

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K160082

B. Purpose for Submission:

To make a substantial equivalence determination for the Puritan[®] Opti-Tranz[™] Cary-Blair Collection and Transport System for the collection, transport and storage of fecal specimens for laboratory culture of bacteria and yeast.

C. Measurand:

Not applicable.

D. Type of Test:

Collection and transport culture medium device

E. Applicant:

Puritan Medical Products, LLC

F. Proprietary and Established Names:

Puritan[®] Opti-Tranz[™] Cary-Blair Collection and Transport System

G. Regulatory Information:

1. Regulation section:

866.2390; Transport Culture Medium

2. Classification:

Class I

3. Product code:

JSM; Culture Media, Non-Propagating Transport
LIO: Device, Specimen Collection

JTW: System, Transport, Aerobic

4. Panel:

83- Microbiology

H. Intended Use:

1. Intended use(s):

The Puritan Opti-Tranz Cary-Blair 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.

2. Indication(s) for use:

Same as intended use.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

None.

I. Device Description:

Puritan[®] Opti-Tranz[™] Cary-Blair Collection and Transport System is comprised of a peel pouch containing a rayon tipped swab applicator for collecting specimens and a polypropylene, round-bottomed, capped tube containing 5 ml of a semi-solid Cary-Blair medium.

Cary-Blair medium is a non-nutritive balanced salt solution containing disodium phosphate to provide buffering capability, sodium chloride and calcium chloride to provide essential ions that help maintain osmotic balance. Agar is a solidifying agent and gives a semisolid texture to the medium. Sodium thioglycollate helps maintained an oxygen-reduced environment to help maintain the viability of enteric bacteria during the transport to the laboratory.

The semi-solid Cary Blair medium is composed of the following components:

- Sodium chloride 5.0 g/L
- Disodium Phosphate, 1.1 g/L

- Sodium thioglycollate 1.5 g/L
- Calcium chloride, 0.09 g/L
- Bacteriological agar, 5.6 g/L
- Deionized water 1 L

J. Substantial Equivalence Information:

1. Predicate device name(s):

Copan Venturi Transystem Cary-Blair Medium product (132C)

2. Predicate 510(k) number(s):

k946286

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	Puritan[®] Opti-Tranz[™] Cary-Blair Collection and Transport System (k160082)	Copan Venturi Transystem Cary-Blair Medium product (132C) (k946286)
Intended Use	The Puritan Opti-Tranz Cary-Blair 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.	Copan Venturi Transystem Cary-Blair Medium product (132C) is a sterile ready-to-use system intended for the safe collection, transport, and preservation of clinical specimens for bacteriological examination. Product 132C is supplied with a plastic applicator swab. The Venturi Transystem with Cary-Blair Transport Medium is recommended for the collection and transport of fecal and rectal swab samples for the investigation of enteric pathogenic bacteria.

Similarities		
Item	Device	Predicate
	Puritan[®] Opti-Tranz[™] Cary-Blair Collection and Transport System (k160082)	Copan Venturi Transystem Cary-Blair Medium product (132C) (k946286)
Specimen Storage	Up to 48 h at 20 – 25 °C and up to 72 h at refrigerated conditions 2 – 8 °C	Same
Tube	Polypropylene, round bottom	Same
Medium Volume	5 mL	Same
Single Use Device	Yes	Same
Packaging	Peel pouch	Same
Swab	Rayon	Same
Medium Formulation	Sodium chloride 5.0 g/L Disodium Phosphate, 1.1 g/L Sodium thioglycollate 1.5 g/L Calcium chloride, 0.09 g/L Bacteriological agar, 5.6 g/L Deionized water 1 L	Same

Differences		
Item	Device	Predicate
Organisms Tested	<i>Campylobacter jejuni</i> <i>Enterococcus faecalis</i> <i>Escherichia coli</i> <i>Salmonella typhimurium</i> <i>Shigella sonnei</i> <i>Vibrio parahaemolyticus</i> <i>Yersinia enterocolitica</i>	<i>Campylobacter jejuni</i> <i>Escherichia coli</i> <i>Shigella flexneri</i> <i>Yersinia enterocolitica</i>
pH	6.9 – 7.5	8.4 ± 0.2
Shelf life	20 months	24 months

K. Standard/Guidance Document Referenced (if applicable):

Quality Control of Microbiological Transport Systems; Approved Standard – Second Edition, M40-A2, Clinical and Laboratory Standards Institute (CLSI), Wayne, PA, 2014.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Analytical studies were conducted to determine the ability of the Puritan® Opti-Tranz™ Cary-Blair Collection and Transport System to maintain the viability of enteric microorganisms.

The performance of the Puritan® Opti-Tranz™ Cary-Blair Collection and Transport System was determined using quantitative colony enumeration techniques outlined in the Clinical and Laboratory Standards Institute (CLSI) M40-A2 document. Bacterial viability studies were performed. The swabs from each transport system were inoculated with 100 µL of select bacterial concentrations prepared in a fecal matrix and/or 0.85% phosphate buffered saline (PBS). To facilitate testing, a homogeneous fecal matrix was prepared by diluting pre-screened negative fresh clinical fecal material in 0.85% PBS to a 30% concentration by volume.

Once inoculated, the swabs were then placed in their respective transport tubes and held at various time intervals; at the designated time intervals the swabs were removed and processed. To test the viability at various time intervals the inoculated swabs were held at room temperature for 0, 24, and 48 hours and refrigerated for 0, 24, 48, and 72 hours.

The eight ATCC strains listed in **Table 1** below were used to evaluate the performance of the Puritan Opti-Tranz Cary-Blair Collection and Transport System. This device was tested using the swabs included with the transport kit. Viability studies were conducted in duplicate at 0, 24, and 48 at room temperature (20-25°C) and at 0, 24, 48, and 72 hours at refrigerated temperatures (2-8°C) using the Roll-Plate and Swab Elution Methods.

Table 1: Enteric bacteria evaluated for stability in Puritan Opti-Tranz Cary-Blair Collection and Transport System			
Microorganism	ATCC #	Fecal Matrix*	0.85% Saline*
<i>Campylobacter jejuni</i>	ATCC 33291	NO	YES
<i>Escherichia coli</i>	ATCC 25922	NO	YES
<i>Escherichia coli</i> 0157:H7	ATCC 700728	YES	YES
<i>Salmonella typhimurium</i>	ATCC 14028	YES	YES
<i>Shigella sonnei</i>	ATCC 12022	NO	YES
<i>Vibrio parahaemolyticus</i>	ATCC 17802	YES	YES
Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE)	ATCC 51299	NO	YES
<i>Yersinia enterocolitica</i>	ATCC 9610	NO	YES

* 'NO' indicates that strain was not tested in the column heading matrix;
 'YES' indicates that the strain was tested in the column heading matrix.

Roll-Plate Method:

Bacterial suspensions were prepared from fresh 18-24 hour cultures of each microorganism in a separate vial containing 10 mL of fecal matrix or 0.85% sterile saline to obtain 1.5×10^8 CFU/mL suspensions. One \log_{10} serial dilutions were made and 100 µL aliquots of dilutions were absorbed into the swabs and immediately placed into the

Puritan Opti-Tranz Cary-Blair medium. For fecal specimens, the final dilution prior to swab inoculation was done with fecal matrix to maximize the amount of fecal material on the swab.

After incubation at each time point, the swabs were removed from the transport tubes and used to inoculate the entire surface of the appropriate agar plate. The plates were incubated in appropriate culture conditions for 24-48 hours or until countable colonies were visible. Manual colony counts were conducted for each time interval for each swab-organism combination. The dilution yielding colony counts nearest to zero (not to exceed 250 CFU) was reported. Log₁₀ increases or decreases in survival are based on a comparison between time-zero and the last time point collected for each temperature.

Swab Elution Method:

Bacterial suspensions were prepared from fresh 18-24 hour cultures of each microorganism in a separate vial containing 10 mL of fecal matrix or 0.85% sterile saline to obtain 1.5 x 10⁸ CFU/mL suspensions. The suspensions were diluted in 0.85% saline or fecal matrix solution to obtain working suspensions of 1.5 x 10⁷ CFU/ml, and then 100 µL aliquots of dilutions were absorbed into the swabs and immediately placed into the Puritan Opti-Tranz Cary-Blair medium. After incubation at each time point, the swabs were removed from the transport tubes and 100 µL of 1-log₁₀ serial dilutions were made in 0.85% saline. 100 µL of each dilution was plated on the appropriate agar plate for each temperature and time point. The plates were incubated in appropriate culture conditions for 24-48 hours or until countable colonies were visible. Manual colony counts were conducted for each time interval for each swab-organism combination. The dilution yielding zero-time colony counts between 25 and 250 CFU was reported.

Recovery results from Roll Plate and Swab Elution experiments are shown in **Tables 2-9** below for various strains and product lot numbers tested at the storage times, specimen matrix and temperature ranges indicated.

Temperature Range	Plating Method	Fecal Matrix	Saline
20-25 °C	Roll Plate	Table 2	Table 6
2-8 °C	Swab Elution	Table 3	Table 7
20-25 °C	Roll Plate	Table 4	Table 8
2-8 °C	Swab Elution	Table 5	Table 9

Acceptance criteria for recovery of microorganisms were as recommended in the CLSI document M40-A2 and defined as being within two log₁₀ increase or decrease from the starting titer at time zero. Manual colony counts were conducted for each of the time intervals for each microorganism held at each temperature. The results from these studies demonstrated that the Puritan Opti-Tranz Cary-Blair Collection and Transport System can support the viability enteric bacteria for up to 48 hours at 20-25 °C and 72 hours at 2-8 °C.

Table 2. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from fecal matrix using Roll-Plate Method at 20-25°C

Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFUs Recovered: Time 0 h	Average CFUs Recovered: Time 24 h	Average CFUs Recovered: Time 48 h
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 ⁻⁴	Puritan - 151002	94	202	266
		Puritan - 151026	79	181	262
		Puritan - 151105	83	190	279
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 ⁻⁴	Puritan - 151002	89	157	359
		Puritan - 151026	72	141	326
		Puritan - 151105	67	123	338
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 ⁻⁴	Puritan - 151002	99	266	163
		Puritan - 151026	86	234	150
		Puritan - 151105	73	251	153

Table 3. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from fecal matrix using Roll-Plate Method at 2-8°C

Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFUs Recovered: Time 0 h	Average CFUs Recovered: Time 24 h	Average CFUs Recovered: Time 48 h	Average CFUs Recovered: Time 72 h
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 ⁻⁴	Puritan - 151002	94	73	58	53
		Puritan - 151026	79	72	64	56
		Puritan - 151105	83	76	70	62
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 ⁻⁴	Puritan - 151002	89	97	88	123
		Puritan - 151026	72	85	87	93
		Puritan - 151105	67	76	82	111
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 ⁻⁴	Puritan - 151002	99	52	27	31
		Puritan - 151026	86	59	38	24
		Puritan - 151105	73	40	25	19

Table 4. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from fecal matrix using Swab-Elution Method at 20-25°C						
Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU/ml Recovered: Time 0 h	Average CFU/ml Recovered: Time 24 h	Average CFU/ml Recovered: Time 48 h	Log₁₀ Change (48h/0h)
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan - 151002	8.3 x 10 ⁵	1.86 x 10 ⁶	2.62 x 10 ⁶	0.50
		Puritan - 151026	6.8 x 10 ⁵	1.59 x 10 ⁶	2.52 x 10 ⁶	0.57
		Puritan - 151105	7.5 x 10 ⁵	1.61 x 10 ⁶	2.46 x 10 ⁶	0.52
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan - 151002	7.6 x 10 ⁵	1.35 x 10 ⁶	3.18 x 10 ⁶	0.62
		Puritan - 151026	5.7 x 10 ⁵	1.21 x 10 ⁶	3.12 x 10 ⁶	0.74
		Puritan - 151105	6.8 x 10 ⁵	1.4 x 10 ⁶	3.05 x 10 ⁶	0.65
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan - 151002	8.4 x 10 ⁵	2.43 x 10 ⁶	2.12 x 10 ⁶	0.40
		Puritan - 151026	7.1 x 10 ⁵	2.65 x 10 ⁶	2.26 x 10 ⁶	0.50
		Puritan - 151105	6.6 x 10 ⁵	2.31 x 10 ⁶	1.85 x 10 ⁶	0.45

Table 5. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from fecal matrix using Swab-Elution Method at 2-8°C							
Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU/ml Recovered: Time 0 h	Average CFU/ml Recovered: Time 24 h	Average CFU/ml Recovered: Time 48 h	Average CFU/ml Recovered: Time 72 h	Log₁₀ Change (72h/0h)
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan - 151002	8.3 x 10 ⁵	6.7 x 10 ⁵	5.1 x 10 ⁵	4.6 x 10 ⁵	-0.26
		Puritan - 151026	6.8 x 10 ⁵	6.2 x 10 ⁵	5.4 x 10 ⁵	4.7 x 10 ⁵	-0.16
		Puritan - 151105	7.5 x 10 ⁵	5.8 x 10 ⁵	4.9 x 10 ⁵	3.9 x 10 ⁵	-0.28
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan - 151002	7.6 x 10 ⁵	8.5 x 10 ⁵	9.2 x 10 ⁵	1.18 x 10 ⁶	0.19
		Puritan - 151026	5.7 x 10 ⁵	6.3 x 10 ⁵	7.5 x 10 ⁵	1.05 x 10 ⁵	0.27
		Puritan - 151105	6.8 x 10 ⁵	7.3 x 10 ⁵	8.7 x 10 ⁵	9.9 x 10 ⁵	0.16
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan - 151002	8.4 x 10 ⁵	4.7 x 10 ⁵	2.9 x 10 ⁵	1.6 x 10 ⁵	-0.72
		Puritan - 151026	7.1 x 10 ⁵	5.2 x 10 ⁵	3.4 x 10 ⁵	2.0 x 10 ⁵	-0.55
		Puritan - 151105	6.6 x 10 ⁵	4.2 x 10 ⁵	3.1 x 10 ⁵	1.6 x 10 ⁵	-0.62

Table 6. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from saline using Roll-Plate Method at 20-25°C

Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFUs Recovered: Time 0 h	Average CFUs Recovered: Time 24 h	Average CFUs Recovered: Time 48 h
<i>Campylobacter jejuni</i> ATCC 33291	Diluted 10 ⁻⁴	Puritan - 151002	195	132	15
		Puritan - 151026	241	193	37
		Puritan - 151105	243	181	23
<i>Escherichia coli</i> ATCC 25922	Diluted 10 ⁻⁴	Puritan - 151002	32	168	270
		Puritan - 151026	57	185	320
		Puritan - 151105	44	159	284
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 ⁻⁴	Puritan - 151002	34	83	118
		Puritan - 151026	47	100	146
		Puritan - 151105	55	128	222
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 ⁻⁴	Puritan - 151002	31	103	182
		Puritan - 151026	43	117	196
		Puritan - 151105	55	152	269
<i>Shigella sonnei</i> ATCC 12022	Diluted 10 ⁻⁴	Puritan - 151002	54	197	333
		Puritan - 151026	41	175	304
		Puritan - 151105	46	152	241
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 ⁻⁴	Puritan - 151002	38	164	270
		Puritan - 151026	60	212	370
		Puritan - 151105	49	147	251
Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 10 ⁻⁴	Puritan - 151002	27	47	59
		Puritan - 151026	31	54	91
		Puritan - 151105	35	40	98
<i>Yersinia enterocolitica</i> ATCC 9610	Diluted 10 ⁻⁴	Puritan - 151002	37	182	315
		Puritan - 151026	52	209	368
		Puritan - 151105	45	164	264

Table 7. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from saline using Roll-Plate Method at 2-8°C

Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFUs Recovered: Time 0 h	Average CFUs Recovered: Time 24 h	Average CFUs Recovered: Time 48 h	Average CFUs Recovered: Time 72 h
<i>Campylobacter jejuni</i> ATCC 33291	Diluted 10 ⁻⁴	Puritan - 151002	195	117	74	19
		Puritan - 151026	241	166	98	26
		Puritan - 151105	243	172	92	27
<i>Escherichia coli</i> ATCC 25922	Diluted 10 ⁻⁴	Puritan - 151002	32	45	22	8
		Puritan - 151026	57	72	43	22
		Puritan - 151105	44	59	30	16
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 ⁻⁴	Puritan - 151002	34	25	17	9
		Puritan - 151026	47	37	22	11
		Puritan - 151105	55	53	29	15
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 ⁻⁴	Puritan - 151002	31	56	34	20
		Puritan - 151026	43	67	40	29
		Puritan - 151105	55	72	49	39
<i>Shigella sonnei</i> ATCC 12022	Diluted 10 ⁻⁴	Puritan - 151002	54	69	43	32
		Puritan - 151026	41	71	39	28
		Puritan - 151105	46	82	42	39
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 ⁻⁴	Puritan - 151002	38	62	44	27
		Puritan - 151026	60	77	58	41
		Puritan - 151105	49	66	45	34
Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 10 ⁻⁴	Puritan - 151002	27	21	17	12
		Puritan - 151026	31	24	19	13
		Puritan - 151105	35	22	18	16
<i>Yersinia enterocolitica</i> ATCC 9610	Diluted 10 ⁻⁴	Puritan - 151002	37	61	42	28
		Puritan - 151026	52	78	56	43
		Puritan - 151105	45	73	51	41

Table 8. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from saline using Swab Elution Method at 20-25°C

Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU/ml Recovered: Time 0 h	Average CFU/ml Recovered: Time 24 h	Average CFU/ml Recovered: Time 48 h	Log ₁₀ Change (48h/0h)
<i>Campylobacter jejuni</i> ATCC 33291	1:10	Puritan - 151002	1.99 X 10 ⁶	1.29 X 10 ⁶	1.0 X 10 ⁵	-1.30
		Puritan - 151026	2.48 X 10 ⁶	1.83 X 10 ⁶	1.8 X 10 ⁵	-1.14
		Puritan - 151105	2.5 X 10 ⁶	1.72 X 10 ⁶	1.4 X 10 ⁵	-1.25
<i>Escherichia coli</i> ATCC 25922	1:10	Puritan - 151002	4.1 X 10 ⁵	1.54 X 10 ⁶	2.59 X 10 ⁶	0.80
		Puritan - 151026	6.2 X 10 ⁵	1.72 X 10 ⁶	3.0 X 10 ⁶	0.68
		Puritan - 151105	5.1 X 10 ⁵	1.47 X 10 ⁶	2.66 X 10 ⁶	0.72
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan - 151002	3.3 X 10 ⁵	7.6 X 10 ⁵	1.11 X 10 ⁶	0.53
		Puritan - 151026	4.7 X 10 ⁵	9.4 X 10 ⁵	1.34 X 10 ⁶	0.46
		Puritan - 151105	5.5 X 10 ⁵	1.19 X 10 ⁶	2.14 X 10 ⁶	0.59
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan - 151002	3.9 X 10 ⁵	9.6 X 10 ⁵	1.75 X 10 ⁶	0.65
		Puritan - 151026	4.8 X 10 ⁵	1.05 X 10 ⁶	1.84 X 10 ⁶	0.58
		Puritan - 151105	6.0 X 10 ⁵	1.49 X 10 ⁶	2.61 X 10 ⁶	0.64
<i>Shigella sonnei</i> ATCC 12022	1:10	Puritan - 151002	6.0 X 10 ⁵	1.81 X 10 ⁶	1.16 X 10 ⁶	0.72
		Puritan - 151026	4.7 X 10 ⁵	1.63 X 10 ⁶	2.94 X 10 ⁶	0.80
		Puritan - 151105	5.3 X 10 ⁵	1.33 X 10 ⁶	2.28 X 10 ⁶	0.63
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan - 151002	4.6 X 10 ⁵	1.51 X 10 ⁶	2.59 X 10 ⁶	0.75
		Puritan - 151026	6.9 X 10 ⁵	1.98 X 10 ⁶	3.04 X 10 ⁶	0.64
		Puritan - 151105	5.7 X 10 ⁵	1.32 X 10 ⁶	2.44 X 10 ⁶	0.63
Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE) ATCC 51299	1:10	Puritan - 151002	3.3 X 10 ⁵	4.4 X 10 ⁵	5.4 X 10 ⁵	0.21
		Puritan - 151026	3.7 X 10 ⁵	4.8 X 10 ⁵	8.9 X 10 ⁵	0.38
		Puritan - 151105	4.0 X 10 ⁵	4.2 X 10 ⁵	9.0 X 10 ⁵	0.35
<i>Yersinia enterocolitica</i> ATCC 9610	1:10	Puritan - 151002	4.3 X 10 ⁵	1.74 X 10 ⁶	2.99 X 10 ⁶	0.84
		Puritan - 151026	5.7 X 10 ⁵	1.98 X 10 ⁶	3.24 X 10 ⁶	0.75
		Puritan - 151105	4.9 X 10 ⁵	1.57 X 10 ⁶	2.55 X 10 ⁶	0.72

Table 9. Recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System from saline using Swab Elution Method at 2-8°C							
Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFU/ml Recovered: Time 0 h	Average CFU/ml Recovered: Time 24 h	Average CFU/ml Recovered: Time 48 h	Average CFU/ml Recovered: Time 72 h	Growth/Death: Log₁₀ (72h/0h)
<i>Campylobacter jejuni</i> ATCC 33291	1:10	Puritan - 151002	1.99 X 10 ⁶	1.14 X 10 ⁶	6.5 X 10 ⁵	1.1 X 10 ⁵	-1.26
		Puritan - 151026	2.48 X 10 ⁶	1.52 X 10 ⁶	9.4 X 10 ⁵	2.1 X 10 ⁵	-1.07
		Puritan - 151105	2.5 X 10 ⁶	1.59 X 10 ⁶	8.6 X 10 ⁵	1.9 X 10 ⁵	-1.12
<i>Escherichia coli</i> ATCC 25922	1:10	Puritan - 151002	4.1 X 10 ⁵	3.5 X 10 ⁵	1.8 X 10 ⁵	7.0 X 10 ⁴	-0.77
		Puritan - 151026	6.2 X 10 ⁵	6.8 X 10 ⁵	4.0 X 10 ⁵	1.6 X 10 ⁵	-0.59
		Puritan - 151105	5.1 X 10 ⁵	5.2 X 10 ⁵	2.4 X 10 ⁵	1.1 X 10 ⁵	-0.67
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan - 151002	3.3 X 10 ⁵	1.2 X 10 ⁵	8.0 X 10 ⁴	3.5 X 10 ⁴	-0.97
		Puritan - 151026	4.7 X 10 ⁵	3.4 X 10 ⁵	1.9 X 10 ⁵	4.0 X 10 ⁴	-1.07
		Puritan - 151105	5.5 X 10 ⁵	4.8 X 10 ⁵	2.2 X 10 ⁵	5.0 X 10 ⁴	-1.04
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan - 151002	3.9 X 10 ⁵	4.3 X 10 ⁵	2.7 X 10 ⁵	1.9 X 10 ⁵	-0.31
		Puritan - 151026	4.8 X 10 ⁵	6.1 X 10 ⁵	3.6 X 10 ⁵	2.1 X 10 ⁵	-0.36
		Puritan - 151105	6.0 X 10 ⁵	6.7 X 10 ⁵	4.1 X 10 ⁵	3.3 X 10 ⁵	-0.26
<i>Shigella sonnei</i> ATCC 12022	1:10	Puritan - 151002	6.0 X 10 ⁵	5.8 X 10 ⁵	4.1 X 10 ⁵	3.0 X 10 ⁵	-0.30
		Puritan - 151026	4.7 X 10 ⁵	6.5 X 10 ⁵	3.3 X 10 ⁵	2.1 X 10 ⁵	-0.35
		Puritan - 151105	5.3 X 10 ⁵	7.4 X 10 ⁵	3.6 X 10 ⁵	2.7 X 10 ⁵	-0.29
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan - 151002	4.6 X 10 ⁵	5.8 X 10 ⁵	3.7 X 10 ⁵	2.0 X 10 ⁵	-0.36
		Puritan - 151026	6.9 X 10 ⁵	7.2 X 10 ⁵	5.4 X 10 ⁵	3.7 X 10 ⁵	-0.27
		Puritan - 151105	5.7 X 10 ⁵	6.0 X 10 ⁵	4.0 X 10 ⁵	2.8 X 10 ⁵	-0.31
Vancomycin-resistant <i>Enterococcus faecalis</i> (VRE) ATCC 51299	1:10	Puritan - 151002	3.3 X 10 ⁵	1.6 X 10 ⁵	1.3 X 10 ⁵	9.0 X 10 ⁴	-0.56
		Puritan - 151026	3.7 X 10 ⁵	1.9 X 10 ⁵	1.2 X 10 ⁵	6.0 X 10 ⁴	-0.79
		Puritan - 151105	4.0 X 10 ⁵	2.0 X 10 ⁵	1.5 X 10 ⁵	1.2 X 10 ⁵	-0.52
<i>Yersinia enterocolitica</i> ATCC 9610	1:10	Puritan - 151002	4.3 X 10 ⁵	5.4 X 10 ⁵	3.8 X 10 ⁵	2.3 X 10 ⁵	-0.27
		Puritan - 151026	5.7 X 10 ⁵	7.1 X 10 ⁵	4.7 X 10 ⁵	3.5 X 10 ⁵	-0.21
		Puritan - 151105	4.9 X 10 ⁵	6.7 X 10 ⁵	4.2 X 10 ⁵	3.4 X 10 ⁵	-0.16

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Shelf-life Stability: Shelf life stability tests were performed successfully on three lots of products stored for 20 months at room temperature. Recovery of microorganisms from fecal matrix was assessed by the Roll Plate method, as described in section M.1 above (see **Table 10** below for results).

Table 10. Roll plate recovery results for Puritan Opti-Tranz Cary-Blair Collection and Transport System stored for 20 months then inoculated with specified organism in fecal matrix and stored at 20-25°C					
Microorganism	0.5 McFarland microorganism suspension diluted with saline	Product Lot Numbers	Average CFUs Recovered: Time 0 h	Average CFUs Recovered: Time 24 h	Average CFUs Recovered: Time 48 h
<i>Escherichia coli</i> 0157:H7 ATCC 700728	Diluted 10 ⁻⁴	Puritan - 151002	86	183	260
		Puritan - 151026	91	198	257
		Puritan - 151105	77	186	249
<i>Salmonella typhimurium</i> ATCC 14028	Diluted 10 ⁻⁴	Puritan - 151002	82	151	303
		Puritan - 151026	68	135	294
		Puritan - 151105	61	129	288
<i>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 ⁻⁴	Puritan - 151002	93	258	117
		Puritan - 151026	82	232	111
		Puritan - 151105	59	226	104

pH Stability: The pH of the test device was measured at predetermined time intervals for up to 20 months after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan Opti-Tranz Cary-Blair Collection and Transport System. All samples tested were found to maintain pH within the specified range of pH 6.90 to 7.50.

Cytotoxicity: Cytotoxicity testing was conducted to evaluate the glue, shaft and rayon tipped swabs for potential cytotoxicity effects following ISO Elution Method-1X MEM Extract. No evidence of cytotoxicity was detected.

Sterilization: Puritan Opti-Tranz Cary-Blair Collection and Transport System are sterilized by gamma irradiation and validated following ANSI/ AAMI/ISO 11137:2006, Sterilization of health care products Radiation guidelines.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable.

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.