GI Panel Limitations:
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Include in all sections:

This test is a qualitative test and does not provide a quantitative value for the organism(s) in the sample.

The performance of this test has not been established for patients without signs and symptoms of gastrointestinal illness.

Virus, bacteria, and parasite nucleic acid may persist in vivo independently of organism viability. Additionally, some organisms may be carried asymptomatically. Detection of organism targets does not imply that the corresponding organisms are infectious or are the causative agents for clinical symptoms.

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A negative FilmArray GI Panel result does not exclude the possibility of gastrointestinal infection. Negative test results may occur from sequence variants in the region targeted by the assay, the presence of inhibitors, technical error, sample mix-up, or an infection caused by an organism not detected by the panel. Test results may also be affected by concurrent antimicrobial therapy or levels of organism in the sample that are below the limit of detection for the test. Negative results should not be used as the sole basis for diagnosis, treatment, or other management decisions.

The performance of this test has not been evaluated for immunocompromised individuals.

Campylobacter (C. jejuni/C. coli/C. upsaliensis)

The FilmArray GI Panel contains two assays (Campy 1 and Campy 2) designed to together detect, but not differentiate, the most common Campylobacter species associated with human gastrointestinal illness: C. jejuni, C. coli, and C. upsaliensis. These are the same three species that are identified using standard clinical laboratory practices. Other Campylobacter species will not be identified by the FilmArray GI Panel. Empirical testing and in silico sequence analysis indicates reduced sensitivity for a less common subspecies of C. jejuni (C. jejuni subsp. doylei). A positive result for one or both assays will give a Campylobacter Detected test result.

Discrepancies between the FilmArray GI Panel and other microbial identification methods may be caused by the inability to reliably differentiate species based on standard phenotypic microbial identification methods. Examples include differentiation of Yersinia enterocolitica from other Y.

enterocolitica group members such as Y. kristensenii or Y. fredricksonii, differentiation of Entamoeba histolytica from E. dispar, and differentiation of Helicobacter pullorum from Campylobacter.

This test only detects Campylobacter jejuni, C. coli and C. upsaliensis and does not differentiate between these three species of Campylobacter. Additional testing is required to differentiate between these species and to detect other Campylobacter species that may be present in stool specimens.

Campylobacter inclusivity testing and in silico analyses demonstrated that the FilmArray GI Panel may have variable detection or reduced sensitivity for some organisms detected by the Campylobacter assays (Note: The Campylobacter assays only detect C. jejuni, C. coli, and C. upsaliensis). Campylobacter upsaliensis strain ATCC 43954 and Campylobacter jejuni subsp. doylei may not be detected and in silico analysis indicates primer mismatches that might lead to reduced assay sensitivity or lack of reactivity with 11/138 C. coli sequences currently in NCBI databases.

Clostridium difficile toxin A/B

The FilmArray GI Panel contains a single multiplexed assay (Cdiff) for the identification of toxigenic C. difficile which targets both the toxin A gene (tcdA) and the toxin B gene (tcdB). Typical toxigenic strains produce both toxins, but the presence of either is indicative of a pathogenic strain. Empirical testing and in silico sequence analysis support that the assay will detect all toxinotypes and the epidemic BI/NAP1/027 hypervirulent strain, although these will not be specifically differentiated by the assay. Detection of either or both toxin genes by this assay gives a test result for Clostridium difficile toxin A/B Detected. As rates of asymptomatic carriage of C. difficile can be high in very young children and hospitalized patients, the detection of toxigenic C. difficile should be interpreted within the context of guidelines developed by the testing facility or other experts (e.g., guidelines/policy statements published by The American Academy of Pediatrics or the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America).

Results from this test must be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. Due to high rates of asymptomatic carriage of Clostridium difficile, especially in very young children and hospitalized patients, the detection of toxigenic C. difficile should be interpreted within the context of guidelines developed by the testing facility or other experts (e.g., guidelines/policy statements published by The American Academy of Pediatrics or the Society for Healthcare Epidemiology of America and the Infectious Disease Society of America).

Plesiomonas shigelloides

The FilmArray GI Panel contains a single assay (Pshig) for detection of P. shigelloides, the only known species in the genus Plesiomonas.

Salmonella

The FilmArray GI Panel contains a single assay (Salm) designed to detect both species of Salmonella; S. enterica and S. bongori. Empirical testing and in silico sequence analysis support detection of all subspecies and serovars of Salmonella. Cross-reactivity may occur with certain E. coli strains containing variants of the cryptic ETT2 typeIII secretion system (see Inclusivity for additional information).

Several organisms were shown to have the potential to cross-react with FilmArray GI Panel assays. These include Entamoeba dispar when present at high levels (E. histolytica assay); Bifidobacterium spp. and Ruminococcus spp. (G. lamblia assay); certain strains of Citrobacter koseri, Citrobacter sedlakii, Hafnia alvei, and Cedeceae davisiae containing variants of a flagellar assembly protein (ETEC 2 assay), E. coli containing a variant type III secretion protein (Salmonella assay), Grimontia hollisae which was formerly classified as a Vibrio sp. (Vibrio assay), Yersinia frederiksenii and Yersinia kristensenii, which are members of the Y. enterocolitica group (Y. enterocolitica assay).

Not all Salmonella serotypes were tested in validation studies; however, representatives of the 20 most prevalent serotypes recently circulating in the US (CDC National Salmonella Surveillance Annual Summary 2009) were evaluated. In silico sequence analysis supports detection of all subspecies and serotypes of Salmonella.

Cross-reactivity with the Salmonella assay may occur with certain E. coli strains containing variants of the cryptic ETT2 type-III secretion system.

Vibrio (V. parahaemolyticus/V. vulnificus/V. cholerae) and Vibrio cholerae

The FilmArray GI Panel contains a single assay (Vibrio) for detection of Vibrio species most commonly implicated in gastroenteritis (V. parahaemolyticus, V. vulnificus, and V. cholerae). Empirical testing and in silico sequence analysis indicate that the assay may also react with some less common Vibrio species (i.e., V. alginolyticus, V. fluvialis, and V. mimicus). The Vibrio assay does not indicate which species has been detected and the Vibrio assay is not expected to detect the rarer V. cincinnatiensis, V. furnissii and V. metschnikovii. A second assay (Vchol) is also included for the specific detection of Vibrio cholerae. A Vibrio cholerae Detected result will only be reported when the V. cholerae-specific assay is positive, while a positive result for either assay will give a Vibrio Detected test result (see Table 2 below).

Several organisms were shown to have the potential to cross-react with FilmArray GI Panel assays. These include Entamoeba dispar when present at high levels (E. histolytica assay); Bifidobacterium spp. and Ruminococcus spp. (G. lamblia assay); certain strains of Citrobacter koseri, Citrobacter sedlakii, Hafnia alvei, and Cedeceae davisiae containing variants of a flagellar assembly protein (ETEC 2 assay), E. coli containing a variant type III secretion protein (Salmonella assay), Grimontia hollisae which was formerly classified as a Vibrio sp. (Vibrio assay), Yersinia frederiksenii and Yersinia kristensenii, which are members of the Y. enterocolitica group (Y. enterocolitica assay).

Empirical testing and in silico sequence analysis indicate that the Vibrio assay (V. parahaemolyticus/V. vulnificus /V. cholerae) may react with some less common Vibrio species (i.e., V. alginolyticus, V.

fluvialis, and V. mimicus) but it is not expected to detect the rarer Vibrio cincinnatiensis, Vibrio furnissii, and Vibrio metschnikovii (Note: Vibrio spp. not associated with human disease were not evaluated).

V. cholerae isolates with highly divergent toxR genes will be non-reactive with the FilmArray GI Panel V. cholerae assay. Additionally, very rare strains of pathogenic V. cholerae that do not carry that toxR gene will also not be detected by the Vchol assay.

Rare isolates of V. harveyi, V. mimicus, and V. vulnificus that have acquired a homolog of the toxR gene have been reported and may show cross-reactivity with the Vchol assay.

Table 2

FilmArray GI Interpretations	Vibrio (Vibrio Assay)	V. cholerae (Vcol) Assay	Description
Vibrio: Not Tetected Vibrio cholerae: Not Detected	Negative	Negative	No Vibrio species detected
Vibrio: Detected Vibrio cholerae: Not Detected	Positive	Negative	Vibrio species detected (not V. cholerae)
Vibrio: Detected Vibrio cholerae: Detected	Any Results	Positive	Vibrio cholerae detected OR Vibrio cholerae and one or more other Vibrio species detected.

Yersinia enterocolitica

The FilmArray GI Panel contains a single assay (Yent) designed to detect all known serotypes/biotypes of Y. enterocolitica. Empirical testing and in silico sequence analysis indicate a potential for cross-reactivity with Y. kristensenii and Y. frederiksenii when present at high levels (>108 CFU/mL). These two species are in the Y. enterocolitica group and are difficult to differentiate from Y. enterocolitica by culture methods; both are suspected human pathogens.

Discrepancies between the FilmArray GI Panel and other microbial identification methods may be caused by the inability to reliably differentiate species based on standard phenotypic microbial identification methods. Examples include differentiation of Yersinia enterocolitica from other Y. enterocolitica group members such as Y. kristensenii or Y. fredricksonii, differentiation of Entamoeba histolytica from E. dispar, and differentiation of Helicobacter pullorum from Campylobacter.

Diarrheagenic E. coli (This is the precursor to all E. coli results)

The FilmArray GI Panel contains multiple assays designed to detect genetic determinants associated with classic diarrheagenic E. coli/Shigella pathotypes. Horizontal transfer of these genes between organisms has been documented; therefore, Detected results for multiple diarrheagenic E. coli/Shigella may be due to the presence of multiple pathotypes or a single strain containing the characteristic

determinants of multiple pathotypes. An example of this is the 2011 E. coli O104:H4 outbreak strain that contains determinants of both Shiga-like toxinproducing E. coli (STEC) and Enteroaggregative E. coli (EAEC).

The identification of several diarrheagenic E. coli pathotypes has historically relied upon phenotypic characteristics, such as adherence patterns or toxigenicity in certain tissue culture cell lines. The FilmArray GI Panel targets genetic determinants characteristic of most pathogenic strains of these organisms but may not detect all strains having phenotypic characteristics of a pathotype. In particular, the FilmArray GI Panel will only detect Enteroaggregative E. coli (EAEC) strains carrying the aggR and/or aatA genes on the pAA (aggregative adherence) plasmid; it will not detect all strains exhibiting an aggregative adherence pattern.

Target genes associated with the diarrheagenic E. coli/Shigella pathotypes are capable of horizontal transfer between strains, thus Detected results for multiple diarrheagenic E. coli/Shigella may be due to co-infection with multiple pathotypes or, less frequently, may be due to the presence of a single organism containing genes characteristic of multiple pathotypes.

Enteroaggregative E. coli (EAEC)

The FilmArray GI Panel contains a single multiplexed assay (EAEC) for the identification of two gene targets typically associated with enteroaggregative E. coli; the aggR regulatory gene and the putative outer membrane protein, aatA, both located on the partially-conserved pAA plasmid. Note: pAA is not present in all strains phenotypically identified as EAEC, and not all pAA plasmids carry aggR and aatA genes; therefore the FilmArray GI Panel will not detect all members of this diverse pathotype, but is likely to detect most pathogenic strains (including E. coli O104:H4, which was responsible for recent outbreaks in Europe).

Enterotoxigenic (ETEC) heat-labile (lt) and heat-stable (st) Enterotoxins

The FilmArray GI Panel contains three assays (ETEC 1, ETEC 2, and ETEC 3) for the detection of genes encoding enterotoxins found in Enterotoxigenic E. coli (ETEC). The assays are designed for the detection of the genes encoding heat-labile (LT) enterotoxin (ltA) and two heat-stable (ST) enterotoxin variants (st1a, also known as STp; and st1b, also known as STh). The reported results do not indicate which of these toxin gene(s) have been detected. A positive result for any combination of the three assays will give an Enterotoxigenic E. coli (ETEC) lt/st Detected test result. The genes encoding the variant LT-II toxin (structurally similar to LT) and the STB/ST2 toxin (structurally dissimilar to ST1) are not targeted by the ETEC assays and have not been established as important in human disease. Empirical testing and in silico sequence analysis indicates the potential for cross-reactivity with certain strains of Hafnia alvei, C. koseri, C. sedlakii, and Cedecea davisae.

The FilmArray GI Panel detects the heat-labile toxin (LT) and heat-stable toxin variants (ST1a and ST1b) of Enterotoxigenic E. coli (ETEC), which are associated with human disease. The variant LT-II toxin (structurally similar to LT) and the STB/ST2 toxin (structurally dissimilar to ST1) are not targeted by the ETEC assays and have not been established as important in human disease.

Several organisms were shown to have the potential to cross-react with FilmArray GI Panel assays. These include Entamoeba dispar when present at high levels (E. histolytica assay); Bifidobacterium spp. and Ruminococcus spp. (G. lamblia assay); certain strains of Citrobacter koseri, Citrobacter sedlakii, Hafnia alvei, and Cedeceae davisiae containing variants of a flagellar assembly protein (ETEC 2 assay), E. coli containing a variant type III secretion protein (Salmonella assay), Grimontia hollisae which was formerly classified as a Vibrio sp. (Vibrio assay), Yersinia frederiksenii and Yersinia kristensenii, which are members of the Y. enterocolitica group (Y. enterocolitica assay).

Enteropathogenic E. coli (EPEC)

The FilmArray GI Panel contains a single assay (Ec eae) for the detection of eae, the gene encoding the adhesin intimin. Both typical and atypical EPEC will be detected, but not differentiated. The LEE pathogenicity island, which includes the eae gene, is also found in some Shiga-like toxin producing E. coli (STEC; O157 and non-O157 strains). Therefore, the results of the eae assay (positive or negative) are only reported when STEC is not detected. When STEC is detected, Enteropathogenic E. coli (EPEC) will be reported as N/A (Not Applicable), regardless of the EPEC assay result (see Table 3 below). Consequently, the FilmArray GI Panel cannot distinguish between STEC containing eae and a co-infection of EPEC and STEC.

The FilmArray GI Panel detects Enteropathogenic E. coli (EPEC) through targeting of the eae gene, which encodes the adhesin intimin. As some Shiga-like toxin-producing E. coli (STEC) also carry eae (in particular, strains identified as enterohemorrhagic E. coli; EHEC), the FilmArray GI Panel cannot distinguish between STEC containing eae and a co-infection of EPEC and STEC. Therefore, the EPEC result is not applicable (N/A) and not reported for specimens in which STEC has also been detected. In rare cases, STEC may be reported as EPEC when an STEC carrying eae (EHEC) is present in a specimen below the LoD of the STEC assay(s), or the strain carries an stx variant that is not detected well by the STEC assay(s) (e.g. stx2 variant f).. Rare instances of other organisms carrying eae have been documented; e.g., Aeromonas spp., Citrobacter spp., Escherichia albertii, and Shigella boydii.

Shiga-like toxin-producing E. coli (STEC) Shiga-like toxin genes 1 and 2 (stx1/stx2)

The FilmArray GI Panel contains two assays (STEC 1 and STEC 2) for the detection of Shiga-like toxin 1 (stx1) and Shiga-like toxin 2 (stx2) sequences. The reported results do not indicate which of these toxin(s) have been detected. A positive result for either or both of these assays will give a Shiga-like toxin-producing E. coli (STEC) stx1/stx2 Detected test result (see Table 3 below). Note: Shiga toxin (stx; identical to stx1 of STEC) is found in Shigella dysenteriae; therefore, a FilmArray GI Panel report with positive test results for Shiga-like toxin-producing E. coli (STEC) stx1/stx2 and Shigella/Enteroinvasive E. coli (EIEC) in the same sample may indicate the presence of S. dysenteriae.

Shigella dysenteriae possess a shiga toxin gene (stx) that is identical to the stx1 gene of STEC. The detection of both Shigella/Enteroinvasive E. coli (EIEC) and STEC stx1/stx2 analytes in the same

specimen may indicate the presence of S. dysenteriae. Rare instances of the detection of shiga-like toxin genes in other genera/species have been reported; e.g., Aeromonas caviae, Acinetobacter haemolyticus, Shigella sonnei, Enterobacter cloacae, Citrobacter freundii, and Klebsiella pneumoniae.

E. coli O157

To aid in the identification of STEC of the O157 serotype, the FilmArray GI Panel contains a single assay (Ec O157) to detect a gene target that is specific to this serotype. Strains of E. coli O157 that do not carry the Shiga-like toxin genes have also been identified. However, as the pathogenicity of these non-STEC strains remains undefined, the E. coli O157 assay result is not reported unless a Shiga-like toxin gene is also detected (STEC detected). Detection of STEC stx1/stx2 and the E. coli O157 target results in a reporting of E. coli O157 as a qualifier to the positive STEC result. If STEC stx1/stx2 is Not Detected, the result for E. coli O157 is indicated as N/A (Not Applicable). The FilmArray GI Panel cannot distinguish between infections with a single toxigenic STEC O157 or rare co-infections of STEC (non-O157) with an stx1/stx2-negative E. coli O157 (see Table 3 below).

The E. coli O157 result is only reported in association with STEC stx1/stx2. While non-STEC O157 strains have been detected in human stool, their role in disease has not been established. Serotype O157 EPEC have been identified and will be detected by the FilmArray GI Panel (by the EPEC assay) due to their carriage of the eae gene.

The FilmArray GI Panel cannot distinguish between infections with a single toxigenic STEC O157 or rare coinfections of STEC (non-O157) with an stx1/stx2-negative E. coli O157.

FilmArray GI Results	EPEC (Ec eae) Assay	STEC stx1/2 (STEC 1/ STEC 2) Assays	E. coli O157 (Ec O157) Assay	Description
Enteropathogenic E. coli (EPEC): Not Detected Shiga-like toxin-producing E. coli (STEC) stx1/stx2: Not Detected E. coli O157: N/A	Negative	Negative	Any Result	Enteropathogenic E. coli (EPEC) not detected and Shiga-like toxin-producing E. coli (STEC) stx1/stx2 not detected. E. coli O157 result is not applicable when STEC is not detected
Enteropathogenic E. coli (EPEC): Detected Shiga-like toxin-producing E. coli	Positive	Negative	Any Result	Enteropathogenic E. coli (EPEC) detected Shiga-like toxin-producing E. coli

(STEC) stx1/stx2: Not Detected E. coli O157: N/A				(STEC) stx1/stx2 not detected E. coli O157 result is not applicable when STEC is not detected
Enteropathogenic E. coli (EPEC): N/A Shiga-like toxin-producing E. coli (STEC) stx1/stx2: Detected E. coli O157: Not Detected	Any Result	Positive[1]	Negative	EPEC result is not applicable (detection cannot be differentiated from eae containing STEC) Shiga-like toxin-producing E. coli (STEC) stx1/stx2 detected, O157 serotype not detected
Enteropathogenic E. coli (EPEC): N/A Shiga-like toxin-producing E. coli (STEC) stx1/stx2: Detected E. coli O157: Detected	Any Result	Positive[1]	Positive	EPEC result is not applicable (detection cannot be differentiated from eae containing STEC) Shiga-like toxin-producing E. coli (STEC) stx1/stx2 detected, O157 serotype detected[2]

[1] Positive results for the STEC assay(s) and the Shigella/Enteroinvasive E. coli (EIEC) assay may indicate the presence of Shigella dysenteriae.

[2]O157 determinant may be from the STEC or may be due to the rare possibility of a shiga-like toxin-negative E. coli O157 being in the same specimen with a non-O157 STEC.

Shigella/Enteroinvasive E. coli (EIEC)

The FilmArray GI Panel contains a single assay (Shig) for the detection of ipaH, a gene specifically found in all Shigella species as well as Enteroinvasive E. coli (EIEC). It is not possible to differentiate Shigella from EIEC using this method, and detection of ipaH will result in a Shigella/Enteroinvasive E. coli (EIEC) Detected test result. Note: Shiga toxin (stx; identical to stx1 of STEC) is found in Shigella dysenteriae,

therefore a FilmArray GI Panel report with positive test results for Shiga-like toxin-producing E. coli (STEC) stx1/stx2 with Shigella/Enteroinvasive E. coli (EIEC) in the same sample may indicate the presence of S. dysenteriae.

Shigella dysenteriae possess a shiga toxin gene (stx) that is identical to the stx1 gene of STEC. The detection of both Shigella/Enteroinvasive E. coli (EIEC) and STEC stx1/stx2 analytes in the same specimen may indicate the presence of S. dysenteriae. Rare instances of the detection of shiga-like toxin genes in other genera/species have been reported; e.g., Aeromonas caviae, Acinetobacter haemolyticus, Shigella sonnei, Enterobacter cloacae, Citrobacter freundii, and Klebsiella pneumoniae.

Cryptosporidium

The FilmArray GI Panel contains two assays (Crypt 1 and Crypt 2) for detection of Cryptosporidium species. Empirical testing and in silico sequence analysis support detection of approximately 23 different Cryptosporidium, including the most common species of human clinical relevance (i.e., C. hominis and C. parvum), as well as several less common species (e.g., C. meleagridis, C. felis, C. canis, C. cuniculus, C. muris, and C. suis). The assays do not differentiate between species and the very rare species C. bovis, C. ryanae and C. xiaoi may not be detected. A positive result for either or both assays will give a Cryptosporidium Detected test result.

Based on the available sequences, a few Cryptosporidium species, or certain variants of species, including C. bovis, C. ryanae, and C. xiaoi, may not be efficiently detected by the Cryptosporidium assays. These species are rarely detected in human samples.

Cyclospora cayetanensis

The FilmArray GI Panel contains a single assay (Ccayet) for the detection of C. cayetanensis, the only Cyclospora species implicated in human disease.

Entamoeba histolytica

The FilmArray GI Panel contains a single assay (Ehist) for the detection of E. histolytica, the only Entamoeba species implicated in gastroenteritis. This assay may cross-react with the closely related E. dispar when present at higher levels (approximately 105 oocysts/mL or greater).

Discrepancies between the FilmArray GI Panel and other microbial identification methods may be caused by the inability to reliably differentiate species based on standard phenotypic microbial identification methods. Examples include differentiation of Yersinia enterocolitica from other Y. enterocolitica group members such as Y. kristensenii or Y. fredricksonii, differentiation of Entamoeba histolytica from E. dispar, and differentiation of Helicobacter pullorum from Campylobacter.

Several organisms were shown to have the potential to cross-react with FilmArray GI Panel assays. These include Entamoeba dispar when present at high levels (E. histolytica assay); Bifidobacterium spp. and

Ruminococcus spp. (G. lamblia assay); certain strains of Citrobacter koseri, Citrobacter sedlakii, Hafnia alvei, and Cedeceae davisiae containing variants of a flagellar assembly protein (ETEC 2 assay), E. coli containing a variant type III secretion protein (Salmonella assay), Grimontia hollisae which was formerly classified as a Vibrio sp. (Vibrio assay), Yersinia frederiksenii and Yersinia kristensenii, which are members of the Y. enterocolitica group (Y. enterocolitica assay).

Giardia lamblia

The FilmArray GI Panel contains a single assay (Glam) designed to detect G. lamblia (aka G. intestinalis, G. duodenalis), the only Giardia species infectious to humans. A very low frequency of cross-reactivity with commensal microorganisms (i.e., Bifidobacterium and Ruminococcus) was observed in the clinical evaluation.

Several organisms were shown to have the potential to cross-react with FilmArray GI Panel assays. These include Entamoeba dispar when present at high levels (E. histolytica assay); Bifidobacterium spp. and Ruminococcus spp. (G. lamblia assay); certain strains of Citrobacter koseri, Citrobacter sedlakii, Hafnia alvei, and Cedeceae davisiae containing variants of a flagellar assembly protein (ETEC 2 assay), E. coli containing a variant type III secretion protein (Salmonella assay), Grimontia hollisae which was formerly classified as a Vibrio sp. (Vibrio assay), Yersinia frederiksenii and Yersinia kristensenii, which are members of the Y. enterocolitica group (Y. enterocolitica assay).

Adenovirus F40/41

The FilmArray GI Panel contains a single multiplexed assay (AdenoF) for the specific detection of both Adenovirus F40 and F41 (i.e., will not cross-react with respiratory non-40/41 Adenovirus species when shed in the stool). The reported results do not indicate which serotype (40 or 41) has been detected. The assay will not detect other adenovirus species, such as species B, C, and E, which are associated with respiratory infections.

Astrovirus

The FilmArray GI Panel contains a single assay (Astro) designed to detect eight subtypes (HAstV1-8) of human Astrovirus. The assay is not predicted to detect newly-identified astroviruses of the MLB and VA clades.

Norovirus GI/GII

The FilmArray GI Panel contains two assays (Noro 1 and Noro 2) that together target the Norovirus genogroups most commonly associated with human infections (GI and GII). Neither assay will detect genogroup GIV, nonhuman genogroups, or closely related Caliciviruses such as Sapovirus. The reported results do not indicate which genogroup(s) (GI and/or GII) have been detected. A positive result for either or both assays will produce test result of Norovirus GI/GII Detected.

Rotavirus A

The FilmArray GI Panel contains two separate Rotavirus A assays (RotaA 1 and RotaA 2) to be inclusive of all strains of Rotavirus A. In silico sequence analysis indicates that these assays will not cross-react with Rotavirus B and C, which are less common in human disease, or Rotavirus D, E, and F, which have not been found in humans. Empirical testing has demonstrated that these assays will detect recombinant viruses included in Rotavirus vaccines. A FilmArray GI Panel test result of Rotavirus A Detected is reported if either or both assays are positive.

The performance of the FilmArray GI Panel has not been established in individuals who received Rotavirus A vaccine. Recent oral administration of a Rotavirus A vaccine may cause positive results for Rotavirus A if the virus is passed in the stool.

Sapovirus (Genogroups I, II, IV, and V)

The FilmArray GI Panel contains a single assay (Sapo) designed to detect, but not differentiate, Sapovirus genogroups identified in human infections (I, II, IV and V). Genogroup III, a porcine pathogen will not be detected.