



Puritan®

Quality since 1919

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Puritan® Opti-Tranz® Cary-Blair Collection & Transport System

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Puritan® Opti-Tranz® Cary-Blair Collection & Transport System

INTENDED USE

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.

SUMMARY AND PRINCIPLES

Proper specimen collection and transport is critical for rapid and accurate diagnosis of clinical specimens. Puritan Opti-Tranz Cary-Blair Collection and Transport System is a sterile, ready-to-use system for collection and transport of clinical fecal and rectal swab specimen for bacteriological analysis.

Each kit is comprised of a sterile peel pouch containing a rayon swab applicator to collect specimen and a polypropylene plugged tube containing 5mL of Cary-Blair medium. The rayon swab applicator can be used to collect the clinical specimen. After specimen collection using the swab, it is placed inside the tube containing Cary-Blair medium and transported to the laboratory to be processed.¹

Cary-Blair medium is a nonnutritive 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 provides a reduced environment. It is recommended for maintaining the viability of enteric bacteria during the transport to the laboratory.²

REAGENTS

Approximate Puritan Opti-Tranz Cary-Blair formulation per liter

Sodium chloride5.0g	Calcium chloride	0.09g
Disodium phosphate	1.1g	Bacteriological agar	5.6g
Sodium thioglycollate	1.5g	Deionized water	1 liter

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.^{3,6}
- 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*.^{3,6}
- 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 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 Opti-Tranz Cary-Blair Collection and Transport System includes a sterile pre-labeled and plugged polypropylene tube containing 5mL of Cary-Blair medium and one plastic shaft rayon tipped swab applicator.

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.⁷

DIRECTIONS FOR USE

- [1] Peel open sterile pouch.
- [2] Remove plug from the transport tube.
- [3] Remove swab applicator and collect specimen. *Do not touch the swab tip.*
- [4] Insert swab into the transport tube.
- [5] Record patient information in space provided on the tube label.
- [6] Transport specimen to laboratory for immediate analysis.

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.^{1,8,10} To maintain optimum organism viability, transport the specimens collected using Puritan Opti-Tranz Cary-Blair Collection and Transport System to the laboratory within 2 h of collection. 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. Specimens should be processed as soon as they are received in the laboratory.

Specimen cultures in the laboratory

In the laboratory, specimens 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.^{1,7,10}

QUALITY CONTROL

Each lot of Puritan Opti-Tranz Cary-Blair 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.⁹

LIMITATIONS

1. 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.^{7,8,10,11}
2. Puritan Opti-Tranz Cary-Blair Collection and Transport System is recommended for the collection and transport of enteric bacteriological specimens only. Viruses, chlamydia, mycoplasma and ureaplasma require a transport medium formulated specifically for use with these organisms.^{2,11}
3. Extreme temperature should be avoided during transportation of Puritan Opti-Tranz Cary-Blair Collection and Transport System.
4. Viability of microorganisms in Puritan Opti-Tranz Cary-Blair Collection and Transport System other than the ones shown in the Performance Characteristics section have not been established. This includes obligate anaerobic organisms such as *Clostridium difficile*.

PERFORMANCE CHARACTERISTICS

The performance characteristics of Puritan Opti-Tranz Cary-Blair 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.⁹ A variety of ATCC type enteric bacteria were included 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 tube and held for 0, 24, 48 hours at room temperature and 0, 24, 48, and 72 hours at refrigerated; 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, and *Campylobacter jejuni* ATCC 33291.

Puritan Opti-Tranz Cary-Blair Collection and Transport System was able to maintain viability of all organisms up to 48 hours at room temperatures and 72 hours at refrigerated.

Table 1. Recovery results for bacteria prepared in fecal matrix for Puritan Opti-Tranz Cary-Blair Collection and Transport System using Roll-Plate Method at room temperature 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
<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 2. Recovery results for bacteria prepared in fecal matrix for Puritan Opti-Tranz Cary-Blair Collection and Transport System using Roll-Plate Method at 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 ⁻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 3. Recovery results for bacteria prepared in fecal matrix for Puritan Opti-Tranz Cary-Blair Collection and Transport System using Swab Elution Method at room temperature.

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	8.3×10^5	1.86×10^5	2.62×10^5	0.50
		Puritan 151026	6.8×10^5	1.59×10^5	2.52×10^5	0.57
		Puritan 151105	7.5×10^5	1.61×10^5	2.46×10^5	0.52
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 151002	7.6×10^5	1.35×10^5	3.18×10^5	0.62
		Puritan 151026	5.7×10^5	1.21×10^5	3.12×10^5	0.74
		Puritan 151105	6.8×10^5	1.4×10^5	3.05×10^5	0.65
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 151002	8.4×10^5	2.43×10^5	2.12×10^5	0.40
		Puritan 151026	7.1×10^5	2.65×10^5	2.26×10^5	0.50
		Puritan 151105	6.6×10^5	2.31×10^5	1.85×10^5	0.45

Table 4. Recovery results for bacteria prepared in fecal matrix for Puritan Opti-Tranz Cary-Blair Collection and Transport System using Swab Elution Method at 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	8.3×10^5	6.7×10^5	5.1×10^5	4.6×10^5	-0.26
		Puritan 151026	6.8×10^5	6.2×10^5	5.4×10^5	4.7×10^5	-0.16
		Puritan 151105	7.5×10^5	5.8×10^5	4.9×10^5	3.9×10^5	-0.28
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 151002	7.6×10^5	8.5×10^5	9.2×10^5	1.18×10^6	0.19
		Puritan 151026	5.7×10^5	6.3×10^5	7.5×10^5	1.05×10^5	0.27
		Puritan 151105	6.8×10^5	7.3×10^5	8.7×10^5	9.9×10^5	0.16
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 151002	8.4×10^5	4.7×10^5	2.9×10^5	1.6×10^5	-0.72
		Puritan 151026	7.1×10^5	5.2×10^5	3.4×10^5	2.0×10^5	-0.55
		Puritan 151105	6.6×10^5	4.2×10^5	3.1×10^5	1.6×10^5	-0.62

Table 5. Recovery results for bacteria prepared in 0.85% saline Puritan Opti-Tranz Cary-Blair Collection and Transport System using Roll-Plate Method at room temperature 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
<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>Shigella sonnei</i> ATCC 12022	Diluted 10 ⁻⁴	Puritan 151002	54	197	333
		Puritan 151026	41	175	304
		Puritan 151105	46	152	241
<i>Yersinia enterocolitica</i> ATCC 9610	Diluted 10 ⁻⁴	Puritan 151002	37	182	315
		Puritan 151026	52	209	368
		Puritan 151105	45	164	264
<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>Enterococcus faecalis</i> <i>vancomycin resistant (VRE)</i> ATCC 51299	Diluted 10 ⁻⁴	Puritan 151002	27	47	59
		Puritan 151026	31	54	91
		Puritan 151105	35	40	98
<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>Vibrio parahaemolyticus</i> ATCC 17802	Diluted 10 ⁻⁴	Puritan 151002	38	164	270
		Puritan 151026	60	212	370
		Puritan 151105	49	147	251
<i>Campylobacter jejuni</i> ATCC 33291	Diluted 10 ⁻⁴	Puritan 151002	195	132	15
		Puritan 151026	241	193	37
		Puritan 151105	243	181	23

Table 6. Recovery results for bacteria prepared in 0.85% saline Puritan Opti-Tranz Cary-Blair Collection and Transport System using Roll-Plate Method at 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 ⁻⁴	Puritan 151002	32	45	22	8
		Puritan 151026	57	72	43	22
		Puritan 151105	44	59	30	16
<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>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
<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>Enterococcus faecalis</i> <i>vancomycin resistant</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>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>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
<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

Table 7. Recovery results for bacteria prepared in 0.85% saline Puritan Opti-Tranz Cary-Blair Collection and Transport System using Swab Elution Method at room temperature 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	Log reduction (-) or log increase (+)
<i>Escherichia coli</i> ATCC 25922	1:10	Puritan 151002	4.1×10^5	1.54×10^5	2.59×10^6	0.80
		Puritan 151026	6.2×10^5	1.72×10^6	3.0×10^6	0.68
		Puritan 151105	5.1×10^5	1.47×10^6	2.66×10^6	0.72
<i>Shigella sonnei</i> ATCC 12022	1:10	Puritan 151002	6.0×10^5	1.81×10^6	3.16×10^6	0.72
		Puritan 151026	4.7×10^5	1.63×10^6	2.94×10^6	0.80
		Puritan 151105	5.3×10^5	1.33×10^6	2.28×10^6	0.63
<i>Yersinia enterocolitica</i> ATCC 9610	1:10	Puritan 151002	4.3×10^5	1.74×10^6	2.99×10^6	0.84
		Puritan 151026	5.7×10^5	1.98×10^6	3.24×10^6	0.75
		Puritan 151105	4.9×10^5	1.57×10^6	2.55×10^6	0.72
<i>Escherichia coli</i> O157:H7 ATCC 700728	1:10	Puritan 151002	3.3×10^5	7.6×10^5	1.11×10^6	0.53
		Puritan 151026	4.7×10^5	9.4×10^5	1.34×10^6	0.46
		Puritan 151105	5.5×10^5	1.19×10^6	2.14×10^6	0.59
<i>Enterococcus faecalis</i> <i>vancomycin resistant (VRE)</i> ATCC 51299	1:10	Puritan 151002	3.3×10^5	4.4×10^5	5.4×10^5	0.21
		Puritan 151026	3.7×10^5	4.8×10^5	8.9×10^5	0.38
		Puritan 151105	4.0×10^5	4.2×10^5	9.0×10^5	0.35
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 151002	3.9×10^5	9.6×10^5	1.75×10^6	0.65
		Puritan 151026	4.8×10^5	1.05×10^6	1.84×10^6	0.58
		Puritan 151105	6.0×10^5	1.49×10^6	2.61×10^6	0.64
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 151002	4.6×10^5	1.51×10^6	2.59×10^6	0.75
		Puritan 151026	6.9×10^5	1.98×10^6	3.04×10^6	0.64
		Puritan 151105	5.7×10^5	1.32×10^6	2.44×10^6	0.63
<i>Campylobacter jejuni</i> ATCC 33291	1:10	Puritan 151002	1.99×10^6	1.29×10^6	1.0×10^5	-1.30
		Puritan 151026	2.48×10^6	1.83×10^6	1.8×10^5	-1.14
		Puritan 151105	2.5×10^6	1.72×10^6	1.4×10^5	-1.25

Table 8. Recovery results for bacteria prepared in 0.85% saline Puritan Opti-Tranz Cary-Blair Collection and Transport System using Swab Elution Method at 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 151002	4.1×10^5	3.5×10^5	1.8×10^5	7.0×10^4	-0.77
		Puritan 151026	6.2×10^5	6.8×10^5	4.0×10^5	1.6×10^5	-0.59
		Puritan 151105	5.1×10^5	5.2×10^5	2.4×10^5	1.1×10^5	-0.67
<i>Shigella sonnei</i> ATCC 12022	1:10	Puritan 151002	6.0×10^5	5.8×10^5	4.1×10^5	3.0×10^5	-0.30
		Puritan 151026	4.7×10^5	6.5×10^5	3.3×10^5	2.1×10^5	-0.35
		Puritan 151105	5.3×10^5	7.4×10^5	3.6×10^5	2.7×10^5	-0.29
<i>Yersinia enterocolitica</i> ATCC 9610	1:10	Puritan 151002	4.3×10^5	5.4×10^5	3.8×10^5	2.3×10^5	-0.27
		Puritan 151026	5.7×10^5	7.1×10^5	4.7×10^5	3.5×10^5	-0.21
		Puritan 151105	4.9×10^5	6.7×10^5	4.2×10^5	3.4×10^5	-0.16
<i>Escherichia coli</i> 0157:H7 ATCC 700728	1:10	Puritan 151002	3.3×10^5	1.2×10^5	8.0×10^4	3.5×10^4	-0.97
		Puritan 151026	4.7×10^5	3.4×10^5	1.9×10^5	4.0×10^4	-1.07
		Puritan 151105	5.5×10^5	4.8×10^5	2.2×10^5	5.0×10^4	-1.04
<i>Enterococcus faecalis</i> <i>vancomycin resistant (VRE)</i> ATCC 51299	1:10	Puritan 151002	3.3×10^5	1.6×10^5	1.3×10^5	9.0×10^4	-0.56
		Puritan 151026	3.7×10^5	1.9×10^5	1.2×10^5	6.0×10^4	-0.79
		Puritan 151105	4.0×10^5	2.0×10^5	1.5×10^5	1.2×10^5	-0.52
<i>Salmonella typhimurium</i> ATCC 14028	1:10	Puritan 151002	3.9×10^5	4.3×10^5	2.7×10^5	1.9×10^5	-0.31
		Puritan 151026	4.8×10^5	6.1×10^5	3.6×10^5	2.1×10^5	-0.36
		Puritan 151105	6.0×10^5	6.7×10^5	4.1×10^5	3.3×10^5	-0.26
<i>Vibrio parahaemolyticus</i> ATCC 17802	1:10	Puritan 151002	4.6×10^5	5.8×10^5	3.7×10^5	2.0×10^5	-0.36
		Puritan 151026	6.9×10^5	7.2×10^5	5.4×10^5	3.7×10^5	-0.27
		Puritan 151105	5.7×10^5	6.0×10^5	4.0×10^5	2.8×10^5	-0.31
<i>Campylobacter jejuni</i> ATCC 33291	1:10	Puritan 151002	1.99×10^6	1.14×10^6	6.5×10^5	1.1×10^5	-1.26
		Puritan 151026	2.48×10^6	1.52×10^6	9.4×10^5	2.1×10^5	-1.07
		Puritan 151105	2.5×10^6	1.59×10^6	8.6×10^5	1.9×10^5	-1.12

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