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# Puritan<sup>®</sup> Fecal Opti-Swab<sup>®</sup> Collection and Transport System

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# Puritan<sup>®</sup> Fecal Opti-Swab<sup>®</sup>

## Collection and Transport System

**Rx Only**

### Intended Use

Puritan<sup>®</sup> Fecal Opti-Swab<sup>®</sup> Collection and Transport System is intended for use in the collection and transport of clinical fecal and rectal swab specimens to preserve the viability of enteric bacteria during transport from the collection site to the testing laboratory for bacteriological examination and culture.

### Summary and Principles

Foodborne illnesses and other diarrheal infections present as a major public health issue. While enteric infections can be caused by different types of bacteria, most routine stool cultures are used to screen for *Salmonella* spp., *Shigella* spp., and *Campylobacter* spp. Cultures for *Vibrio* spp., *Yersinia* spp., *E. coli* O157:H7, *C. difficile* and *E. faecalis vancomycin resistant* (VRE) require additional media or incubation conditions and therefore require more extensive preparation.<sup>1, 2, 3</sup>

The Puritan Fecal Opti-Swab Collection and Transport System allows for collection of rectal swab or stool samples as well as preserve the samples prior to laboratory processing.

Each kit is comprised of a sterile peel pouch containing a HydraFlock<sup>®</sup> swab applicator for specimen collection, and a polypropylene screw-cap vial containing 2 mL of Fecal Opti-Swab medium. The HydraFlock swab applicator can be used to collect the clinical rectal specimen or as a transferring tool for stool specimens. Once the specimen is collected with a swab, it is placed inside the vial containing Fecal Opti-Swab medium and transported to the laboratory for processing.<sup>4</sup>

Fecal Opti-Swab medium is a nonnutritive balanced salt solution containing phosphates to provide buffering capability, and chloride salts to provide essential ions that help maintain osmotic balance. Agar is a solidifying agent that increases the viscosity of the medium. Sodium thioglycolate and L-cysteine provide an oxygen-reduced environment that aids in maintaining the viability of enteric bacteria during transport to the laboratory.<sup>5</sup>

### Reagents

#### Fecal Opti-Swab Medium

Sodium chloride	Disodium phosphate	Sodium thioglycolate	
Calcium chloride	L-cysteine	Bacteriological agar	Deionized water

### Precautions

#### For *in vitro* Diagnostic Use

- For single use only.
- All clinical specimens may contain infectious microorganisms and should be considered biohazards and handled with care. Appropriate personal protective equipment should be worn. Follow laboratory and biosafety guidelines when handling clinical specimens.<sup>6-9</sup>
- For use by trained qualified personnel.
- Read and follow the instructions in this package insert carefully and use aseptic techniques.
- Refer to the recommendations of the Center for Disease Control and Prevention's *Biosafety in Microbiological and Biomedical Laboratories*.<sup>6-9</sup>
- The content of the kit is sterile as long as the package integrity is not compromised.
- Do not use the device if the sterile peel pouch seal is damaged.
- Sterilize the unit after use and dispose of it according to biohazard waste disposal regulations.
- Do not use beyond expiry date.
- Do not ingest the medium.

### Storage

For optimum performance, store at 2-25°C (36-77°F). Avoid freezing and excessive heat.

### Materials Provided

Each Puritan Fecal Opti-Swab Collection and Transport System includes a sterile pre-labeled and polypropylene screw-cap vial containing 2 mL of Fecal Opti-Swab medium and one HydraFlock swab.

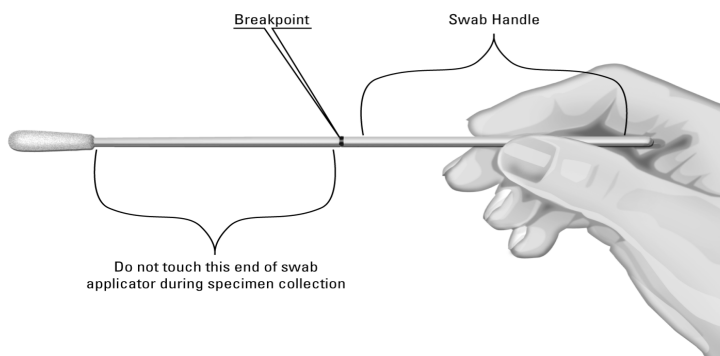
## Materials Not Provided

Materials for cultivation, isolation, identification and other microbiological procedures of bacteria from clinical specimens are not provided. Refer to standard laboratory procedures or referenced standards for the cultivation, isolation and identification of bacteria from clinical specimens.<sup>10</sup>

## Directions for Use

Care should be taken to avoid splashes and aerosols when breaking the swab handle into the vial containing medium. When collecting specimen with swab applicator, the area below the color printed breakpoint must not be touched (area from the breakpoint to the tip of the HydraFlock flocked swab).

**Figure 1. Collection swab showing breakpoint indication line and proper hand placement.**



## For Rectal Swab Collection:

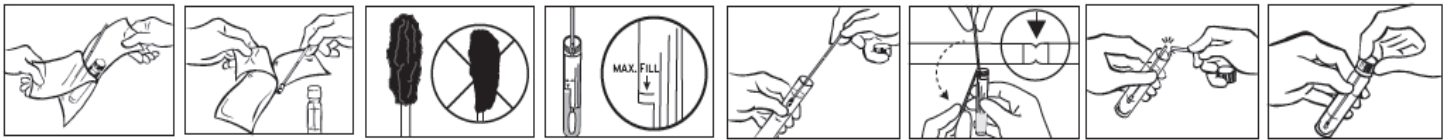
- [1] Peel open sterile pouch and remove the vial of medium and the HydraFlock swab. *Do not touch the swab tip.*
- [2] Collect rectal specimen by inserting the HydraFlock swab through the rectal sphincter 2 to 3 cm and gently rotate.<sup>11</sup>
- [3] Withdraw and examine to make sure there is fecal material visible on the swab tip.<sup>11</sup>
- [4] Using appropriate aseptic technique, remove the vial cap and insert the swab into the vial. Visually confirm the "Max Fill" line is not exceeded. If the sample exceeds the "Max Fill" line, the sample should be discarded and a second sample should be collected.
- [5] Holding the swab shaft between thumb and finger, mash and mix the stool specimen against the side of the vial to evenly disperse and suspend the specimen in the medium.
- [6] Place the swab shaft with the breakpoint against the rim of the vial. Bend and break the swab shaft at the breakpoint.
- [7] Replace the vial cap, securing tightly. Record patient information in the space provided on the vial label and transport the specimen to the laboratory.

## For Stool Specimen Collection:

- [1] Have the patient pass stool into a clean, dry pan or a special container mounted on the toilet.
- [2] Peel open sterile pouch and remove the vial of medium and the HydraFlock swab. *Do not touch the swab tip.*
- [3] Collect a small amount of stool by inserting entire tip of the HydraFlock swab into stool sample and rotate it. Bloody, slimy or watery area of stools should be selected and sampled.<sup>12</sup>
- [4] Withdraw and examine to make sure there is fecal material visible on the swab tip.<sup>11</sup>
- [5] Using appropriate aseptic technique, remove the vial cap and insert the swab into the vial. Visually confirm the "Max Fill" line is not exceeded. If the sample exceeds the "Max Fill" line, the sample should be discarded and a second sample should be collected.

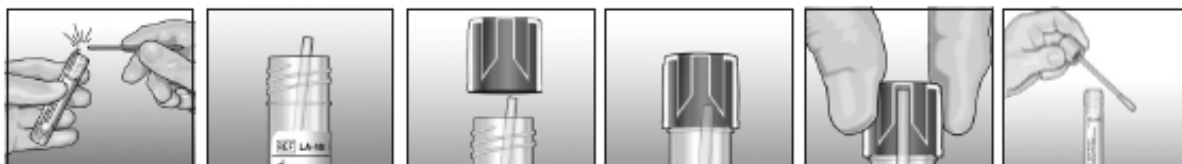
- [6] Holding the swab shaft between thumb and finger, mash and mix the stool specimen against the side of the vial to evenly disperse and suspend the specimen in the medium.
- [7] Place the swab shaft with the breakpoint against the rim of the vial. Bend and break the swab shaft at the breakpoint.
- [8] Replace the vial cap, securing tightly. Record patient information in the space provided on the vial label and transport the specimen to the laboratory.

**Figure 2. Specimen Collection Instructions for Use**



Puritan Fecal Opti-Swab Collection and Transport System is offered with swab capture feature. After collecting specimen, place the swab inside the vial and break the handle at the breakpoint. The broken off handle is discarded. The cap is replaced and tightly secured.

**Figure 3. Capture of broken swab applicator stick by vial cap.**



## **Specimen Collection, Storage and Transport**

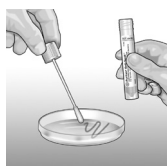
Proper specimen collection is critical for successful isolation and identification of infectious organisms. For specific guidance regarding specimen collection procedures, consult published reference manuals.<sup>4, 13, 15</sup> To maintain optimum organism viability, transport the specimens collected using Puritan Fecal Opti-Swab Collection and Transport System to the laboratory within 2 h of collection. Specimens should be processed as soon as they are received in the laboratory. If immediate processing is delayed, then specimens should be refrigerated at 2-8°C or stored at room temperature (20-25°C) and processed within 48 hours when stored at room temperature or 72 hours when refrigerated, unless *C. difficile* infection is suspected. In case of *C. difficile* culture investigation, specimens should be refrigerated and processed within 48 hours or stored at room temperature and processed within 24 hours.

## **Specimen Cultures in the Laboratory**

### **Manual Processing**

- [1] Vortex or mix well by shaking the Fecal Opti-Swab vial with the swab inside to release cells and create even suspension in the medium.
- [2] Remove the cap with swab applicator.
- [3] Using the swab applicator, streak the first quadrant of an agar plate while rolling the swab tip to create a primary inoculum. If additional plates are required replace swab back into the vial for a few seconds to recharge the swab and repeat section 3. Alternatively, a pipette with a sterile pipette tip can be used to transfer 100µl of the suspension onto an agar plate.
- [4] Use standard laboratory practices to streak or spread the primary inoculum of the specimen onto the rest of the agar culture plate.

Manual processing *with* swab applicator



Manual processing *without* swab applicator



Streak plating example



In the laboratory, specimens should be processed for bacteriological culture using recommended culture media and laboratory techniques depending 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.<sup>4, 10, 13-15</sup>

## Quality Control

Each lot of Puritan Fecal Opti-Swab Collection and Transport System is tested for sterility, pH, and nonviable bio-burden levels. Representative samples of each lot are further evaluated for their ability to maintain the viability of selected bacterial agents over pre-defined time periods.

All bacterial test isolates and testing procedures were established using criteria outlined in the Clinical and Laboratory Standards Institute's M40-A2 document.<sup>14</sup>

## Limitations

1. For optimal recovery of *C. difficile*, fecal specimens should be refrigerated at 2-8°C and processed within 48 hours or stored at room temperature (20-25°C) and processed within 24 hours.
2. Reliable specimen collection and transport depends on many factors, including collection and handling, specimen condition, volume, and timing. Best results are achieved when specimens are processed shortly after the time of collection. For detailed information, refer to corresponding reference standards and procedures for optimum collection techniques.<sup>10, 13, 15, 16, 17</sup>
3. Puritan Fecal Opti-Swab Collection and Transport System is recommended for the collection and transport of bacteriological samples only. Viruses, chlamydia, mycoplasma, and ureaplasma require a transport medium formulated specifically for use with these organisms.<sup>5, 16</sup>
4. Extreme temperature should be avoided during transportation of Puritan Fecal Opti-Swab Collection and Transport System.
5. Viability of microorganisms in Puritan Fecal Opti-Swab Collection and Transport System other than the ones shown in the Performance Characteristics section has not been established.

## Performance Characteristics

The performance characteristics of Puritan Fecal Opti-Swab Collection and Transport System were determined using the Roll-Plate and Swab Elution Methods outlined in the Clinical Laboratory Standards Institute (CLSI) M40-A2 document.<sup>14</sup> The enteric bacteria listed below (acquired from ATCC) were evaluated in this study. To perform viability studies, the swabs from each transport system were inoculated with a specified volume of select bacterial concentrations. These swabs were then placed in their respective transport vial and held for 0, 24, 48 hours at room temperature (20-25°C) and 0, 24, 48, and 72 at refrigerated (2-8°C); at the designated time intervals the swabs were removed and processed.

### Organisms evaluated:

Prepared in 30% fecal matrix:

*Escherichia coli* 0157:H7 ATCC 700728, *Salmonella typhimurium* ATCC 14028, and *Vibrio parahaemolyticus* ATCC 17802

Prepared in 0.85% sodium chloride saline:

*Escherichia coli* ATCC 25922, *Escherichia coli* 0157:H7 ATCC 700728, *Salmonella typhimurium* ATCC 14028, *Shigella sonnei* ATCC 12022, *Vibrio parahaemolyticus* ATCC 17802, *Enterococcus faecalis vancomycin resistant* (VRE) ATCC 51299, *Yersinia enterocolitica* ATCC 9610, *Campylobacter jejuni* ATCC 33291, and *Clostridium difficile* ATCC 9689.

Puritan Fecal Opti-Swab Collection and Transport System was able to maintain viability of all organisms, except *C. difficile*, up to 48 hours at room temperature and 72 hours at refrigerated. *C. difficile* was able to remain viable up to 24 hours at room temperature and 48 hours at refrigerated.

**Table 1. Recovery results for bacteria prepared in fecal matrix for Puritan Fecal Opti-Swab Collection and Transport System using Roll-Plate Method at room temperature (20-25°C).**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 <sup>-4</sup>	Puritan 151002	51	145	269
		Puritan 151026	38	118	244
		Puritan 151105	44	126	257
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 <sup>-4</sup>	Puritan 151002	63	148	355
		Puritan 151026	57	139	337
		Puritan 151105	45	123	314
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 <sup>-4</sup>	Puritan 151002	80	258	195
		Puritan 151026	57	234	152
		Puritan 151105	65	243	208

**Table 2. Recovery results for bacteria prepared in fecal matrix for Puritan Fecal Opti-Swab Collection and Transport System using Roll-Plate Method in refrigerated (2-8°C) conditions.**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs	Average CFU's Recovered: Time 72 hrs
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 <sup>-4</sup>	Puritan 151002	51	44	29	23
		Puritan 151026	38	31	25	16
		Puritan 151105	44	36	26	14
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 <sup>-4</sup>	Puritan 151002	63	49	37	21
		Puritan 151026	57	51	42	33
		Puritan 151105	45	36	29	22
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 <sup>-4</sup>	Puritan 151002	80	125	69	53
		Puritan 151026	57	93	46	39
		Puritan 151105	65	109	61	47

**Table 3. Recovery results for bacteria prepared in fecal matrix for Puritan Fecal Opti-Swab Collection and Transport System using Swab Elution Method at room temperature (20-25°C).**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 24 hrs	Average CFU/mL Recovered: Time 48 hrs	Log reduction (-) or Log increase (+)
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan 151002	$4.7 \times 10^5$	$1.21 \times 10^6$	$2.48 \times 10^6$	0.72
		Puritan 151026	$3.2 \times 10^5$	$1.06 \times 10^6$	$2.16 \times 10^6$	0.83
		Puritan 151105	$3.9 \times 10^5$	$1.17 \times 10^6$	$2.22 \times 10^6$	0.76
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 151002	$2.9 \times 10^5$	$8.4 \times 10^5$	$1.51 \times 10^6$	0.72
		Puritan 151026	$7.1 \times 10^5$	$1.41 \times 10^6$	$3.14 \times 10^6$	0.65
		Puritan 151105	$6.7 \times 10^5$	$1.46 \times 10^6$	$3.29 \times 10^6$	0.69
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 151002	$5.8 \times 10^5$	$1.37 \times 10^6$	$3.12 \times 10^6$	0.73
		Puritan 151026	$5.4 \times 10^5$	$1.28 \times 10^6$	$2.46 \times 10^6$	0.66
		Puritan 151105	$4.9 \times 10^5$	$1.14 \times 10^6$	$2.59 \times 10^6$	0.72

**Table 4. Recovery results for bacteria prepared in fecal matrix for Puritan Fecal Opti-Swab Collection and Transport System using Swab Elution Method in refrigerated (2-8°C) conditions.**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU/mL Recovered: Time 0 hrs	Average CFU/mL Recovered: Time 24 hrs	Average CFU/mL Recovered: Time 48 hrs	Average CFU/mL Recovered: Time 72 hrs	Log reduction (-) or Log increase (+)
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan 151002	$4.7 \times 10^5$	$4.0 \times 10^5$	$3.1 \times 10^5$	$1.9 \times 10^5$	-0.39
		Puritan 151026	$3.2 \times 10^5$	$2.7 \times 10^5$	$2.0 \times 10^5$	$1.5 \times 10^5$	-0.33
		Puritan 151105	$3.9 \times 10^5$	$3.2 \times 10^5$	$2.5 \times 10^5$	$1.4 \times 10^5$	-0.44
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 151002	$2.9 \times 10^5$	$1.8 \times 10^5$	$1.1 \times 10^5$	$8.0 \times 10^4$	-0.56
		Puritan 151026	$7.1 \times 10^5$	$6.3 \times 10^5$	$4.8 \times 10^5$	$3.6 \times 10^5$	-0.29
		Puritan 151105	$6.7 \times 10^5$	$5.7 \times 10^5$	$4.1 \times 10^5$	$2.9 \times 10^5$	-0.36
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 151002	$5.8 \times 10^5$	$4.8 \times 10^5$	$3.9 \times 10^5$	$3.1 \times 10^5$	-0.27
		Puritan 151026	$5.4 \times 10^5$	$4.5 \times 10^5$	$3.2 \times 10^5$	$2.4 \times 10^5$	-0.35
		Puritan 151105	$4.9 \times 10^5$	$3.8 \times 10^5$	$3.0 \times 10^5$	$2.4 \times 10^5$	-0.31

**Table 5. Recovery results for bacteria prepared in saline for Puritan Fecal Opti-Swab Collection and Transport System using Roll-Plate Method at room temperature (20-25°C).**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs
<i>Escherichia coli</i> ATCC 25922	Diluted 10 <sup>-4</sup>	Puritan 160311	52	164	299
		Puritan 160315	38	157	282
		Puritan 160322	44	142	278
<i>Shigella sonnei</i> ATCC 12022	Diluted 10 <sup>-4</sup>	Puritan 160311	40	153	275
		Puritan 160315	56	169	314
		Puritan 160322	30	146	251
<i>Yersinia enterocolitica</i> ATCC 9610	Diluted 10 <sup>-4</sup>	Puritan 160311	58	216	315
		Puritan 160315	65	228	356
		Puritan 160322	51	209	318
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 <sup>-4</sup>	Puritan 160311	56	137	254
		Puritan 160315	43	123	209
		Puritan 160322	34	116	196
<i>Enterococcus faecalis vancomycin resistant</i> (VRE) ATCC 51299	Diluted 10 <sup>-4</sup>	Puritan 160311	32	89	156
		Puritan 160315	45	98	153
		Puritan 160322	37	91	149
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 <sup>-4</sup>	Puritan 160311	55	176	326
		Puritan 160315	42	157	299
		Puritan 160322	47	168	285
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 <sup>-4</sup>	Puritan 160311	80	236	328
		Puritan 160315	73	224	316
		Puritan 160322	67	215	311
<i>Campylobacter jejuni</i> ATCC 33291	Diluted 10 <sup>-4</sup>	Puritan 160311	238	165	31
		Puritan 160315	246	172	27
		Puritan 160322	231	158	23
<i>Clostridium difficile</i> ATCC 9689	Diluted 10 <sup>-4</sup>	Puritan 160311	88	18	
		Puritan 160315	62	13	
		Puritan 160322	57	11	

**Table 6. Recovery results for bacteria prepared in saline for Puritan Fecal Opti-Swab Collection and Transport System using Roll-Plate Method in refrigerated (2-8°C) conditions.**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs	Average CFU's Recovered: Time 72 hrs
<i>Escherichia coli</i> ATCC 25922	Diluted 10 <sup>-4</sup>	Puritan 160311	52	48	31	19
		Puritan 160315	38	32	25	16
		Puritan 160322	44	36	29	17
<i>Shigella sonnei</i> ATCC 12022	Diluted 10 <sup>-4</sup>	Puritan 160311	40	34	28	22
		Puritan 160315	56	47	42	33
		Puritan 160322	30	23	19	14
<i>Yersinia enterocolitica</i> ATCC 9610	Diluted 10 <sup>-4</sup>	Puritan 160311	58	74	50	43
		Puritan 160315	65	86	53	47
		Puritan 160322	51	68	38	31
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 <sup>-4</sup>	Puritan 160311	56	47	34	26
		Puritan 160315	43	38	31	23
		Puritan 160322	34	29	24	19
<i>Enterococcus faecalis vancomycin resistant (VRE)</i> ATCC 51299	Diluted 10 <sup>-4</sup>	Puritan 160311	32	25	19	14
		Puritan 160315	45	39	27	20
		Puritan 160322	37	29	23	18
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 <sup>-4</sup>	Puritan 160311	55	71	48	43
		Puritan 160315	42	57	36	29
		Puritan 160322	47	62	44	37
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 <sup>-4</sup>	Puritan 160311	80	92	65	42
		Puritan 160315	73	85	57	45
		Puritan 160322	67	78	49	38
<i>Campylobacter jejuni</i> ATCC 33291	Diluted 10 <sup>-4</sup>	Puritan 160311	238	196	167	149
		Puritan 160315	246	202	180	163
		Puritan 160322	231	187	172	145
<i>Clostridium difficile</i> ATCC 9689	Diluted 10 <sup>-4</sup>	Puritan 160311	88	31	12	
		Puritan 160315	62	26	9	
		Puritan 160322	57	21	5	

**Table 7. Recovery results for bacteria prepared in saline for Puritan Fecal Opti-Swab Collection and Transport System using Swab Elution Method at room temperature (20-25°C).**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs	Log reduction (-) or log increase (+)
<i>Escherichia coli</i> ATCC 25922	1:10	Puritan 160311	$4.1 \times 10^5$	$1.58 \times 10^6$	$2.73 \times 10^6$	0.82
		Puritan 160315	$3.3 \times 10^5$	$1.51 \times 10^6$	$2.65 \times 10^6$	0.90
		Puritan 160322	$3.8 \times 10^5$	$1.37 \times 10^6$	$2.48 \times 10^6$	0.81
<i>Shigella sonnei</i> ATCC 12022	1:10	Puritan 160311	$3.4 \times 10^5$	$1.42 \times 10^6$	$2.56 \times 10^6$	0.88
		Puritan 160315	$4.2 \times 10^5$	$1.57 \times 10^6$	$2.79 \times 10^6$	0.82
		Puritan 160322	$2.9 \times 10^5$	$1.39 \times 10^6$	$2.38 \times 10^6$	0.91
<i>Yersinia enterocolitica</i> ATCC 9610	1:10	Puritan 160311	$4.9 \times 10^5$	$2.21 \times 10^6$	$3.27 \times 10^6$	0.82
		Puritan 160315	$5.0 \times 10^5$	$2.39 \times 10^6$	$3.56 \times 10^6$	0.85
		Puritan 160322	$3.5 \times 10^5$	$2.16 \times 10^6$	$3.02 \times 10^6$	0.94
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan 160311	$4.6 \times 10^5$	$1.53 \times 10^6$	$2.39 \times 10^6$	0.72
		Puritan 160315	$3.8 \times 10^5$	$1.45 \times 10^6$	$1.95 \times 10^6$	0.71
		Puritan 160322	$3.4 \times 10^5$	$1.30 \times 10^6$	$2.18 \times 10^6$	0.81
<i>Enterococcus faecalis</i> vancomycin resistant (VRE) ATCC 51299	1:10	Puritan 160311	$3.7 \times 10^5$	$9.5 \times 10^5$	$1.55 \times 10^6$	0.62
		Puritan 160315	$4.0 \times 10^5$	$1.14 \times 10^6$	$1.78 \times 10^6$	0.65
		Puritan 160322	$3.3 \times 10^5$	$1.01 \times 10^6$	$1.69 \times 10^6$	0.71
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 160311	$4.5 \times 10^5$	$1.96 \times 10^6$	$3.25 \times 10^6$	0.86
		Puritan 160315	$3.6 \times 10^5$	$1.83 \times 10^6$	$2.99 \times 10^6$	0.92
		Puritan 160322	$4.1 \times 10^5$	$1.71 \times 10^6$	$3.06 \times 10^6$	0.87
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 160311	$5.7 \times 10^5$	$2.61 \times 10^6$	$3.57 \times 10^6$	0.80
		Puritan 160315	$4.8 \times 10^5$	$2.53 \times 10^6$	$3.72 \times 10^6$	0.89
		Puritan 160322	$3.6 \times 10^5$	$2.28 \times 10^6$	$3.02 \times 10^6$	0.92
<i>Campylobacter jejuni</i> ATCC 33291	1:10	Puritan 160311	$2.09 \times 10^6$	$1.57 \times 10^6$	$2.1 \times 10^5$	-1.00
		Puritan 160315	$2.24 \times 10^6$	$1.64 \times 10^6$	$2.4 \times 10^5$	-0.97
		Puritan 160322	$2.15 \times 10^6$	$1.43 \times 10^6$	$2.6 \times 10^5$	-0.92
<i>Clostridium difficile</i> ATCC 9689	1:10	Puritan 160311	$9.7 \times 10^5$	$1.1 \times 10^5$		-0.95
		Puritan 160315	$7.4 \times 10^5$	$6.0 \times 10^4$		-1.09
		Puritan 160322	$6.6 \times 10^5$	$8.0 \times 10^4$		-0.92

**Table 8. Recovery results for bacteria prepared in saline for Puritan Fecal Opti-Swab Collection and Transport System using Swab Elution Method in refrigerated (2-8°C) conditions.**

Organism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU's Recovered: Time 0 hrs	Average CFU's Recovered: Time 24 hrs	Average CFU's Recovered: Time 48 hrs	Average CFU's Recovered: Time 72 hrs	Log reduction (-) or log increase (+)
<i>Escherichia coli</i> ATCC 25922	1:10	Puritan 160311	4.1 x 10 <sup>5</sup>	3.4 x 10 <sup>5</sup>	1.6 x 10 <sup>5</sup>	1.1 x 10 <sup>5</sup>	-0.57
		Puritan 160315	3.3 x 10 <sup>5</sup>	2.5 x 10 <sup>5</sup>	1.8 x 10 <sup>5</sup>	1.3 x 10 <sup>5</sup>	-0.40
		Puritan 160322	3.8 x 10 <sup>5</sup>	3.1 x 10 <sup>5</sup>	2.1 x 10 <sup>5</sup>	1.7 x 10 <sup>5</sup>	-0.35
<i>Shigella sonnei</i> ATCC 12022	1:10	Puritan 160311	3.4 x 10 <sup>5</sup>	2.6 x 10 <sup>5</sup>	1.8 x 10 <sup>5</sup>	1.2 x 10 <sup>5</sup>	-0.45
		Puritan 160315	4.2 x 10 <sup>5</sup>	3.7 x 10 <sup>5</sup>	2.9 x 10 <sup>5</sup>	2.1 x 10 <sup>5</sup>	-0.30
		Puritan 160322	2.9 x 10 <sup>5</sup>	2.3 x 10 <sup>5</sup>	1.7 x 10 <sup>5</sup>	1.0 x 10 <sup>5</sup>	-0.46
<i>Yersinia enterocolitica</i> ATCC 9610	1:10	Puritan 160311	4.9 x 10 <sup>5</sup>	6.4 x 10 <sup>5</sup>	3.8 x 10 <sup>5</sup>	2.5 x 10 <sup>5</sup>	-0.29
		Puritan 160315	5.0 x 10 <sup>5</sup>	6.7 x 10 <sup>5</sup>	4.3 x 10 <sup>5</sup>	3.3 x 10 <sup>5</sup>	-0.18
		Puritan 160322	3.5 x 10 <sup>5</sup>	5.2 x 10 <sup>5</sup>	3.1 x 10 <sup>5</sup>	2.0 x 10 <sup>5</sup>	-0.24
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan 160311	4.6 x 10 <sup>5</sup>	3.9 x 10 <sup>5</sup>	2.7 x 10 <sup>5</sup>	1.9 x 10 <sup>5</sup>	-0.38
		Puritan 160315	3.8 x 10 <sup>5</sup>	3.1 x 10 <sup>5</sup>	2.4 x 10 <sup>5</sup>	1.7 x 10 <sup>5</sup>	-0.35
		Puritan 160322	3.4 x 10 <sup>5</sup>	2.6 x 10 <sup>5</sup>	1.9 x 10 <sup>5</sup>	1.2 x 10 <sup>5</sup>	-0.45
<i>Enterococcus faecalis vancomycin resistant (VRE)</i> ATCC 51299	1:10	Puritan 160311	3.7 x 10 <sup>5</sup>	3.0 x 10 <sup>5</sup>	2.2 x 10 <sup>5</sup>	1.4 x 10 <sup>5</sup>	-0.42
		Puritan 160315	4.0 x 10 <sup>5</sup>	2.9 x 10 <sup>5</sup>	2.0 x 10 <sup>5</sup>	1.2 x 10 <sup>5</sup>	-0.52
		Puritan 160322	3.3x 10 <sup>5</sup>	2.7 x 10 <sup>5</sup>	1.9 x 10 <sup>5</sup>	1.1 x 10 <sup>5</sup>	-0.48
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 160311	4.5 x 10 <sup>5</sup>	3.8 x 10 <sup>5</sup>	2.6 x 10 <sup>5</sup>	1.8 x 10 <sup>5</sup>	-0.40
		Puritan 160315	3.6 x 10 <sup>5</sup>	3.2 x 10 <sup>5</sup>	2.3 x 10 <sup>5</sup>	1.6 x 10 <sup>5</sup>	-0.35
		Puritan 160322	4.1 x 10 <sup>5</sup>	3.4 x 10 <sup>5</sup>	2.8 x 10 <sup>5</sup>	2.0 x 10 <sup>5</sup>	-0.31
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 160311	5.7 x 10 <sup>5</sup>	7.2 x 10 <sup>5</sup>	4.5 x 10 <sup>5</sup>	3.8 x 10 <sup>5</sup>	-0.18
		Puritan 160315	4.8 x 10 <sup>5</sup>	6.6 x 10 <sup>5</sup>	4.1 x 10 <sup>5</sup>	3.3 x 10 <sup>5</sup>	-0.16
		Puritan 160322	3.6 x 10 <sup>5</sup>	5.2 x 10 <sup>5</sup>	3.2 x 10 <sup>5</sup>	2.7 x 10 <sup>5</sup>	-0.12
<i>Campylobacter jejuni</i> ATCC 33291	1:10	Puritan 160311	2.09 x 10 <sup>6</sup>	1.76 x 10 <sup>6</sup>	1.52 x 10 <sup>6</sup>	1.37 x 10 <sup>6</sup>	-0.18
		Puritan 160315	2.24 x 10 <sup>6</sup>	1.91 x 10 <sup>6</sup>	1.75 x 10 <sup>6</sup>	1.54 x 10 <sup>6</sup>	-0.16
		Puritan 160322	2.15 x 10 <sup>6</sup>	1.83 x 10 <sup>6</sup>	1.67 x 10 <sup>6</sup>	1.45 x 10 <sup>6</sup>	-0.17
<i>Clostridium difficile</i> ATCC 9689	1:10	Puritan 160311	9.7 x 10 <sup>5</sup>	2.8 x 10 <sup>5</sup>	1.0 x 10 <sup>5</sup>		-0.99
		Puritan 160315	7.4 x 10 <sup>5</sup>	2.3 x 10 <sup>5</sup>	7.0 x 10 <sup>4</sup>		-1.02
		Puritan 160322	6.6 x 10 <sup>5</sup>	1.7 x 10 <sup>5</sup>	5.0 x 10 <sup>4</sup>		-1.12

If you encounter problems or for questions and technical support call: Puritan Medical Products, LLC at 1-800-321-2313. Test system problems may also be reported to the FDA through the MedWatch medical products reporting program (phone: 1-800-FDA-1088; fax: 1-800-FDA-0178; <http://www.fda.gov/medwatch>).

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