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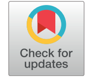
Evaluation of Copan FecalSwab™ preserved stool specimens with the BD MAX™ Enteric Bacterial Panel and the BD MAX™ Extended Enteric Bacterial Panel



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ABSTRACT

The objectives of this study were to assess the ideal volume of Copan FecalSwab™ (FS) preserved stool sample to use with the BD MAX™ Enteric Bacterial Panel and the Extended Enteric Bacterial Panel (BDM GIP) and to compare the performance of FS to the recommended Meridian Para-Pak Cary-Blair medium (PP) for the BDM GIP. Three different input volumes (10, 25, and 50 µL) of stool inoculated with American Type Culture Collection strains representing the targets detected by BDM GIP were tested. Additionally, 144 unpreserved stool samples submitted for gastrointestinal (GI) testing were transferred to PP and FS media and tested by the BDM GIP using 10 µL of PP and 50 µL of FS media. A 100% agreement was observed between PP and FS results. The performance of 50 µL of FS stool preserved sample was equivalent to 10 µL of traditional Cary-Blair PP preserved specimens for GI pathogens detection using the BDM GIP.

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1. Introduction

Gastrointestinal (GI) diseases are a major cause of office visits, emergency department visits, and hospitalization, accounting for substantial morbidity, mortality, and cost. It has been estimated that the annual healthcare expenditures in the United States for GI disease is as much as $136 billion, greater than some common diseases such as heart disease, trauma, or mental health (Peery et al., 2019). Diarrheal diseases account for as many as 1.6 million people per year globally and are among the leading causes of malnutrition in children who live in economically challenge areas (Kosek et al., 2003; Anonymous, 2018a). According to the United States Department of Agriculture, foodborne diseases caused by just 14 of the 31 major enteric pathogens account for over 8 million cases that accrued over $14.0 billion in cost of illness and a loss of 61,000 quality-adjusted life year per year (Hoffmann et al., 2012; Batz et al., 2014). Among the most common causative agents of foodborne related diarrheal disease in the United States are *Salmonella*, *Campylobacter*, *Shigella*, and Shiga toxin–producing *Escherichia coli* (STEC) (DeBurger et al., 2017).

Diagnosing diarrheal disease can be very challenging due to the variety of pathogens involved. Isolating these pathogens is very difficult due to the quick overgrowth and interference of commensal microorganisms present in stool, leading to delays in diagnosis and susceptibility testing (Goneau et al., 2019). Conventional microbiological techniques are still considered to be the gold standard for GI pathogens identification despite being time-consuming, labor-intensive methods that require high technical skills and provide low sensitivity (Harrington et al., 2015). Traditional culture methods typically require 24 h to 72 h of incubation time, plus additional time necessary for the identification of the pathogen through biochemical techniques, or mass spectrometry techniques, such as matrix-assisted laser desorption ionization–time of flight (Harrington et al., 2015). The use of multiplex molecular techniques, which offer faster turnaround time, increased sensitivities, and the ability to detect mixed infections, has become a more accepted alternative for the detection of enteric pathogenic bacteria (Harrington et al., 2015; Simner et al., 2017).

The BD MAX™ System (BD Life Sciences, Sparks, MD) is a fully integrated automated molecular platform that can test up to 24 samples at once in approximately 3 h with less than 5 min of hands-on time per sample. As opposed to other platforms that feature very comprehensive GI panels combining bacterial, viral, and parasitic targets, BD takes a more targeted approach in which GI bacterial panels are designed and tested independently from viral or parasitic panels (Mashock et al., 2017). The BD MAX Enteric Bacterial Panel detects *Salmonella* spp., *Shigella* spp., *Campylobacter jejuni*/*coli*, and Shiga toxin genes, while the optional BD MAX Extended Enteric Bacterial Panel (which comes as an additional master mix to be used in conjunction with the BD MAX Enteric Bacterial Panel) detects *Yersinia enterocolitica*, enterotoxigenic *E. coli* (ETEC), *Vibrio* sp. (*V. vulnificus*, *V. parahaemolyticus*, and

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V. cholerae), and *Plesiomonas shigelloides* simultaneously (Simner et al., 2017). The BD MAX Enteric Bacterial Panel and BD MAX Extended Bacterial Panel have been approved for use with fresh, unpreserved stools or Cary-Blair media preserved stools from symptomatic patients (Harrington et al., 2015; Simner et al., 2017).

The Copan FecalSwab is a convenient stool transport device that consists of a Copan flocked swab (FLOQSwab™) and 2 mL of Cary-Blair medium for stool preservation, while needing very little stool sample (Mashock et al., 2017). Flocked swabs, when used as part of a liquid-based microbiology collection device, have shown an improved absorption of bacteria, as well as a greater transfer of material onto Gram stain slides, when compared to a traditional swab (Mashock et al., 2017). These increase in microorganism absorption and release from the flocked swab can help improve detection rates and increase the sensitivity of diagnostic tests (Mashock et al., 2017; Jean et al., 2019). The objectives of this study were (Peery et al., 2019) to determine the appropriate volume of stool preserved in Copan FecalSwab™ (FS) to be used with the BD MAX Enteric Bacterial Panel in conjunction with BD MAX Extended Enteric Bacterial Panel (BDM GIP) on the BD MAX System and (Anonymous, 2018a) to compare the performance of FS to the recommended Meridian Para-Pak Cary-Blair medium (PP) for the BDM GIP.

2. Materials and methods

2.1. Specimen enrollment

Specimen collection was performed according to the Tampa General Hospital's standard procedures and in compliance with the Western Institutional Review Board–approved protocol. The acceptable specimens included unformed, unpreserved prospective and retrospective residual stool specimens obtained from pediatric and adult inpatient or outpatient whose stool cultures had been ordered by a healthcare provider. Retrospective specimens included in this study were collected and stored at −80 °C between November 2017 and July 2018, while prospective specimens were collected and tested on the BD MAX within 5 days after collection and stored at 2–8 °C. Specimens submitted only for *C. difficile* testing from gastroenteritis, enteritis, or colitis were excluded from the study. Specimens used for the analytical study were previously characterized with the BDM GIP to confirm the absence of the targets.

2.2. Analytical testing

Strains acquired from the American Type Culture Collection (ATCC), namely, *Salmonella typhimurium* (ATCC 14028), *Shigella sonnei* (ATCC 9290), STEC (ATCC 43890), *Campylobacter jejuni* (ATCC 33291), *P. shigelloides* (ATCC 14029), *Vibrio parahaemolyticus* (ATCC 17802), ETEC (ATCC 35401), and *Y. enterocolitica* (ATCC 9610), were cultured on appropriate media and incubated under recommended incubation conditions. Cultures were examined after 48-h incubation, and a 0.5 McFarland suspension was prepared in phosphate-buffered saline (pH 7.20; Sigma Life Science) for each strain individually. A working dilution of 1:20 from the 0.5 McFarland suspension was made for each organism. Five milliliters of the dilution was used to inoculate 50 mL of pooled stool prepared from 5 different patients (10 mL per patient) previously characterized as negative by the BDM GIP. The sample was mixed by vortexing to obtain a homogeneous inoculated stool mix. Eight different mixtures of negative stool samples were made, and each one of them was inoculated with 1 of the 8 BDM GIP targets represented by each of the 8 ATCC strains described above. The inoculated stools were plated in triplicate on both blood agar plates (BBL™ TSA II 5% SB) and differential and selective plates for colony-forming unit (CFU) counts to estimate the bacterial burden. The selective media used in this study included Hardy Diagnostics HardyCHROM™ SS NoPro (*S. typhimurim* and *S. sonnei*), BBL™ CHROMagar® O157 (STEC), Karmali agar (*C. jejuni*), thiosulfate-citrate-bile salts-sucrose agar (*P. shigelloides* and *V. parahaemolyticus*), and cefsulodin irgasan novobiocin agar (*Y. enterocolitica*).

To prepare samples for analytical testing on the BD MAX, Copan FecalSwab™ (FS; Copan Diagnostics, Murrieta, CA) and Meridian Para-Pak® Cary-Blair medium (PP; Meridian Bioscience, Cincinnati, OH) devices were spiked with inoculated stool sample mixtures and processed according to package inserts. Briefly, for PP, the provided sampling paddle was used to collect enough stool to reach the "fill line" indicated on the tube. For FS, the flocked swab was inserted, rotated into the stool sample, and transferred into the FS medium not exceeding the "fill line". Six PP and 18 FS devices were prepared per organism. The FS devices were divided into 3 groups of 6 based on the input volumes transferred into the BD MAX Sample Processing Tubes (SBTs) for the BDM GIP testing. Group 1 had an input volume of 10 μL, group 2 used an input volume of 25 μL, and group 3 had an input volume of 50 μL compared to the 10-μL recommended input volume from the PP reference method device.

All 24 devices (18 FS and 6 PP) were tested on the BD MAX System immediately after inoculation (T0) according to the BD MAX assay's package insert. Additionally, to investigate the effect of time and storage condition on the performance of the stool specimen transport media, half ($n = 3$) of the PP devices and half of FS devices tested at T0 were kept at room temperature (20–24 °C) for testing at 24 h postinoculation (T1), while the other half was placed in the refrigerator (2–8 °C) for testing at 5 days postinoculation (T2). All samples testing using the BDM GIP was performed in triplicate. This procedure was repeated for all stool specimens inoculated with each 1 of the 8 ATCC strains.

2.3. Clinical sample testing

A total of 144 unpreserved clinical stool specimens submitted for GI testing at Tampa General Hospital laboratory were included in this study. All of the stool specimens were initially tested using the BioFire® Gastrointestinal Panel (bioMerieux, France) on the BioFire® FilmArray® System, our standard of care methodology. Out of 144 clinical specimens tested, 96 were retrospective frozen specimens and 48 were prospective fresh specimens selected consecutively if tested positive for the BDM GIP targets. After routine analysis, residual unpreserved stool specimens were stored at −80 °C for the study. Prior to testing, the retrospective stool specimens were thawed at room temperature for approximately 1 h, and the FS and PP devices were inoculated with the stool specimen reaching the "fill line" according to the manufacturers' recommendations. Immediately after inoculation, 50 μL of FS stool sample was transferred into the BD MAX SBT, and the recommended 10 μL of the PP stool sample was transferred into the BD MAX SBT for testing. The samples were tested on the BD MAX System using the BDM GIP according to manufacturer's instructions.

2.4. Statistical analysis

The results obtained from the BDM GIP for the prospective and retrospective specimens were compared with those collected with the reference method. Positive percent agreement and negative percent agreement were calculated with 95% confidence intervals for Copan FS preserved specimens compared to those obtained with the PP Cary-Blair reference method.

3. Results

3.1. Analytical testing

In order to estimate the bacterial burden, the inoculated stools were serially diluted and plated on selective media. Due to the inability of culture media to discriminate enterotoxigenic *E. coli* from the normal flora, ETEC was plated directly from the working dilution and its

concentration in the inoculated stool was calculated accordingly. CFU counts showed that an average of 4.8×10^5 CFU/mL of *S. typhimurium*, 3.5×10^4 CFU/mL of *S. sonnei*, 2.3×10^5 CFU/mL of STEC, 6.7×10^2 CFU/mL of *C. jejuni*, 9.0×10^3 CFU/mL of enterotoxigenic *E. coli*, and 1.5×10^3 CFU/mL of *P. shigelloides* was present in the initial inoculated stool mixture. No growth was observed on *V. parahaemolyticus* and *Y. enterocolitica* cultures.

The ideal volume for testing to obtain an equivalent or better performance of stool preserved in Copan FS compared to the reference transport PP medium was determined using pooled stool specimens inoculated with the target pathogens acquired from the ATCC. Three different input volumes (10 μL, 25 μL, and 50 μL) of stool preserved in FS and the recommended volume (10 μL) of stool preserved in PP Cary-Blair medium were tested on the BD MAX after storage for different lengths of time at varying temperatures. Each sample was tested in triplicate, and out of more than 288 replicates tested across all samples (FS and PP), 11 resulted in unresolved (UNR) due to BD MAX reagent failure. For PP, 7 replicates resulted in UNR: 1 in the 10-μL inoculum (*Vibrio* at T2), 1 in the 25-μL inoculum (*Campylobacter* at T2), and 5 in 50-μL inoculum (STEC at T1, *Salmonella* at T1 and T3, *Campylobacter* at T2, *Plesiomonas* at T1). On the other hand, 4 replicates (STEC at T1, 2 *Salmonella* replicates at T3, *Plesiomonas* at T1) resulted in UNR for the PP reference testing.

We considered a difference of ≤1.5 cycle threshold (Ct) values not significant since that may be due to variation between runs and within replicates. As expected, the pooled stools were all positive for the inoculated targets (Table 1). The data showed that regardless of the length or method of stool preservation (FS or PP), the Ct values for each input volume were comparable with the exception of *V. parahaemolyticus,* which had Ct values differences greater than 1.5 when preserved in both FS and PP for 24 h at RT and in PP for 5 days at 2–8 °C. There were noticeable differences (Ct > 1.5) between FS and PP for the 10-μL input volumes for *S. typhimurium* (T = 24 h), *E. coli* STEC (T = 24 h and T = 5 days), *C. jejuni* (T = 5 days), *P. shigelloides* (T = 5 days), *V. parahaemolyticus* (T = 0 h and T = 24 h), ETEC (T = 0 h), and *Y. enterocolitica* (T = 0 h, T = 24 h, and T = 5 days). On the other hand, no difference between 25-μL and 50-μL input volumes from the FS was observed when compared with the 10 μL used for the PP. The 50- L input volume for FS seemed to perform equally or better than the 10-μL PP reference method for any time points and storage conditions tested in the study. Therefore, 50 μL of input volume for the FS was used for testing the prospective and retrospective clinical samples in the study.

3.2. Clinical study

In order to confirm the results obtained in the analytical study on clinical samples, a total of 96 retrospective (66.7%) and 48 (33.3%) prospective unpreserved specimens were enrolled in this study. Aliquots of the unpreserved specimens were transferred into the Copan FS and Meridian PP transport media and tested concurrently by the BDM GIP. Of the 144 samples tested, 97 (67.4%) were positive for at least 1 of the targets tested, and 47 (32.6%) were negative for all targets. Except for *Vibrio* species, which were not detected in either transport media, each target had at least 1 positive detected in both stool transport media (*Salmonella* positive $n = 42$, *Shigella* positive $n = 14$, STEC positive $n = 8$, *Campylobacter* positive $n = 30$, *Plesiomonas* positive $n = 3$, ETEC positive $n = 1$, *Yersinia* positive $n = 3$). Four of the 97 samples were positive for 2 different targets in both transport media. There was a 100% positive and negative percent agreement for the FS transport medium when compared to the recommended Meridian PP Cary-Blair medium for each target using the BDM GIP testing (Table 2).

Ct values detected from clinical samples were also compared. The mean and range Ct values for each target in the study were calculated based on the number of positive samples for each of the assay targets (Table 3). There do not seem to be significant differences between the mean and range Ct values for FS and PP except for *Plesiomonas*, which was only 3 positive samples. Based on these results, the relative detection range in this study was between 16.4 and 39.0. Of the 101 positive targets, more than 83% had a Ct value difference lower than 1, 96% had a Ct value difference less than 1.5, and less than 14% had a significantly different Ct value. For the PP device, 9 of the samples had significantly higher Ct values compared to 5 of the samples for the FS device (Table 3). The differences observed were not particularly target related.

4. Discussion

The Copan FS, comprised of a flocked swab (FLOQSwab™) and 2 mL of Cary-Blair medium, requires less stool than would be necessary with the PP, making it ideal for patients who are presenting with GI symptoms but cannot pass a large enough specimen (DeBurger et al., 2017; Jean et al., 2019). Stool specimen collections may present with some difficulties in the collection methods, as well as the appropriate and safe transportation (Goldfarb et al., 2014; Freedman et al., 2017). Moreover, fecal swab collection can lead to more timely testing due to the ability to routinely collect fecal swab specimens at first physician encounter which may not always be possible in the case of bulk fecal specimens, especially for patient who cannot pass enough stool or patients who are more severely dehydrated (Arvelo et al., 2013; Sperou et al., 2017). The Copan FS sample collection device has been successfully evaluated by either culture or multiplex-PCR panels and shown to help maintain the stability and accurate detection of enteric pathogens (Mashock et al., 2017; Silbert et al., 2017; Jean et al., 2019; Kotar et al., 2019). A recent study evaluating flocked rectal swab using paired rectal swab and stool specimens for molecular detection of enteric pathogens using the BioFire FilmArray assay reported equal performance between the 2 collection methods in detecting bacterial pathogens (Walker et al., 2019). Goldfarb et al., on the other hand, reported that flocked rectal swabs allow for significantly higher bacterial pathogen detection than bulk stool samples (Goldfarb et al., 2014). Most studies, however,

Table 1
Average of Ct values using different FS volumes, incubation temperatures, and times.

	S. typhimurium (ATCC 14028)			*S. sonnei* (ATCC 9290)			*E. coli STEC* (ATCC43890)			*E. coli ETEC* (ATCC 35401)		
	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
FS_10 μL	34.4 ± 1.1	34.6 ± 1.0	33.9 ± 1.0	30.0 ± 0.5	30.5 ± 0.3	30.9 ± 0.3	35.5 ± 1.0	35.6 ± 2.8	34.8 ± 1.6	31.5 ± 0.2	32.3 ± 1.4	31.7 ± 0.7
FS_25 μL	32.3 ± 0.6	31.3 ± 0.3	32.1 ± 0.7	28.8 ± 0.3	29.0 ± 0.2	28.5 ± 0.0	33.7 ± 0.6	32.2 ± 0.5	32.7 ± 0.6	28.6 ± 0.4	29.4 ± 0.1	29.2 ± 0.2
FS_50 μL	32.7 ± 0.4	30.5 ± 0.6	30.7 ± 0.1	28.7 ± 0.4	28.1 ± 0.2	28.2 ± 0.3	32.7 ± 0.5	31.4 ± 0.4	31.9 ± 0.8	28.1 ± 0.3	28.5 ± 0.2	28.0 ± 0.1
PP_10 μL	33 ± 0.5	31.0 ± 0.7	32.4	29.5 ± 0.3	29.2 ± 0.7	28.9 ± 0.8	32.9 ± 0.6	30.6 ± 0.4	31.7 ± 0.5	28.5 ± 0.3	32.1 ± 0.8	30.2 ± 0.5
	C. jejuni (ATCC 33291)			*P. shigelloides* (ATCC 14029)			*V. parahaemolyticus* (ATCC 35401)			*Y. enterocolitica* (ATCC 9610)		
	T1	T2	T3	T1	T2	T3	T1	T2	T3	T1	T2	T3
FS_10 μL	28.7 ± 0.4	29.4 ± 0.5	29.7 ± 0.3	30.6 ± 0.6	31.4 ± 0.7	33.5 ± 1	32.0 ± 0.6	35.7 ± 0.5	33.0 ± 0.4	32.8 ± 0.8	33.1 ± 0.7	33.0 ± 0.4
FS_25 μL	27.2 ± 0.2	27.3 ± 0.1	27.9 ± 0.7	29.5 ± 0.3	29.7 ± 0.2	29.2 ± 0.1	29.4 ± 0.1	32.7 ± 0.5	30.7 ± 0.3	31.1 ± 0.4	31.3 ± 0.4	31.2 ± 0.2
FS_50 μL	27.2 ± 0.2	27.1 ± 0.0	26.8 ± 0.4	29.8 ± 0.6	29 ± 0.2	28.8 ± 0.8	28.4 ± 0.2	31.6 ± 0.2	29.3 ± 0.2	30.7 ± 0.6	30.1 ± 0.3	29.8 ± 0.1
PP_10 μL	27.7 ± 0.2	27.8 ± 0.7	26.8 ± 0.0	30.6 ± 0.8	30 ± 0.3	30.3 ± 0.4	28.6 ± 0.3	32.3 ± 0.6	31.1 ± 0.7	30.1 ± 0.2	30.8 ± 0.2	30.0 ± 0.1

T1 = 0 h; T2 = 24 h at room temperature; T3 = 5 days at 2–8 °C.

Table 2
Result agreement between FecalSwab and Para-Pak for 144 clinical samples tested.

		Para-Pak results							
		Salmonella		*Shigella/EIEC*		*STEC*		*ETEC*	
		Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
FecalSwab results	Positive	42	0	14	0	8	0	1	0
	Negative	0	102	0	130	0	136	0	143
		Campylobacter		*Plesiomonas*		*Vibrio*		*Yersinia*	
		Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
	Positive	30	0	3	0	0	0	3	0
	Negative	0	114	0	141	0	144	0	141

reported that due to a shorter time to collection, the flocked swab system has a faster result turnaround time than a bulk stool specimen, indicating that the use of the flocked swab system may lead to improvements within the clinical workflow as well as potential outcomes (Jean et al., 2019).

In this study, we first determine the optimal input volume of stool sample in Copan FS transport media needed for testing using the BD MAX Enteric and Extended Enteric Bacterial Panels. We report that 50 μL is the ideal input volume for FS specimens based on the overall performance of the assays for detection of all the target organisms at different storage conditions, compared to the 10-μL input volume for the reference PP Cary-Blair medium. It is not surprising that a higher input volume of FS is needed to achieve an equivalent or better performance than the reference method since the Meridian PP Cary-Blair media might have a greater amount of stool present than the flocked swab in the FS. Different studies evaluated flocked swabs on molecular panels with positive performance compared to stool specimen testing. DeBurger et al. reported using 10 μL of input volume in their BD MAX™ Enteric Bacterial Panel assay (DeBurger et al., 2017), while other studies using different molecular testing platforms such as the BioFire FilmArray and the GeneXpert® (Cepheid, CA) use 200-μL and 400-μL input volume for their GI panel and *C. difficile* assay, respectively (Mashock et al., 2017; Silbert et al., 2017; Walker et al., 2019).

A good transport medium for molecular testing not only should be compatible with a wide range of DNA extraction systems and molecular platforms but also should have the intrinsic ability to preserve the integrity of the target analytes. Therefore, we tested the ability of the FS stool transport medium to preserve the specimens and maintain the integrity of the target nucleic acid at different storage conditions and lengths of time. We have shown that the test performance was not affected when FS specimens are stored for at least 24 h at room temperature or 5 days at 2–8 °C. We did not assess the effect of other storage conditions since testing would most likely be done within 5 days of collection. Moreover, FS has been shown to be a well-suitable device for extended storage and transportation of enteric pathogens (Hirvonen and Kaukoranta, 2014).

We evaluated 144 clinical samples using 50-μL input volume to compare the performance of the FS with the Meridian PP Cary-Blair transport medium. Due to the low prevalence for each target, in addition to prospective samples, we included frozen retrospective samples. A previous study to evaluate the fresh and frozen specimens was performed by BD Life Sciences to support inclusion of frozen archived specimens in the clinical study submitted for 510(K) of the BD MAX Enteric Bacterial Panel (#K140111). Results from that study and published data showed that 1–2 freeze/thaw cycles did not significantly affect the bacterial community profiles (Bassis et al., 2017). The results of the clinical sample testing showed 100% agreement between the Copan FecalSwab and the Meridian Para-Pak transport media. Therefore, the input volume of 50 μL of the Copan FecalSwab proved to be equivalent in performance to the recommended 10 μL of the Meridian Para-Pak when used with the BD MAX Enteric and Extended Enteric Bacterial Panels. The most prevalent pathogens in our study were *Salmonella* at 29.2%, followed by *Campylobacter* at 21% and *Shigella/EIEC* at 9.7%. No *Vibrio* spp. were detected. This result is in agreement with previously reported data showing *Salmonella* and *Campylobacter* as the most common causative agents of bacterial diarrheal disease (Stutman, 1994; Goldfarb et al., 2014).

Though the scope of this study was to determine the optimal input volume that would display equal or better performance than the reference method, some limitations were worth noting. Paired fecal swab and bulk stool specimens were not used in this study nor was the analytical limit of detection for each target in either of the devices. Moreover, the initial bacterial burden for each target was not calculated from the original McFarland suspension but rather in the stool mixture. That may explain the discrepancy in CFUs across each of the bacterial targets. One can argue that this discrepancy does not affect the results of the study since the FS and PP inocula were taken from the same inoculated stool mixture.

Diarrheal disease is a life-threatening condition that globally affects individuals from all walks of life. It has, however, disproportionally affected children and individuals living in areas with inadequate access to healthcare, safe water, and hygiene (Anonymous, 2018b). Timely and accurate identification of the causative agents can exponentially improve patient outcome and reduce the financial burden associated with GI disease. This study has established the feasibility and performance characteristics of the BDM GIP with stool specimens in Copan

Table 3
Ct value differences between FecalSwab and Para-Pak media clinical samples.

		Mean/range (Ct)		Ct value differences between FS and PP			
				1–1.5 Ct		>1.5 Ct	
Pathogens detected	No. of positive by both FS and PP	FS	PP	FS[a]	PP[b]	FS[a]	PP[b]
Salmonella	42	27.45/18.59–36.66	27.35/18.75–36.66	NA	NA	3/42	5/42
Campylobacter	30	25.51/17.46–34.79	25.59/18.19–34.46	1/30	NA	NA	2/30
STEC	8	26.36/20.98–33.71	26.86/22.42–35.96	NA	1/8	NA	2/8
Shigella/EIEC	14	21.33/16.37–31.45	20.67/16.62–30.72	2/14	NA	NA	NA
Yersinia	3	35.74/34.51–37.48	34.65/32.11–37.76	NA	NA	1/3	NA
ETEC	1	NA	NA	NA	NA	NA	NA
Plesiomonas	3	33.01/26.6–38.89	31.29/25.85–34.88	NA	NA	1/3	NA
Vibrio	0	NA	NA	NA	NA	NA	NA

[a] FS Ct value is higher than PP.
[b] PP Ct value is higher than FS.

FecalSwab. It was shown to be a good alternative to the bulk Cary-Blair transport device for preserving enteric pathogenic bacterial nucleic acid for testing fecal specimens from patients suspected of GI infection with the BDM GIP on the BD MAX System.

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