
Becton, Dickinson and Company
BD Diagnostic Systems
7 Loveton Circle
Sparks, Maryland 21152
USA

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 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.

Special Conditions for Use Statement: For prescription use.

Special Instrument Requirements: BD MAX™ System

Device Description

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.

The BD MAX™ System and the BD MAX™ Enteric Viral Panel is run with the instrument with associated hardware and accessories, disposable microfluidic cartridges, master mixes, unitized reagent strips, extraction reagents, and sample buffer tubes. The instrument automates sample preparation including target lysis, DNA/RNA extraction and concentration, reagent rehydration, and 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/RNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances. The BD MAX™ System software automatically interprets test results. A test result may be called as POS (Positive), NEG (Negative), or UNR (Unresolved) for each of the assay's targets, based on the amplification status of the target and of the Sample Processing Control. IND (Indeterminate) or INC (Incomplete) results are due to BD MAX™ System failure.

Test Principle

Stool specimens are collected from subjects and transported to the laboratory unpreserved in a clean container or preserved in Cary-Blair transport media. A loop is inserted to the depth of the loop into the specimen and expressed via swirling motion into a BD MAX™ Sample Buffer Tube included in the BD MAX™ Enteric Viral Panel kit. The Sample Buffer Tube is closed with a septum cap, vortexed and transferred to the BD MAX™ System. Once the work list is generated and the specimen is loaded on the BD MAX™ instrument, along with a BD MAX™ Enteric Viral Panel Unitized Reagent Strip and PCR Cartridge, the run is started and no further operator intervention is required. The BD MAX™ System

automates specimen preparation, including target organism lysis, DNA/RNA extraction and concentration, reagent rehydration, target nucleic acid sequence amplification and detection using real-time PCR. The interpretation of the signal is performed automatically by the BD MAX™ System. The assay also includes a Sample Processing Control that is provided in the Extraction Tube and subjected to extraction, concentration and amplification steps. The Sample Processing Control monitors for the presence of potential inhibitory substances as well as system or reagent failures. Following enzymatic viral lysis at elevated temperature, the released nucleic acids are captured by magnetic affinity beads.

The beads, with the bound nucleic acids, are washed and the nucleic acids are eluted. Eluted DNA/RNA is neutralized and transferred to the Master Mix tubes to rehydrate the PCR reagents. After rehydration, the BD MAX™ System dispenses a fixed volume of PCR-ready solution into the BD MAX™ PCR Cartridge. Microvalves in the BD MAX™ PCR Cartridge are sealed by the system to prevent evaporation and amplicon contamination prior to the initiation of reverse transcriptase PCR to convert RNA to cDNA and subsequent real time PCR.

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 amplicons of the viral targets (Norovirus GI & GII, Rotavirus A, Adenovirus F40/41, Sapovirus (genogroups I, II, IV, V), and hAstro) 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.

Substantial Equivalence[1]

Table 1 shows the similarities and **Table 2** shows the differences between the BD MAX™ Enteric Viral Panel and the 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: Similarities Comparison to Predicate Device

Similarities		
Item	*BD MAX™ Enteric Viral Panel (EVP)*	*FilmArray GI Panel (K143005)*
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 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.	The FilmArray Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based in vitro diagnostic test intended for use with FilmArray systems. The FilmArray GI Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary Blair transport media obtained from individuals with signs and/or symptoms of gastrointestinal infection. The following bacteria (including several diarrheagenic *E. coli/Shigella* pathotypes), parasites, and viruses are identified using the FilmArray GI Panel: • *Campylobacter (C. jejuni/C. coli/C. upsaliensis)* • *Clostridium difficile (C. difficile)* toxin A/B • *Plesiomonas shigelloides* • *Salmonella* • *Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae)*, including specific identification of *Vibrio cholerae* • *Yersinia enterocolitica* • Enteroaggregative *Escherichia coli* (EAEC) • Enteropathogenic *Escherichia coli* (EPEC) • Enterotoxigenic *Escherichia coli* (ETEC) *lt/st* • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2* (including specific identification of the *E. coli* O157 serogroup within STEC) • *Shigella*/Enteroinvasive *Escherichia coli* (EIEC) • *Cryptosporidium* • *Cyclospora cayetanensis* • *Entamoeba histolytica* • *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*) • Adenovirus F 40/41 • Astrovirus • Norovirus GI/GII • Rotavirus A • Sapovirus (Genogroups I, II, IV, and V) The FilmArray GI Panel is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule out co-infection with organisms not included in the FilmArray GI Panel. The agent detected may not be the definite cause of the disease. Concomitant culture is necessary for organism recovery and further typing of bacterial agents. This device is not intended to monitor or guide treatment for *C. difficile* infection. Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for *E. coli* O157, *Plesiomonas shigelloides, Yersinia enterocolitica*, Astrovirus, and

Similarities		
Item	*BD MAX™ Enteric Viral Panel (EVP)*	*FilmArray GI Panel (K143005)*
		Rotavirus A were established primarily with retrospective clinical specimens. Performance characteristics for *Entamoeba histolytica*, and *Vibrio (V. parahaemolyticus, V. vulnificus*, and *Vibrio cholerae)* were established primarily using contrived clinical specimens. Negative FilmArray GI Panel 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. A gastrointestinal microorganism multiplex nucleic acid-based assay also aids in the detection and identification of acute gastroenteritis in the context of outbreaks.
Specimen Type	Cary-Blair preserved stool Unpreserved soft to diarrheal stool	Cary-Blair preserved stool. Not claimed (see Differences below)
Assay Format	Amplification: PCR Detection: fluorogenic target-specific hybridization.	Amplification: PCR Detection: non target-specific fluorescent dye
Organisms Detected	• Norovirus GI & GII • Rotavirus A • Adenovirus F40/41 • Sapovirus (genogroups I, II, IV, V) • Human Astrovirus (hAstro)	• Norovirus GI/GII • Rotavirus A • Adenovirus F 40/41 • Sapovirus (Genogroups I, II, IV, V) • Astrovirus
Interpretation of Test Results	Automated: BD MAX™ System diagnostic software	Automated
Analysis Platform	BD MAX™ System	Film Array Instrument
PCR Sample preparation	Automated: BD MAX™ System	Automated: Film Array Instrument
Detection Probes	TaqMan® Probe	Fluorescent double stranded DNA binding dye (LC Green Plus)
Assay Controls	Sample Processing Control (SPC)	Two controls are included in each reagent pouch to control for sample processing and both stages of PCR and melt analysis.

Table 2: Differences Comparison to Predicate Device

Differences		
Item	*BD MAX™ Enteric Viral Panel (EVP)*	*FilmArray GI Panel*
Specimen Type	Unpreserved soft to diarrheal stool	Not claimed
Organisms Detected	Listed in device Similarities above.	Other organisms detected: • *Campylobacter (C. jejuni/C. coli/C. upsaliensis)* • *Clostridium difficile (C. difficile)* toxin A/B • *Plesiomonas shigelloides* • *Salmonella* • *Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae)*, including specific identification of *Vibrio cholerae* • *Yersinia enterocolitica* • Enteroaggregative *Escherichia coli* (EAEC) • Enteropathogenic *Escherichia coli* (EPEC) • Enterotoxigenic *Escherichia coli* (ETEC) *lt/st* • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2* (including specific identification of the *E. coli* O157 serogroup within STEC) • *Shigella*/Enteroinvasive *Escherichia coli* (EIEC) • *Cryptosporidium* • *Cyclospora cayetanensis* • *Entamoeba histolytica* • *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*)

Analytical Performance

Precision

Within-laboratory precision was evaluated for the BD MAX™ Enteric Viral Panel at one (1) internal site. Testing was performed over 12 days, with two (2) runs per day (one each by 2 operators), for a total of 24 runs. The Precision panel members were divided into four (4) concentration categories, based upon organism concentration relative to the LoDs established for each of the assay targets and expected correct percent positive/negative. The panel members contained Norovirus, Rotavirus, Adenovirus, Sapovirus and Astrovirus. The following values were used as spike levels for the target organisms contained in each panel member:

Moderate Positive (MP): ≥2 to ≤3x LoD; 100% agreement with expected results (within CI_{95})

Low Positive (LP): ≥1 to <2x LoD; ≥95% agreement with expected results (within CI_{95})

True Negative (TN): No target; 100% agreement with expected results (within CI_{95})

Each panel member was spiked with negative unpreserved stool matrix. True negative samples contained no target. Results are summarized by target and concentration in **Table 3.**

Table 3: Precision Study Result Using One Lot of BD MAX Enteric Viral Panel

Category	***Agreement with Expected Results***				
	Norovirus *(95% CI)*	***Rotavirus*** *(95% CI)*	***Adenovirus*** *(95% CI)*	***Sapovirus*** *(95% CI)*	***Astrovirus*** *(95% CI)*
TN[a]	100% 192/192 (98.0-100)	99.5% 191/192 (97.1-99.9)	100% 192/192 (98.0-100)	100% 192/192 (98.0-100)	100% 192/192 (98.0-100)
LP	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)
MP	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)	100% 48/48 (92.6-100)

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

Reproducibility

The Site-to-Site reproducibility study was performed at three (3) clinical sites using one (1) reagent lot. Two (2) operators performed a run per day, over five (5) distinct days (consecutive or not), for a total of 30 runs. The panels used were the same as described under the Precision heading, above.

The overall site-to-site reproducibility percent agreement was 100% for the TN category for all targets, and ranged from 97.8 to 100% and 96.7 to 100% for the LP and MP categories, respectively. Results are summarized in **Table 4**. The quantitative reproducibility results across sites by target are presented in **Table 5**. Ct. Score is an internal criterion used to determine final assay results and was selected as a means of assessing quantitative assay reproducibility. Mean Ct. Score and the mean Cycle EP values with variance components (SD and % CV) are shown in **Table 5**.

Table 4: Site-to-Site Reproducibility Results Using One Lot of BD MAX Enteric Viral Panel

Category	***Agreement with Expected Results***				
	Norovirus (95% CI)	***Rotavirus (95% CI)***	***Adenovirus (95% CI)***	***Sapovirus (95% CI)***	***Astrovirus (95% CI)***
TN[a]	100 360/360 (98.9, 100)	100 360/360 (98.9, 100)	100 360/360 (98.9, 100)	100 360/360 (98.9, 100)	100 360/360 (98.9, 100)
LP	100 90/90 (95.9, 100)	97.8 88/90 (92.3, 99.4)	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	98.9 89/90 (94.0, 99.8)
MP	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	96.7 87/90 (90.7, 98.9)	100 90/90 (95.9, 100)

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

Table 5: Quantitative Site-to-Site Reproducibility Results for BD MAX Enteric Viral Panel

PCR Metric	***Parameter***	***Norovirus***		***Rotavirus***		***Adenovirus***		***Sapovirus***		***Astrovirus***		***SPC for MM1 (D6)***	***SPC for MM2 (D5)***
		LP	***MP***	***LP***	***MP***	***LP***	***MP***	***LP***	***MP***	***LP***	***MP***	***TN***	***TN***
Ct. Score	N	90	90	88	90	90	90	90	87	89	90	90	90
	Mean	29.8	29.6	32.3	31.3	28.5	28.6	29.1	28.6	28.9	27.7	26.8	27.5
	SD	0.41	0.43	0.66	0.52	0.65	0.62	0.44	0.50	0.45	0.32	0.27	0.37
	%CV	1.4	1.4	2.0	1.7	2.3	2.2	1.5	1.7	1.6	1.2	1.0	1.3
Cycle EP	N	90	90	88	90	90	90	90	87	89	90	90	90
	Mean	4553.4	4129.3	737.5	925.2	1067.0	1097.1	754.2	962.5	3165.7	4785.5	8581.7	7667.9
	SD	1269.47	1769.10	359.91	382.36	564.59	498.22	305.02	315.07	1163.93	1266.39	1161.23	1948.77
	%CV	27.9	42.8	48.8	41.3	52.9	45.4	40.4	32.7	36.8	26.5	13.5	25.4

Lot-to-lot reproducibility study was performed at one (1) site using three (3) reagent lots. Two (2) operators performed two (2) runs per day, over five (5) distinct days (consecutive or not), for a total of 30 runs. The panels used were the same as described under the Precision heading, above. Results from 5 days of the accuracy and precision study were used to comprise data for one lot of reagents for the Lot-to-Lot study.

The overall Lot-to-lot reproducibility percent agreements were 99.7 to 100% for TN, and ranged from 97.8 to 100% and 98.9 to 100% and 100% for the LP and MP, respectively. Results are summarized in **Table 6**. The quantitative results across lots and by target are presented in **Table 7**. Ct.Score and the

Cycle EP, an internal criteria used to determine a final assay result, was selected as a means of assessing quantitative assay reproducibility. Mean Ct.Score and the mean Cycle EP values with variance components (SD and % CV) are shown in **Table 7**.

Table 6: Lot-to-lot Reproducibility Results for BD MAX Enteric Viral Panel

Category	***Agreement with Expected Results***				
	Norovirus (95% CI)	***Rotavirus (95% CI)***	***Adenovirus (95% CI)***	***Sapovirus (95% CI)***	***Astrovirus (95% CI)***
TN[a]	100 360/360 (98.9, 100)	99.7 359/360 (98.4, 100)	100 360/360 (98.9, 100)	100 360/360 (98.9, 100)	100 360/360 (98.9, 100)
LP	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	98.9 89/90 (94.0, 99.8)	100 90/90 (95.9, 100)
MP	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)	100 90/90 (95.9, 100)

[a] For the True Negative (TN) category, the reported agreement indicates the percent of negative results.

Table 7: Quantitative Lot-to-lot Reproducibility Results for BD MAX Enteric Viral Panel

PCR Metric	***Parameter***	***Norovirus***		***Rotavirus***		***Adenovirus***		***Sapovirus***		***Astrovirus***		***SPC for MM1 (D6)***	***SPC for MM2 (D5)***
		LP	***MP***	***LP***	***MP***	***LP***	***MP***	***LP***	***MP***	***LP***	***MP***	***TN***	***TN***
Ct. Score	N	90	90	90	90	90	90	89	90	90	90	90	90
	Mean	29.7	29.5	32.0	31.1	28.4	28.6	28.8	28.5	28.9	27.6	26.8	27.3
	SD	0.41	0.35	0.46	0.35	0.54	0.53	0.36	0.74	0.42	0.33	0.39	0.45
	%CV	1.4	1.2	1.5	1.1	1.9	1.9	1.3	2.6	1.5	1.2	1.5	1.7
Cycle EP	N	90	90	90	90	90	90	89	90	90	90	90	90
	Mean	4945.6	4948.5	1117.1	1345.6	1191.2	1171.3	1184.0	1310.7	3277.9	4724.1	8993.5	8739.9
	SD	2117.85	2255.71	267.15	220.59	709.80	743.55	383.17	406.34	931.80	937.73	966.88	1564.86
	%CV	42.8	45.6	23.9	16.4	59.6	63.5	32.4	31.0	28.4	19.8	10.8	17.9

Storage and Stability

- Collected specimens, either unpreserved stool or stool stored in 15 mL Cary-Blair transport media, should be kept between 2 °C and 25 °C during transport. Protect against exposure to excessive heat.
- Specimens can be stored for up to 120 hours (5 days) at 2–8 °C or for up to 48 hours at 2–25 °C before testing.
- BD MAX™ Enteric Viral Panel components are stable at 2–25 °C through the stated expiration date. Do not use expired components.
- BD MAX™ Enteric Viral Master Mix and Extraction Tubes are provided in sealed pouches. To protect product from humidity, immediately re-seal after opening. Master Mix tubes are stable for up to 14 days at 2–25 °C after initial opening and re-sealing of the pouch.

Controls

External Control materials are not provided by BD. External Positive and Negative Controls are not used by the BD MAX™ System software for the purpose of sample test result interpretation. External Controls are treated as if they were patient samples. However, Quality Control strains and procedures are included in the package insert. Various types of External Controls are recommended to allow the user to select the most appropriate for their laboratory quality control program:

a. External Negative Control: Commercially available control material or a previously characterized sample known to be negative. BD recommends that the External negative Control be prepared prior to the External Positive Control in order to reduce the potential for contamination as a result of control preparation.
b. External Positive Control: Commercially available control materials, such as the ZeptoMetrix® strains listed below, or previously characterized samples known to be positive:

External Positive Control Strain	***Part Number***
Recombinant Norovirus GI or GII	ZeptoMetrix 0810086CF or 0810087CF
Rotavirus A	ZeptoMetrix 0810041CF or 0810281CF
Adenovirus F40 or F41	ZeptoMetrix 0810084CF or 810085CF
Human Astrovirus Type 4 or Type 8	ZeptoMetrix 0810276CF or 0810277CF

The assay includes a Specimen Processing Control (SPC) that is present in the Extraction Tube. The Sample Processing Control monitors the efficiency of DNA capture, washing and elution during the sample processing steps, as well as the efficiency of DNA target amplification and detection during PCR analysis.

Analytical Sensitivity

The analytical sensitivity (Limit of Detection or LoD) for the BD MAX™ Enteric Viral Panel was determined as follows: Each target organism was prepared and quantified prior to inclusion in this study. Individual inoculating loops were dipped into each organism preparation and were then transferred to a Sample Buffer Tube already containing fecal matrix (preserved or unpreserved) that was pre-determined to be negative for all the targets detected by the BD MAX™ Enteric Viral Panel. Each organism was tested with a minimum of twenty (20) replicates per sample type (preserved or unpreserved), by two (2) operators, using three (3) different production lots of the BD MAX™ Enteric Viral Panel. The LoD for a specific organism was confirmed by testing at least twenty (20) additional replicates at the determined LoD concentration. Analytical sensitivity (LoD), defined as the lowest concentration at which greater than or equal to 95% of all replicates are expected to test positive (refer to **Table 8**).

Table 8: BD MAX™ Enteric Viral Panel Limit of Detection for Individual Targets

Target Organism	*Strain*	*Unpreserved LoD (cp/mL in stool)*	*Cary-Blair Preserved LoD (cp/mL in stool)*
Norovirus	GI	6.28E+06	4.71E+06
	GII	2.49E+05	2.49E+05
Rotavirus	WA	6.46E+03	1.29E+04
	Va70	1.16E+04	5.82E+03
Adenovirus	F40	6.89E+04	2.75E+05
	F41	8.16E+04	1.22E+05
human Astrovirus	Type 4	1.75E+07	3.49E+07
	Type 8	5.23E+06	2.09E+07
Sapovirus	GI	6.51E+07	6.51E+07
	GII	1.94E+06	1.94E+06

Analytical Inclusivity

A variety of BD MAX Enteric Viral Panel assay target strains were included in this study. Strain selection criteria included prevalence, serotype and geographic location, where appropriate. Fifty-eight (58) strains were tested, including strains from public collections and well-characterized clinical isolates.

Inclusivity testing included ten (10) strains of Adenovirus F40/F41, ten (10) strains of Astrovirus, 22 strains of Norovirus GI & GII, five (5) strains of Rotavirus, and eleven (11) strains of Sapovirus. The strains were tested at ≥ 3 x LoD (Limit of Detection) of the corresponding strain in unpreserved stool matrix. The BD MAX Enteric Viral Panel correctly identified all 58 strains tested upon initial testing. Sapovirus GI clinical strains BA0145AP and BA0141AP, as well as Rotavirus strain WISC2 VR-2517, required testing above 3x LoD. Sapovirus GI clinical strain BA0145AP resolved at 6x LoD. Sapovirus GI clinical strain BA0141AP and Rotavirus strain WISC2 VR-2517 resolved at 20x LoD. *In silico* analysis predicts that most strains of all genotypes will be detected, though some variant strains may be detected with reduced sensitivity or may not be detected due to inefficient amplification or exclusion by melt analysis. For Norovirus *in silico* analysis, three (3) sequences showed more than one mismatch, two GI.3 variants and one GI.7 variant. Some Norovirus sequences showed more than two mismatches, one GII.3 variant, one GII.4 variant, one GII.6 variant and one GII.12 variant. These mutations could affect the detection of these variants. For Rotavirus A *in silico* analysis, there were five (5) variants that had more than three (3) mismatches. There were ten (10) Rotavirus A sequences that were truncated by four (4) nucleotides. These mutations could affect the detection of these variants. For Sapovirus GI *in silico* analysis, one GI.2 variant showed more than one mismatch, this mutation could affect the detection of this variant. One Sapovirus GV sequence showed two mismatches, these mutations could affect the detection of this variant.

Noroviruses are genetically diverse. *In silico* analysis predicts that most strains, including NoV GI.3, GII.P16_GII.4, GII.P16_GII.2, and GII.Pe_GII.2, may be detected (refer to **Table 9**). Some variant strains may be detected with reduced sensitivity, or may not be detected due to inefficient amplification.

Table 9: Analytical Inclusivity Strains Tested

Virus	Type	Strains Tested
Adenovirus	F40	10
	F41	
Astrovirus	1	1
	2	1
	3	1
	4	2
	5	1
	6	1
	7	1
	8	1
	Unknown	1
Norovirus GI	3	0[a]
	4	1
	6	1
Norovirus GII	1	2
	2	1
	3	2
	4	8
	6	3
	12	2
	17	1
	P16-GII.2	0[a]
	P16-GII.4	0[a]
	Pe_GII.2	0[a]
	Unknown	1
Rotavirus	A	5
Sapovirus	GI	6
	GII	1
	GIV	3
	GV	1

[a] Genotypes with unavailable strains were evaluated with *in silico* binding analysis.

Analytical Specificity

The BD MAX™ Enteric Viral Panel was performed on samples containing phylogenetically related species and other organisms (bacteria, viruses, parasites and yeast) likely to be found in stool specimens. The bacterial cells, yeasts, parasites and viruses were tested in the Sample Buffer Tube at $\geq 10^6$ CFU, cells or genome equivalents/mL in stool, or $\geq 10^5$ PFU/mL in stool or $TCID_{50}$/mL in stool. Overall, 112 organisms were tested.

- Most of bacterial strains, yeast, parasites and viruses tested produced negative results with the BD MAX™ Enteric Viral Panel.
- Adenovirus Type 1 associated with human disease, produced positive results with the BD MAX™ Enteric Viral Panel. However, no positive result was recorded at $\leq 1.0 \times 10^{4.8}$ $TCID_{50}$ units/mL in stool with this strain.

Interfering Substances

Thirty-two (32) biological and chemical substances that may occasionally be present in stool specimens were evaluated for potential interference with the BD MAX™ Enteric Viral Panel. Included in this study was an Antibiotics Mixture, which consisted of a combination of seven (7) different antibiotics or analgesics tested simultaneously. These antibiotics or analgesics included Naproxen sodium, Ceftriaxone disodium, Erythromycin, Metronidazole, Sulfamethoxazole, Tetracycline hydrochloride, and Trimethoprim. Hydrocortisone cream was found to interfere at levels above 25% volume/volume. RotaTeq vaccine was also yielded positive results as expected because the vaccine can be present in the stool up to nine (9) days post vaccination (Yen et al., 2011). Results demonstrated no reportable interference with any other substance tested (refer to **Table 10**).

In addition, microorganisms that may be endogenously present in stool specimens were evaluated for potential interference with the BD MAX™ Enteric Viral Panel. Five (5) organisms were tested at high concentration (1 x10^6 cells/mL of stool). Results demonstrated no reportable interference with any microorganism tested (refer to **Table 11**).

Table 10: Endogenous and Commercial Exogenous Substances tested with the BD MAX Enteric Viral Panel

Brand Name or Description	***Result***	***Brand Name or Description***	***Result***
Fecal Fat	NI	Spermicial Lubricant	NI
Mucus	NI	Suppository (Glycerin)	NI
Whole Human Blood	NI	Vagisil	NI
Hydrocortisone Cream	I	Laxatives	NI
Antiseptic Towelettes	NI	Anti-Diarrheal (liquid)	NI
Enema; Mineral Oil	NI	Anti-Diarrheal (pill)	NI
Hemorrhoidal Gel	NI	Antibiotics Mixture	NI
Nystatin Cream	NI	Antacids	NI
Topical Antibiotic	NI	Non-Steroidal Anti-Inflamatory (NSAID)	NI

I: Reportable Interference with the BD MAX™ Enteric Viral Panel at high concentrations.
NI: No reportable interference with the BD MAX™ Enteric Viral Panel.

Table 11: Microorganisms Tested for Interference with the BD MAX Enteric Viral Panel

Microorganism	**Result**
Salmonella typhimurium	NI
Escherichia coli	NI
Proteus vulgaris	NI
Enterococcus faecalis	NI
Peptostreptococcus anaerobius	NI

NI: No reportable interference with the BD MAX™ Enteric Viral Panel.

Carryover/Cross-Contamination

A study was conducted to investigate within-run carryover and between-run carryover while processing samples with high viral load of analytes in the BD MAX™ Enteric Viral Panel. A panel made of one (1) high positive member from each Master Mix containing one (1) target organism and one (1) negative member was used to prepare numerous samples. Adenovirus for Master Mix D6 and human Astrovirus for Master Mix D5 were used to represent the high positive panel member for each Master Mix. The negative member did not contain any target analyte. Twelve (12) replicates of the high positive panel member and twelve (12) replicates of the negative panel member were tested in each run by alternating negative and positive samples. Two (2) operators performed three (3) consecutive runs across three (3) BD MAX instruments for a total of nine (9) runs containing 24 samples. Of the 108 negative samples tested in this study, two (2) samples produced a positive result.

Mixed Infection/Competitive Interference

The mixed infection/competitive interference study was designed to evaluate the ability of the BD MAX™ Enteric Viral Panel to detect low positive results in the presence of other targets at high concentrations. A mix of two (2) out of three (3) organisms (Norovirus, Rotavirus, Adenovirus) for Master Mix D6 or a mix of one (1) out of two (2) organisms (Sapovirus, human Astrovirus) for Master Mix D5 were prepared at the 95th percentile observed in the clinical trial to simulate a high clinical load to serve as high targets in the BD MAX™ Enteric Viral Panel Sample Buffer Tube. The BD MAX™ Enteric Viral Panel analyte absent from the high targets mix was spiked into the Sample Buffer Tube at a concentration 2x their respective LoD representing a low load target along with 5 µL of unpreserved stool and tested to simulate mixed infections. In the presence of high loads, all organisms corresponding to their respective simulated mixed infection preparations were successfully detected by the BD MAX Enteric Viral Panel.

Freeze/Thaw Study

This study was designed to evaluate multiple freeze/thaw cycles at varied LoD levels (1.99x, 4x and 10x). Based on the study results, three (3) freeze/thaw cycles do not affect the performance of BD MAX Enteric Viral Panel. The BD MAX Enteric Viral Panel was able to detect 100% proportion positive for all enteric viral targets spiked in preserved and unpreserved, negative, clinical stool specimens before and after undergoing multiple freeze/thaw cycles.

Table 12: Summary of Freeze/Thaw Study Results

Condition		***Target Positive Matrix Proportion Positive (%) and total number of samples tested (across all LoD levels)***				
Matrix	*Freeze/Thaw Cycles*	*Norovirus GII*	*Rotavirus Va70*	*Adenovirus F41*	*Astrovirus Type 4*	*Sapovirus GI*
Unpreserved	0 (fresh/baseline)	100 60/60[a]	100 60/60[a]	100 60/60[a]	100 60/60	100 60/60
	1	100 60/60	100 60/60	100 60/60	100 60/60	100 60/60
	2	100 60/60	100 60/60	100 60/60	100 60/60	100 60/60
	3	100 60/60	100 60/60	100 60/60	100 60/60	100 60/60
Preserved	0 (fresh/baseline)	100 60/60	100 60/60	100 60/60	100 60/60[a]	100 60/60[a]
	1	100 60/60[a]	100 60/60[a]	100 60/60[a]	100 60/60[a]	100 60/60[a]
	2	100 60/60[a]	100 60/60[a]	100 60/60[a]	100 60/60[a]	100 60/60[a]
	3	100 60/60[a]	100 60/60[a]	100 60/60[a]	100 60/60[a]	100 60/60[a]

[a] Proportion positive rates were calculated based on total sample number after removal of IND/UNR results, which were excluded from the analysis.

Clinical Performance Studies

Clinical Performance characteristics of the BD MAX Enteric Viral Panel were determined in a multi-site investigational study. The study involved a total of six (6) geographically diverse clinical centers where stool specimens were collected as part of routine patient care, enrolled into the trial, and tested with the BD MAX Enteric Viral Panel. Specimens were obtained from pediatric or adult patients suspected of acute gastroenteritis, enteritis or colitis, for whom diagnostic procedures were indicated and/or ordered by a healthcare provider. The reference method for the prospective specimens was a combination of two (2) sets of alternate PCRs and bi-directional sequencing for one (1) PCR. All prospective specimens were tested fresh (stored 2-8°C and within 5 days of collection) with the BD MAX Enteric Viral Panel Assay, but frozen prior to testing with the reference method. For retrospective specimens, the historical results were recorded at the collection site. All retrospective specimens were frozen prior to testing on the BD MAX Enteric Viral Panel Assay and the reference method. The historical results were confirmed using an alternate PCR assay and bi-directional sequencing in order to confirm the presence of the target DNA.

A total of 1873 prospective specimens (1055 Cary-Blair preserved and 818 unpreserved) and 366 retrospective specimens (136 Cary-Blair preserved and 230 unpreserved) were enrolled in the clinical evaluation for a total of 2239 specimens enrolled. **Table 13** describes the number of compliant specimens enrolled by patient age and specimen type with a total of 2148 compliant specimens overall. **Table 14** through **Table 19** describe the performance characteristics of the BD MAX Enteric Viral Panel that were observed during the clinical trial.

Table 13: Compliant Clinical Trial Enrollment Summary by Age Group and Specimen Type

Age Group	***Cary-Blair Preserved***	***Unpreserved***	***Combined***
0-1 month	4	0	4
1 month to 2 years	188	112	300
2-12	228	153	381
13-18	117	66	183
19-21	20	21	41
Over 21	568	640	1208
Unknown	21	10	31
Total	1146	1002	2148

Norovirus Performance Results

For the Cary-Blair preserved specimen type, the BD MAX Enteric Viral Panel identified 92.5% and 99.2% of the Norovirus prospective positive and negative specimens, respectively, and 100% and 99.1% of the retrospective positive and negative specimens, respectively. For the unpreserved specimen type, the BD MAX Enteric Viral Panel identified 90.7% and 99.6% of the Norovirus prospective positive and negative specimens, respectively and 94.6% and 100% of the Norovirus retrospective positive and negative specimens, respectively. Refer to **Table 14**.

Table 14: Norovirus- Performance Results per Specimen Type and Origin

Specimen Type	Specimen Origin	BD MAX	RM		Total
			P	N	
Cary-Blair Preserved	Prospective (Fresh)	**P**	74	7[a]	*81*
		N	6[b]	835	*841*
		Total	*80*	*842*	*922*
PPA (95% CI): 92.5% (84.6%, 96.5%) NPA (95% CI): 99.2% (98.3%, 99.6%)					
Cary-Blair Preserved	Retrospective (Frozen)	**P**	6	1	*7*
		N	0	105	*105*
		Total	*6*	*106*	*112*
PPA (95% CI): 100% (61%, 100%) NPA (95% CI): 99.1% (94.8%, 99.8%)					
Unpreserved	Prospective (Fresh)	**P**	39	3	*42*
		N	4	694	*698*
		Total	*43*	*697*	*740*
PPA (95% CI): 90.7% (78.4%, 96.3%) NPA (95% CI): 99.6% (98.7%, 99.9%)					
Unpreserved	Retrospective (Frozen)	**P**	35	0	*35*
		N	2	58	*60*
		Total	*37*	*58*	*95*
PPA (95% CI): 94.6% (82.3%, 98.5%) NPA (95% CI): 100% (93.8%, 100%)					

[a] 7/7 Specimens were available to be tested in discrepant analysis and 4/7 tested positive for Norovirus with the FilmArray™ Gastrointestinal Panel.

[b] 6/6 Specimens tested negative for Norovirus during discrepant analysis with the FilmArray™ Gastrointestinal Panel.

Rotavirus Performance Results

For the Cary-Blair preserved specimen type, the BD MAX Enteric Viral Panel identified 100% and 99.2% of the Rotavirus prospective positive and negative specimens, respectively, and 100% and 98.7% of the Rotavirus retrospective positive and negative specimens, respectively. For the unpreserved specimen type, the BD MAX Enteric Viral Panel identified 100% and 99.9% of the Rotavirus prospective positive and negative specimens, respectively and 100% and 97.9% of the Rotavirus retrospective positive and negative specimens, respectively. Refer to **Table 15**.

Table 15: Rotavirus- Performance Results per Specimen Type and Origin

Specimen Type	Specimen Origin	BD MAX	RM		Total
			P	N	
Cary-Blair Preserved	Prospective (Fresh)	**P**	31	7[a]	*38*
		N	0	888	*888*
		Total	*31*	*895*	*926*
PPA (95% CI): 100% (89%, 100%) NPA (95% CI): 99.2% (98.4%, 99.6%)					
Cary-Blair Preserved	Retrospective (Frozen)	**P**	38	1	*39*
		N	0	76	*76*
		Total	*38*	*77*	*115*
PPA (95% CI): 100% (90.8%, 100%) NPA (95% CI): 98.7% (93%, 99.8%)					
Unpreserved	Prospective (Fresh)	**P**	11	1	*12*
		N	0	735	*735*
		Total	*11*	*736*	*747*
PPA (95% CI): 100% (74.1%, 100%) NPA (95% CI): 99.9% (99.2%, 100%)					
Unpreserved	Retrospective (Frozen)	**P**	56	1	*57*
		N	0	47	*47*
		Total	*56*	*48*	*104*
PPA (95% CI): 100% (93.6%, 100%) NPA (95% CI): 97.9% (89.1%, 99.6%)					

[a] 7/7 Specimens were available to be tested in discrepant analysis and 4/7 tested positive for Rotavirus with the FilmArray™ Gastrointestinal Panel.

Adenovirus Performance Results

For the Cary-Blair preserved specimen type, the BD MAX Enteric Viral Panel identified 93.8% and 100% of the Adenovirus prospective positive and negative specimens, respectively, and 100% and 100% of the Adenovirus retrospective positive and negative specimens, respectively. For the unpreserved specimen type, the BD MAX Enteric Viral Panel identified 80.0% and 99.9% of the Adenovirus prospective positive and negative specimens, respectively, and 100% and 100% of the Adenovirus retrospective positive and negative specimens, respectively. Refer to **Table 16**.

As Adenovirus prevalence is low, an evaluation of contrived specimens for the unpreserved specimen type was performed to supplement data collected in the study. These were prepared by spiking two (2) different strains for each species of Adenovirus detected by the BD MAX Enteric Viral Panel in negative stool matrix. Strains were spiked at various clinically relevant loads and randomly distributed

among two (2) clinical sites for BD MAX Enteric Viral Panel testing. A positive agreement of 100% was obtained across the tested loads. Results are shown in **Table 17**.

Table 16: Adenovirus- Performance Results per Specimen Type and Origin

Specimen Type	Specimen Origin	BD MAX	RM		Total
			P	N	
Cary-Blair Preserved	Prospective (Fresh)	**P**	15	0	*15*
		N	1	914	*915*
		Total	*16*	*914*	*930*
PPA (95% CI): 93.8% (71.7%, 98.9%) NPA (95% CI): 100% (99.6%, 100%)					
Cary-Blair Preserved	Retrospective (Frozen)	**P**	18	0	*18*
		N	0	84	*84*
		Total	*18*	*84*	*102*
PPA (95% CI): 100% (82.4%, 100%) NPA (95% CI): 100% (95.6%, 100%)					
Unpreserved	Prospective (Fresh)	**P**	4	1	*5*
		N	1	747	*748*
		Total	*5*	*748*	*753*
PPA (95% CI): 80.0% (37.6%, 96.4%) NPA (95% CI): 99.9% (99.2%, 100%)					
Unpreserved	Retrospective (Frozen)	**P**	6	0	*6*
		N	0	68	*68*
		Total	*6*	*68*	*74*
PPA (95% CI): 100% (61%, 100%) NPA (95% CI): 100% (94.7%, 100%)					

Table 17: Adenovirus- Contrived Specimens Results

	Expected Result		
BD MAX	**P**	**N**	**Total**
P	48	0	*48*
N	0	48	*48*
Total	*48*	*48*	*96*
PPA (95% CI): 100% (92.6%, 100%) NPA (95% CI): 100% (92.6%, 100%)			

Sapovirus Performance Results

For the Cary-Blair preserved specimen type, the BD MAX Enteric Viral Panel identified 87.8% and 99.0% of the Sapovirus prospective positive and negative specimens, respectively, and 66.7% and 100% of the Sapovirus retrospective positive and negative specimens, respectively. For the unpreserved specimen type, the BD MAX Enteric Viral Panel identified 80.0% and 99.9% of the Sapovirus prospective positive and negative specimens, respectively, and 100% and 97.5% of the Sapovirus retrospective positive and negative specimens, respectively. Refer to **Table 18**.

Table 18: Sapovirus- Performance Results per Specimen Type and Origin

Specimen Type	Specimen Origin	BD MAX	RM		Total
			P	N	
Cary-Blair Preserved	Prospective (Fresh)	**P**	43[e]	9[a]	*52*
		N	6[b]	863	*869*
		Total	*49*	*872*	*921*
PPA (95% CI): 87.8% (75.8%, 94.3%) NPA (95% CI): 99.0% (98.1%, 99.5%)					
Cary-Blair Preserved	Retrospective (Frozen)	**P**	2[e]	0	*2*
		N	1	98	*99*
		Total	*3*	*98*	*101*
PPA (95% CI): 66.7% (20.8%, 93.9%) NPA (95% CI): 100% (96.2%, 100%)					
Unpreserved	Prospective (Fresh)	**P**	24[f]	1[c]	*25*
		N	6[d]	720	*726*
		Total	*30*	*721*	*751*
PPA (95% CI): 80.0% (62.7%, 90.5%) NPA (95% CI): 99.9% (99.2%, 100%)					
Unpreserved	Retrospective (Frozen)	**P**	4[f]	1	*5*
		N	0	39	*39*
		Total	*4*	*40*	*44*
PPA (95% CI): 100% (51%, 100%) NPA (95% CI): 97.5% (87.1%, 99.6%)					

[a] 9/9 Preserved Specimens were available to be tested in discrepant analysis and 4/9 tested positive for Sapovirus with the FilmArray™ Gastrointestinal Panel.
[b] 6/6 Preserved Specimens were available to be tested in discrepant analysis and 4/6 tested negative for Sapovirus with the FilmArray™ Gastrointestinal Panel.
[c] 1/1 Unpreserved Specimens were available to be tested in discrepant analysis and 0/1 tested positive for Sapovirus with the FilmArray™ Gastrointestinal Panel.
[d] 6/6 Unpreserved Specimens were available to be tested in discrepant analysis and 5/6 tested negative for Sapovirus with the FilmArray™ Gastrointestinal Panel.
[e] 45/45 Preserved Specimens were available to be tested in concordant analysis and 43/45 tested positive for Sapovirus with the FilmArray™ Gastrointestinal Panel.
[f] 24/28 Unpreserved Specimens were available to be tested in concordant analysis and 24/24 tested positive for Sapovirus with the FilmArray™ Gastrointestinal Panel.

Human Astrovirus Performance Results

For the Cary-Blair preserved specimen type, the BD MAX Enteric Viral Panel identified 93.5% and 99.9% of the Human Astrovirus prospective positive and negative specimens, respectively, and 90.9% and 98.8% of the Human Astrovirus retrospective positive and negative specimens, respectively. For the unpreserved specimen type, the BD MAX Enteric Viral Panel identified 93.3% and 99.7% of the Human Astrovirus prospective positive and negative specimens, respectively, and 100% and 97.8% of the Human Astrovirus retrospective positive and negative specimens, respectively. Refer to **Table 19**.

Table 19: Human Astrovirus- Performance Results per Specimen Type and Origin

Specimen Type	Specimen Origin	BD MAX	RM		Total
			P	N	
Cary-Blair Preserved	Prospective (Fresh)	**P**	29	1[a]	*30*
		N	2[b]	899	*901*
		Total	*31*	*900*	*931*
PPA (95% CI): 93.5% (79.3%, 98.2%) NPA (95% CI): 99.9% (99.4%, 100%)					
Cary-Blair Preserved	Retrospective (Frozen)	**P**	20	1	*21*
		N	2	80	*82*
		Total	*22*	*81*	*103*
PPA (95% CI): 90.9% (72.2%, 97.5%) NPA (95% CI): 98.8% (93.3%, 99.8%)					
Unpreserved	Prospective (Fresh)	**P**	28	2	*30*
		N	2	722	*724*
		Total	*30*	*724*	*754*
PPA (95% CI): 93.3% (78.7%, 98.2%) NPA (95% CI): 99.7% (99%, 99.9%)					
Unpreserved	Retrospective (Frozen)	**P**	3	1	*4*
		N	0	45	*45*
		Total	*3*	*46*	*49*
PPA (95% CI): 100% (43.9%, 100%) NPA (95% CI): 97.8% (88.7%, 99.6%)					

[a] 1/1 Specimen was available to be tested in discrepant analysis and 1 tested negative for Human Astrovirus with the FilmArray™ Gastrointestinal Panel.
[b] 2/2 Specimens were available to be tested in discrepant analysis and 2/2 tested negative for Human Astrovirus with the FilmArray™ Gastrointestinal Panel.

Non-Reportable Rate

The initial unresolved rate of the 1,873 prospective specimens evaluated in this study was 0.8% of the Cary-Blair preserved and 1.8% of the unpreserved specimens. The unresolved rate following a valid repeat test was only 0.1% of the Cary-Blair preserved specimens and 1.0% of the unpreserved specimens (refer to **Table 20**).

Of the 1,873 prospective specimens evaluated in this study, 0.5% of the Cary-Blair preserved and 2.2% of the unpreserved specimens initially reported as Indeterminate. Following a valid repeat test, 0.1% of the Cary-Blair preserved and none of the unpreserved specimens remained Indeterminate (refer to **Table 20**).

Of the 1,873 prospective specimens evaluated in this study, 0.1% of the Cary-Blair preserved and 0.3% of the unpreserved specimens initially reported as Incomplete. Following a valid repeat test, 0.1% of the Cary-Blair preserved and none of the unpreserved specimens remained Incomplete (refer to **Table 20**).

Table 20: Non-reportable Rates for Combined Target by Specimen Type and Overall

Combined Target	***Unresolved Rate***		***Indeterminate Rate***		***Incomplete Rate***		***Total Rate***	
Specimen Type	***Initial EVP (95% CI)***	***Final EVP (95% CI)***	***Initial EVP (95% CI)***	***Final EVP (95% CI)***	***Initial EVP (95% CI)***	***Final EVP (95% CI)***	***Initial EVP (95% CI)***	***Final EVP (95% CI)***
Cary-Blair Preserved	0.8% 9/1085 (0.4%, 1.6%)	0.1% 1/1076 (0.0%, 0.5%)	0.5% 5/1085 (0.2%, 1.1%)	0.1% 1/1076 (0.0%, 0.5%)	0.1% 1/1085 (0.0%, 0.5%)	0.1% 1/1076 (0.0%, 0.5%)	1.4% 15/1085 (0.8%, 2.3%)	0.3% 3/1076 (0.1%, 0.8%)
Unpreserved	1.8% 18/997 (1.1%, 2.8%)	1.0% 10/982 (0.6%, 1.9%)	2.2% 22/997 (1.5%, 3.3%)	0.0% 0/982 (0.0%, 0.4%)	0.3% 3/997 (0.1%, 0.9%)	0.0% 0/982 (0.0%, 0.4%)	4.3% 43/997 (3.2%, 5.8%)	1.0% 10/982 (0.6%, 1.9%)
Combined	1.3% 27/2082 (0.9%, 1.9%)	0.5% 11/2058 (0.3%, 1.0%)	1.3% 27/2082 (0.9%, 1.9%)	0.0% 1/2058 (0.0%, 0.3%)	0.2% 4/2082 (0.1%, 0.5%)	0.0% 1/2058 (0.0%, 0.3%)	2.8% 58/2082 (2.2%, 3.6%)	0.6% 13/2058 (0.4%, 1.1%)