FecalSwab™

Product Insert & How to Use Guide

Copan FecalSwab Collection, Transport and Preservation System of Enteric Bacteria
Product Insert & How to Use Guide

INTENDED USE

The Copan FecalSwab Collection, Transport and Preservation System is intended for the collection of rectal swab and fecal specimens and to preserve the viability of enteric pathogenic bacteria during transport from the collection site to the testing laboratory. In the laboratory, FecalSwab specimens are processed using standard clinical laboratory operating procedures for culture.

SUMMARY AND PRINCIPLES

Enteric infections can be caused by different types of bacteria. With such a wide array of pathogens and the need for cost containment, physician input and practice guidelines can help the laboratory determine which tests are appropriate for detecting the etiological agent of diarrhea. Microbiology laboratories should review the local epidemiology of bacterial enterocolitis and implement routine stool culture methods that will allow recovery and detection of all the major pathogens causing most of the cases in their geographic area. All microbiology laboratories should routinely test for the presence of *Salmonella* spp., *Shigella* spp., and *Campylobacter* spp. on all stool cultures (2). One of the routine procedures in the diagnosis of enteric infections involves the collection and safe transportation of rectal swab samples or stool samples. This can be accomplished using the Copan FecalSwab Collection, Transport and Preservation System. Copan FecalSwab incorporates a modified Cary-Blair medium which is a non-nutritive transport and preservation medium containing chloride salts, sodium salts, phosphate buffer, L-Cysteine, agar and water. The medium is designed to maintain the viability of enteric pathogenic bacteria during transit to the testing laboratory.

Copan FecalSwab Collection, Transport and Preservation System is supplied in a sterile collection kit format comprising a package containing a tube filled with 2 ml of FecalSwab transport and preservation medium and a regular size nylon flocked specimen collection swab. The flocked swab applicator can be used to collect the clinical rectal specimen or as a transferring tool for stool specimens.

Once the sample is collected, it should be placed immediately into the FecalSwab transport tube where it comes into contact with the transport medium. Swab specimens for bacterial investigations collected using the FecalSwab should be transported directly to the laboratory, preferably within 2 hours of collection (1-5,16, 17) to maintain optimum organism viability. If immediate delivery or processing is delayed, then specimens should be refrigerated at 2–8ºC and processed within 72 hours or stored at room temperature (20–25°C) and processed within 48 hours. In case of *C. difficile* culture investigation, specimens should be refrigerated at 2–8ºC and processed within 48 hours or stored at room temperature (20–25°C) and processed within 24 hours. Independent scientific studies on swab transport systems have shown that for certain bacteria viability is superior at refrigerated temperatures compared with room temperature (7, 9 - 10).

REAGENTS

FecalSwab Transport and Preservation Medium

Chloride salts
Sodium salts
Phosphate buffer
L-Cysteine
Agar
Distilled water

WARNINGS AND PRECAUTIONS

1. For In Vitro Diagnostic Use.
2. Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
3. ⊗ This product is for single use only; reuse may cause a risk of infection and/or inaccurate results.
4. Observe approved biohazard precautions and aseptic techniques. To be used only by adequately trained and qualified personnel.
5. All specimens and handled in a manner which prevents infection of laboratory personnel. Sterilize all biohazard waste including specimens, containers and media after their use. Observe other CDC Biosafety Level 2 recommendations (8, 12 - 15).
6. It must be assumed that all specimens contain infectious micro-organisms and materials used to process them should be considered potentially infectious. Therefore they must be handled with appropriate precautions and dispose according to laboratory regulations for infectious waste.
7. Directions should be read and followed carefully.
8. Tube label shows a maximum filling line. If sample collected exceeds maximum fill line discard the swab and the tube. A second specimen should be collected using a new Copan FecalSwab kit.
9. Do not re-sterilize unused products.
10. Do not re-pack.
11. Not suitable to collect and transport microorganisms other than enteric pathogenic bacteria.
12. Not suitable for any other application than intended use.
13. The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user.
14. Do not use if the swab is visibly damaged (i.e., if the swab tip or swab shaft is broken).
15. Do not use excessive force or pressure when collecting swab samples from patients as this may result in breakage of the swab shaft.
16. FecalSwab is qualified as Class IIa Medical Device according to European Medical Device Directive 93/42/EEC - Surgically Invasive Transient Use. Class IIa means swabs can be used for sampling body surfaces, body orifices (e.g., for example nose, throat, vagina, wounds, groin or skin).
17. Do not ingest the medium.
18. Do not use the FecalSwab medium for pre-moistening or pre-wetting the applicator swab prior to collecting the sample or for rinsing or irrigating the sampling sites

STORAGE

This product is ready for use and no further preparation is necessary. The product should be stored in its original container at 5 – 25°C until used. Do not overheat. Do not incubate or freeze prior to use. Improper storage will result in a loss of efficacy. Do not use after expiration date, which is clearly printed on the outer box and on each individual collection unit and the specimen transport tube label.

PRODUCT DETERIORATION

Copan FecalSwab should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of leakage, (3) the expiration date has passed, (4) the package is open, or (5) there are other signs of deterioration.

SPECIMEN COLLECTION, STORAGE AND TRANSPORTATION
Rectal swab specimens and stool specimens collected for microbiological investigations which comprise the isolation of enteric pathogenic bacteria should be collected and handled following published manuals and guidelines (1 - 5).

To maintain optimum organism viability, transport specimens collected using FecalSwab directly to the laboratory, preferably within 2 hours of collection (1–5,16,17). If immediate delivery or processing is delayed, then specimens should be refrigerated at 2 – 8ºC and processed within 72 hours or stored at room temperature (20 – 25°C) and processed within 48 hours. In case of *C. difficile* culture investigation, specimens should be refrigerated at 2–8ºC and processed within 48 hours or stored at room temperature (20–25°C) and processed within 24 hours.

Specific requirements for the shipment and handling of specimens should be in full compliance with state and federal regulations (12 - 15). Shipping of specimens within medical institutions should comply with internal guidelines of the institution. All specimens should be processed as soon as they are received in the laboratory.

MATERIALS SUPPLIED
Fifty (50) FecalSwab collection kits are contained in a shelf pack and 10 x 50 units are contained in a box. Each collection kit consists of a package containing a plastic screw-cap tube with conical shaped bottom filled with 2 ml of FecalSwab transport and preservation medium and a specimen collection swab that has a tip flocked with soft nylon fiber.

MATERIALS REQUIRED BUT NOT SUPPLIED
Appropriate materials for isolating and culturing enteric pathogenic bacteria. These materials include culture media plates or tubes and incubation systems. Refer to laboratory reference manuals for recommended protocols for culture and identification techniques for enteric pathogenic bacteria from clinical swab samples (1 - 5).

DIRECTIONS FOR USE
The Copan FecalSwab Collection, Transport and Preservation System is available in product configurations indicated in the table below.

Table 1

Catalog No.	Copan FecalSwab Product Descriptions	Pack Size	Capture Cap Feature
4C024S	Single use sample collection pack containing: - Polypropylene screw-cap tube with internal conical shape filled with 2ml of FecalSwab Medium. - One regular size applicator swab with flocked nylon fiber tip.	50 units per shelf pack 10x50 units per box	YES

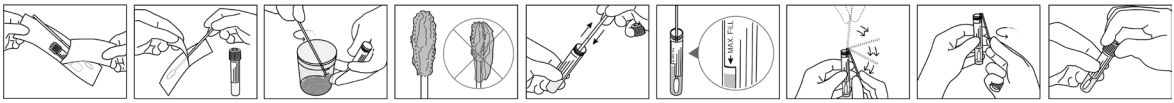
Specimen Collection

Proper specimen collection from the patient is extremely critical for successful isolation and identification of infectious organisms. The patient should be cautioned against the use of antacids, barium, bismuth, anti-diarrheal medication, antibiotics, histamine, nonsteroidal anti-inflammatory drug or oily laxatives prior to collection of the specimen (22, 23).

For Rectal Swab Collection:

1. Peel open the kit package and remove the tube of medium and the flocked swab applicator (see Figure 1a).
2. Use the flocked swab to collect the clinical specimen. The operator must touch the swab applicator only above the marked breakpoint line (the area from the line to the end of the swab shaft), as illustrated in Figure 2, which is the opposite end to the nylon fiber tip. At all times when handling the swab applicator, the operator must not touch the area below the marked breakpoint line as this will lead to contamination of the applicator shaft and the subsequent culture thus invalidating the test results.
3. Insert the flocked swab through the rectal sphincter 2 to 3 cm (1-1.5 inches) and gently rotate (17).
4. Withdraw and examine to make sure there is fecal material visible on the tip (16).
5. After collection, transfer the swab into the tube with the preservation medium and visually check that the maximum filling line (“MAX. FILL”) indicated on the label is not exceeded. NOTE: If sample collected exceeds maximum fill line discard the swab and the tube. A second specimen should be collected using a new Copan FecalSwab kit.
6. Holding the swab shaft between thumb and finger, mash and mix the stool specimen against the side of the tube to evenly disperse and suspend the specimen in the preservation medium.
7. Hold the tube away from your face. Holding the swab shaft close to the rim of the tube, bend it at a 180 degrees angle to break it off at the marked breakpoint. If needed, gently rotate the shaft to completely remove it. Discard the broken upper part of the swab shaft and tighten the cap.
8. Shake the vial until the sample appears homogeneous
9. Write patient’s name and demographics on the tube label and send the sample to the laboratory

Fig 1a. Operation of the FecalSwab Collection, Transport and Preservation System For Rectal Swab Collection



For Stool Specimen Collection:

1. Have the patient obtain stool specimen. Stool specimen should not contain urine or water (23). Patient should pass the stool into a clean, dry pan or a special container mounted on the toilet for this purpose. **Note:** Toilet paper is not suitable to collect stool because it may be impregnated with barium salts, which are inhibitory to some fecal pathogens (18,23).
2. Peel open the kit package and remove the tube of medium and the flocked swab applicator (see Figure 1.b).
3. The operator must touch the swab applicator only above the marked breakpoint line (the area from the line to the end of the swab shaft), as illustrated in Figure 2, which is the opposite end to the nylon fiber tip. At all times when handling the swab applicator, the operator must not touch the area below the marked breakpoint line (the area from the line to the tip of the nylon flocked swab) as this will lead to contamination of the applicator shaft and the subsequent culture thus invalidating the test results.
4. Collect a small amount of stool by inserting all the tip of the flocked swab into stool sample and rotate it (18). Bloody, slimy or watery area of stools should be selected and sampled (16, 19, 20, 21).
5. After collection examine the swab to make sure there is fecal material visible on the tip (16). In case it is not, insert again the flocked swab into stool sample and rotate taking care all the area of the swab tip is in contact with the sample.
6. NOTE: the swab should not be used as a paddle or spoon but as a probe. DO NOT try to collect and transfer an excessive amount of fecal sample into the transport medium tube. The swab tip only needs to be coated with sample material.
7. After collection, transfer the swab into the tube with the preservation medium and visually check that the maximum filling line ("MAX. FILL") indicated on the label is not exceeded. NOTE: If sample collected exceeds maximum fill line discard the swab and the tube. A second specimen should be collected using a new Copan FecalSwab kit.
8. Holding the swab shaft between thumb and finger, mash and mix the stool specimen against the side of the tube to evenly disperse and suspend the specimen in the preservation medium.
9. Hold the tube away from your face. Holding the swab shaft close to the rim of the tube, bend it at a 180 degrees angle to break it off at the marked breakpoint. If needed, gently rotate the shaft to completely remove it. Discard the broken upper part of the swab shaft and tighten the cap.
10. Shake the vial until the sample appears homogeneous.
11. Write patient's name and demographics on the tube label and send the sample to the laboratory.

Fig 1.b Operation of the FecalSwab Collection, Transport and Preservation System For Stool Specimen Collection

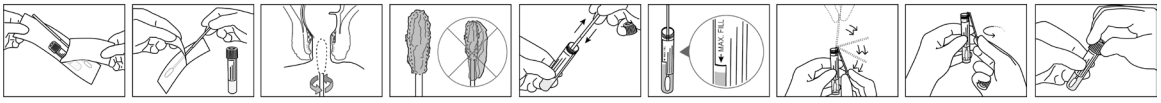
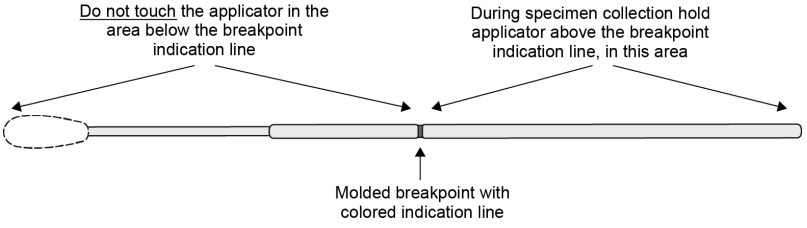
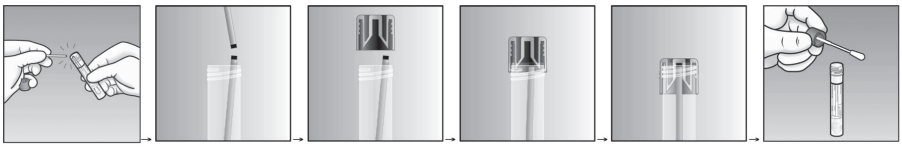


Fig 2. Collection swab showing breakpoint indication line and area for holding the applicator



The operator must only handle the part of the swab applicator shaft above the breakpoint indication line as shown in Fig 2. After the swab sample is taken from the patient or from the stool specimen, the maximum fillig line checked, the swab applicator shaft is broken off at the marked breakpoint indication line into the FecalSwab tube of transport medium. The operator then discards the handle part of the swab. The tube's screw cap is then replaced and secured tightly. The action of screwing the cap onto the tube moves the end of the broken swab shaft into a funnel shaped molded docking receptacle in the cap (see Fig 3). This molded funnel shape captures the end of the broken applicator shaft and secures it firmly in the dock by friction grip.

Fig 3. Capture of broken swab applicator stick by FecalSwab tube cap



In the testing laboratory when the FecalSwab cap is unscrewed and removed, the swab applicator stick is securely attached to the cap. This feature allows the operator to conveniently remove the swab and perform various microbiology analyses using the tube cap as a handle to hold and manipulate the swab.

Processing FecalSwab Specimens in the Laboratory – Bacteriology

FecalSwab samples should be processed for bacteriological culture using recommended culture media and laboratory techniques which will depend on the specimen type and the organism under investigation. For recommended culture media and techniques for the isolation and identification of bacteria from clinical swab specimens refer to published microbiology manuals and guidelines (1 - 5).
Culture investigations of swab specimens for the presence of bacteria routinely involve the use of solid agar culture medium in Petri dish plates. The procedure for inoculation of FecalSwab samples onto solid agar in Petri dishes is as follows.

Note: Wear latex gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe other CDC Biosafety Level 2 recommendations (8, 12-15).

Vortex mix the FecalSwab tube containing the swab sample for 5 seconds to evenly disperse and suspend the patient specimen in the medium

1. Unscrew the FecalSwab cap and remove the swab applicator.
2. Roll the tip of the FecalSwab applicator onto the surface of one quadrant of the culture media plate to provide the primary inoculum.
3. If it is necessary to culture the swab specimen onto a second culture media plate, return the FecalSwab applicator to the transport medium tube for two seconds to absorb and recharge the applicator tip with transport medium/patient sample suspension then repeat Step No. 3.
4. If it is necessary to inoculate additional culture media plates, return the FecalSwab applicator to the transport medium tube and recharge the swab applicator tip with the transport medium/patient sample suspension before inoculating each additional plate.

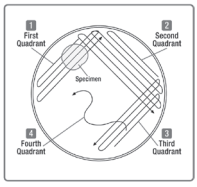
The procedure described above utilizes the FecalSwab applicator like an inoculation wand to transfer the suspension of patient sample in transport medium onto the surface of a culture plate creating the primary inoculum (see Fig 4-1).
Alternatively, the operator can vortex mix the FecalSwab tube with the swab inside for 5 seconds and then transfer 100µl volumes of the suspension onto each culture plate using a volumetric pipettor and sterile pipet tips (see Fig 4-2). Standard laboratory techniques should then be used to streak the primary inoculum of patient sample across the surface of the culture plate (see Fig 5).
Note that following approved internal laboratory procedures, different volumes of suspension can be transferred onto each culture plate using inoculating loops, volumetric pipettor and sterile pipet tips.

Fig 4. Procedures for inoculation of FecalSwab specimens onto solid agar in Petri dishes

1. Using swab to inoculate specimen

2. Using pipettor and sterile pipet tips to inoculate 100µl of specimen

Fig 5. Procedure for streaking FecalSwab specimens on agar Petri dishes for primary isolation (15)



Seed a primary inoculum of FecalSwab specimen onto the surface of an appropriate agar culture plate in the first quadrant.

Use a sterile bacteriology loop to streak the primary inoculum across the surface of the second, third and fourth quadrants of the agar culture plate.

FecalSwab QUALITY CONTROL
FecalSwab applicators are tested to ensure they are non-toxic to enteric pathogenic bacteria. FecalSwab transport medium is tested for pH stability. FecalSwab is quality control tested before release for ability to maintain viable enteric pathogenic bacteria at room temperature (20 – 24°C) for specified time points.

Procedures for quality control of microbiology transport devices should be conducted using testing methods described in Clinical and Laboratory Standards Institute M40-A2 and other publications (6). If aberrant quality control results are noted, patient results should not be reported.

LIMITATIONS

1. For recovery of *C. difficile*, FecalSwab specimens should be refrigerated at 2–8ºC and processed within 48 hours or stored at room temperature (20–25°C) and processed within 24 hours.

In the laboratory, wear latex gloves and other protection commensurate with universal precautions when handling clinical specimens. Observe other CDC Biosafety Level 2 recommendations (8, 12 - 15) when handling or analyzing patient samples.

2. Condition, timing and volume of specimen collected for culture are significant variables in obtaining reliable culture results. Follow recommended guidelines for specimen collection (1 – 5, 7, 9, 10).
3. FecalSwab is intended for use as a collection and transport medium for enteric pathogenic bacteria. FecalSwab cannot be used as enrichment, selective or differential medium.
4. Performance testing with Copan FecalSwab was conducted using laboratory strains spiked onto a swab following the test protocols based on those described in CLSI M40-A2(6).
5. Performance testing with Copan FecalSwab was conducted using Copan flocked swabs.

RESULTS

Results obtained will largely depend on proper and adequate specimen collection, as well as timely transport and processing in the laboratory.

PERFORMANCE CHARACTERISTICS

The test procedures employed for determining bacterial viability performance were based upon the quality control methods described in CLSI M40-A2 (6).

FecalSwab system has an intended use limited to enteric pathogenic bacteria, therefore its field application is restricted to fecal/stool specimen. For this reason the bacterial recovery studies were conducted with the following microorganisms. described and defined in CLSI M40-A2, *Quality Control of Microbiological Transport Systems: Approved Standard* and included only the following enteric pathogenic bacteria strains from the paragraph 9.3.1 of the CLSI M40-A2 document, in particular:

Escherichia coli	ATCC® 25922
Salmonella typhimurium	ATCC® 14028
Shigella flexneri	ATCC® 12022

In addition, Copan included testing of additional clinically relevant enteric pathogenic bacteria. The specific bacterial strains used in these studies are here listed:

Campylobacter jejuni	ATCC® 33291
Yersinia enterocolitica	ATCC® 9610
Vibrio parahaemolyticus	ATCC® 17802
Enterococcus faecalis vancomycin resistant (VRE)	ATCC® 51299
Escherichia coli O157:H7	ATCC® 700728
Clostridium difficile	ATCC® 9689

In addition, Copan included an evaluation of overgrowth as per CLSI M40-A2 document with the following strain:

Pseudomonas aeruginosa	ATCC® BAA-427

All cultures of bacteria were ATCC (American Type Culture Collection) and were obtained commercially.

The selection of these organisms also reflects those enteric pathogenic bacteria of potential interest from rectal and stool specimens that can be present in specimens collected and analyzed in a typical clinical microbiology laboratory.

Bacterial viability studies were performed on inoculated Copan FecalSwab hold at two different ranges of temperature, 2 – 8°C and 20 – 25°C, corresponding to cold temperature and controlled room temperature, respectively. FecalSwab collection swabs were inoculated with 100µl of specific concentrations of organism suspension. Swabs were then placed in transport medium tubes and were held for 0 hrs, 6hrs, 24 hrs, 48 hrs and 72 hrs (72 hours is applicable only for the 2 – 8°C cold temperature range). At the appropriate time intervals, each transport tube was processed swabbing onto appropriate agar plate.

Additional viability tests were performed on *E. coli O157:H7* ATCC® 700728, *Vibrio parahaemolyticus (ATCC® 17802)* and *Salmonella typhimurium (ATCC®14028)* with fecal matrix in order to test the device under the conditions of its intended use.

TEST RESULTS

Viability performance is measured for each test organism at the 48 hrs time point when tubes were held at controlled room temperature (20 – 25°C), or at the 72 hrs time point when held at cold temperature (2 – 8°C), and compared with the acceptance criteria.

Copan FecalSwab System was able to maintain acceptable recovery of all organisms evaluated at both cold temperature (2 – 8ºC) and controlled room temperature (20 – 25ºC). In case of *C. difficile* culture investigation, specimens should be refrigerated at 2–8ºC and processed within 48 hours or stored at room temperature (20–25°C) and processed within 24 hours. Acceptable recovery is defined as a plate count that remains within 2 $\log_{10}$ of the initial microorganism concentration for each microorganism tested.

SUMMARY OF RESULTS FOR BACTERIAL RECOVERY IN PBS

		Average CFU recovered n = 9 (from 3 lots)					T=72 hrs Log reduction (-) or Log increase (+)
Organism*	**Holding Temperature**	**Time 0 hrs**	**Time 6 hrs**	**Time 24 hrs**	**Time 48 hrs**	**Time 72 hrs**	
***Escherichia coli* ATCC 25922**	2-8°C	1.07E+02	1.12E+02	8.46E+01	8.31E+01	7.29E+01	**-0.17**
	20-25°C	1.07E+02	1.35E+02	1.32E+03	5.72E+03	NA	**1.73**
***Escherichia coli O157:H7* ATCC 700728**	2-8°C	8.99E+01	1.01E+02	1.04E+02	1.07E+02	1.04E+02	**0.06**
	20-25°C	8.99E+01	1.28E+02	2.57E+02	4.12E+03	NA	**1.66**
***Salmonella typhimurium* ATCC 14028**	2-8°C	1.38E+02	1.41E+02	1.59E+02	1.58E+02	9.70E+01	**-0.15**
	20-25°C	1.38E+02	5.84E+02	2.27E+03	9.72E+03	NA	**1.85**
***Shigella flexneri* ATCC 12022**	2-8°C	1.27E+02	1.26E+02	4.16E+01	1.46E+02	1.16E+02	**-0.04**
	20-25°C	1.27E+02	4.76E+02	1.91E+03	9.67E+03	NA	**1.88**
***Clostridium difficile* ATCC 9689**	2-8°C	4.42E+01	2.26E+01	6.03E+00	6.30E-01	NA	**-1.85****
	20-25°C	4.42E+01	1.77E+01	5.30E-01	NA	NA	**-1.92****
***Vibrio parahaemolyticus* ATCC 17802**	2-8°C	2.00E+02	1.78E+02	1.76E+02	1.68E+02	1.54E+02	**-0.11**
	20-25°C	2.00E+02	2.22E+02	1.62E+03	1.58E+04	NA	**1.90**
***Enterococcus faecalis vancomicin resistant (VRE)* ATCC 51299**	2-8°C	1.68E+02	1.67E+02	1.52E+02	4.38E+02	1.16E+02	**-0.16**
	20-25°C	1.68E+02	1.70E+02	4.39E+02	2.26E+03	NA	**1.13**
***Yersinia enterocolitica* ATCC 9610**	2-8°C	1.17E+02	1.14E+02	1.12E+02	1.09E+02	1.04E+02	**-0.05**
	20-25°C	1.17E+02	1.72E+02	1.24E+03	9.78E+03	NA	**1.92**
***Campylobacter jejuni* ATCC 33291**	2-8°C	2.14E+02	1.66E+02	1.33E+02	8.63E+01	3.42E+01	**-0.80**
	20-25°C	2.14E+02	1.68E+02	5.83E+01	4.28E+00	NA	**-1.70**

* the organism was diluted in PBS and the pure suspension tested in studies based on CLSI M40-A2
** log difference at Time 48 hrs for hold at 2 - 8°C and at Time 24 hours for hold at 20 – 25°C
NA – not applicable; devices held at 20 – 25°C were not tested at Time 72 hrs

SUMMARY OF RESULTS FOR BACTERIAL RECOVERY IN FECAL MATRIX

		Average CFU recovered n = 9 (from 3 lots)					T=72 hrs Log reduction (-) or Log increase (+)
Organism*	**Holding Temperature**	**Time 0 hrs**	**Time 6 hrs**	**Time 24 hrs**	**Time 48 hrs**	**Time 72 hrs**	
***Escherichia coli O157:H7* ATCC 700728**	2-8°C	1.23E+02	1.37E+02	1.38E+02	1.53E+02	1.60E+02	**0.11**
	20-25°C	1.23E+02	1.34E+02	7.48E+02	7.54E+03	NA	**1.79**

***Salmonella typhimurium* ATCC 14028**	2-8°C	9.46E+01	1.05E+02	1.20E+02	1.32E+02	1.43E+02	**0.18**
	20-25°C	9.46E+01	1.17E+02	6.51E+02	6.38E+03	NA	**1.83**
***Vibrio parahaemolyticus* ATCC 17802**	2-8°C	1.11E+02	1.21E+02	1.29E+02	1.26E+02	1.36E+02	**0.09**
	20-25°C	1.11E+02	1.34E+02	1.14E+03	7.36E+03	NA	**1.82**

* the organism was diluted in fecal matrix and the suspension tested in studies based on CLSI M40-A2
NA – not applicable; devices held at 20 – 25°C were not tested at Time 72 hrs

SUMMARY OF RESULTS FOR BACTERIAL OVERGROWTH STUDY AT 4-8°C

		Average CFU recovered n = 9 (from 3 lots)			**T=48 hrs Log reduction (-) or Log** increase (+)
Organism	**Holding Temperature.**	**Time 0 hrs**	**Time 24 hrs**	**Time 48 hrs**	
Pseudomonas aeruginosa ATCC BAA-427	4-8°C	3.79E+01	3.45E+01	3.22E+01	**-0.07**

* the organism was diluted in PBS and the pure suspension tested in studies based on CLSI M40-A2

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Index of Symbols

Symbol	Meaning
	Manufacturer
CE 0123	Identification number of notified body
STERILE R	Sterile – Method using irradiation
	Do no reuse
REF	Catalogue number.
	Temperature limitation
	Use by
	Consult Instructions for Use
	Peel
LOT	Batch code (Lot)
	Contains sufficient for <n> tests
	Handle with care
	Do not use if package is damaged

 CE 0123

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