

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

A. 510(k) Number:

K142366

B. Purpose for Submission:

To make a substantial equivalence determination for the Puritan Optitranz Liquid Stuart Collection and Transport System intended for the collection and transport of clinical specimens containing aerobic and fastidious microorganisms from the clinic to the laboratory.

C. Measurand:

Not applicable

D. Type of Test:

Collection and transport culture media system

E. Applicant:

Puritan Medical Products LLC

F. Proprietary and Established Names:

Puritan® Optitranz™ Liquid Stuart Collection and Transport System

G. Regulatory Information:

1. Regulation section:

21 CFR 866.2390 – Transport culture medium

2. Classification:

Class I (general controls)

3. Product code:

JSM: Transport culture media

LIO: Device, Specimen Collection

JTW: System transport aerobic

4. Panel:

Microbiology (83)

H. Intended Use:

1. Intended use(s):

Puritan OptiTranz Liquid Stuart Collection and Transport System is intended for use in the collection and transport of clinical specimen containing aerobic and fastidious bacteria from patient to the laboratory for bacteriological examination and culture.

2. Indication(s) for use:

Same as intended use.

3. Special conditions for use statement(s):

For in vitro diagnostic use only

For prescription use only

4. Special instrument requirements:

None

I. Device Description:

Puritan OptiTranz Liquid Stuart Collection and Transport System is comprised of a sterile peel pouch containing a rayon or flock tipped swab applicator for collecting specimen and a polypropylene tube containing 1 ml of liquid Stuart medium.

Puritan OptiTranz Liquid Stuart Medium is a nonnutritive balanced salt solution containing phosphates to provide buffering capability and calcium chloride to provide essential ions that help maintain osmotic balance. Mercaptoacetic acid provides a reduced environment. It is recommended for maintaining the viability of aerobic and fastidious bacteria during the transport to the laboratory.

Approximate Puritan OptiTranz liquid Stuart medium formulation per liter

Calcium Chloride	0.1g
Mercaptoacetic Acid	1.0g
Sodium Glycerophosphate	10.0g

J. Substantial Equivalence Information:

1. Predicate device name(s):
BD Culture Swab collection and transport system, manufactured by Copan Venturi,
Transystem Liquid Stuarts Medium
2. Predicate 510(k) number(s):
K946283
3. Comparison with predicate:

Similarities		
Item	Puritan OptiTranz Liquid Stuart Collection and Transport System K142366	BD CultureSwab™ Collection and Transport K946283
Intended USE	Puritan OptiTranz Liquid Stuart Collection and Transport System is intended for use in the collection and transport of clinical specimen containing aerobic and fastidious bacteria from patient to the laboratory for bacteriological examination and culture.	Copan Venturi Transystem Liquid Stuarts Medium products (141C, 143C & 139C) are sterile ready-to-use systems intended for the safe collection, transport, and preservation of clinical specimens for bacteriological examination. Product 141C (plastic applicator) is intended for collecting samples from the throat, vagina or from wounds. Product 143C (aluminum applicator) is intended for collection of specimens from small or less accessible areas such as the eye, ear, nose, throat, urogenital tract and for pediatric use. Product 139C (two plastic applicators) is used for throat, vaginal or wound sampling. The double swab permits use of the second sample in the laboratory for gram stain analysis or as a backup for verification of initial culture.

Similarities		
Item	Puritan OptiTranz Liquid Stuart Collection and Transport System K142366	BD CultureSwab™ Collection and Transport K946283
Single-use Device	Yes	Same
Medium Formulation	Sodium Glycerophosphate Calcium Chloride Mercaptoacetic acid	Same
pH	7.3 ± 0.2	Same
Storage Temperature	2-25°C (refrigerated and room temperature)	5-25°C (refrigerated and room temperature)
Container	Plastic round bottom tube	Same
Product Configuration	Medium in tubes, Plug & polyurethane foam System including medium and swab in peel pouch option.	Same
Swab Shaft	Plastic	Same
Shelf Life	18 months	Same

Differences		
Item	Device	Predicate
Swab Tip	Rayon or flock tipped swab	Rayon tipped swab

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

Quality Control of Microbiological Transport Systems; Approved Standard-Second Edition.
CLSI Standard M40-A2.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The performance characteristics of Puritan® OptiTranz Liquid Stuart Medium was determined using roll plate and swab elution methods out lined in The Clinical and Laboratory Standards Institute (CLSI) M40-A2 document. Rayon or flock tipped swabs designed for different applications were used. A variety of aerobic and one facultative organism were included in this study. The test organisms comprised of the ten ATCC strains five of which are recommended in the CLSI M40-A2 document for determining performance characteristics of swab transport systems. To determine the performance characteristics of Puritan OptiTranz Liquid Stuart Medium bacterial viability studies were performed. These

studies were conducted under refrigerated (2-8°C) and room temperature (20-25°C) conditions. Rayon and flocked tipped swabs were inoculated in duplicate with specified volume of selective bacterial concentrations. These swabs were then placed in the transport vials containing Liquid Stuarts Media and held for 0, 24, and 48 hours; at the designated time intervals the swabs were removed and processed.

Organisms evaluated:

A. Aerobes

1. *Pseudomonas aeruginosa* ATCC BAA-427
2. *Streptococcus pyogenes* ATCC 19615
3. *Streptococcus pneumoniae* ATCC 6305
4. *Haemophilus influenzae* ATCC 10211

B. Fastidious

1. *Neisseria gonorrhoeae* ATCC 43069.

C. Additional organisms

1. *Streptococcus agalactiae* (Group B Strep) ATCC 13813,
2. *Enterococcus faecalis*(VRE) ATCC 51299,
3. *Staphylococcus aureus* (MRSA) ATCC 43300,
4. *Bordetella parapertussis* ATCC 15311
5. *Bordetella pertussis* ATCC 8467

Acceptance criteria for recovery of bacteria as recommended in the CLSI document M40-A2 are followed. Manual colony counts were conducted for the Roll-Plate Method and the Swab Elution Method at all three time intervals for each swab-organism combination, except *Neisseria gonorrhoeae*, and the average for each lot was recorded. Three dilutions were analyzed for each test organism and the dilution yielding zero-time colony counts between 94 to 300 CFU was reported. These viability results are acceptable.

Roll-Plate Method:

The results of the study by Roll-Plate Method are presented in Tables 1-4 below for 3 lots of Puritan OptiTranz Liquid Stuart Collection and Transport System. The results demonstrate that the Puritan OptiTranz Liquid Stuart Collection and Transport System were able to maintain acceptable viability of all organisms up to 48 hours at room temperature (20-25°C) and under refrigerated (4-8°C) conditions based on the acceptance criteria in CLSI M40-A2. For the transport system to demonstrate acceptable viability by the Roll Plate method, ≥ 5 CFU should be recovered following the specified maintenance time from the specific dilution that yielded time-zero plate counts closest to 300 CFU. *Neisseria gonorrhoeae* results support acceptable recoveries up to 24 h, as recommended in the CLSI guidance M40-A2. There is no CLSI M40-A2 interpretation for *N. gonorrhoeae* beyond 24 h of storage using the Roll Plate Method.

Table 1. Bacterial recovery results for Puritan Liquid Stuart Medium using Rayon swabs and the 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>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 140609	188	104	68
		Puritan - 140610	270	147	54
		Puritan -140611	160	94	86
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 140609	156	128	65
		Puritan - 140610	119	20	10
		Puritan -140611	178	100	44
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 140609	200	113	76
		Puritan - 140610	173	109	70
		Puritan -140611	148	100	49
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 140609	172	114	91
		Puritan - 140610	127	60	36
		Puritan -140611	138	107	27
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 10 ⁻⁴	Puritan - 140609	288	225	150
		Puritan - 140610	235	167	112
		Puritan -140611	240	152	120
<i>Bordetella pertussis</i> ATCC 9797	Diluted 10 ⁻⁴	Puritan - 140609	167	79	70
		Puritan - 140610	175	132	92
		Puritan -140611	203	140	86
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 10 ⁻⁴	Puritan - 140609	166	125	99
		Puritan - 140610	286	263	114
		Puritan -140611	115	32	24
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 10 ⁻⁴	Puritan - 140609	223	87	61
		Puritan - 140610	256	192	104
		Puritan -140611	216	112	80
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 10 ⁻⁴	Puritan - 140609	158	117	82
		Puritan - 140610	252	107	80
		Puritan -140611	110	94	68
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 140609	198	49	
		Puritan - 140610	199	17	
		Puritan -140611	280	80	

Table 2. Bacterial recovery results for Puritan Liquid Stuart Medium using Rayon swabs and the 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
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 140609	188	175	179
		Puritan - 140610	270	246	223
		Puritan -140611	160	146	139
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 140609	156	143	133
		Puritan - 140610	119	64	44
		Puritan -140611	178	168	96
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 140609	200	129	121
		Puritan - 140610	173	130	112
		Puritan -140611	148	113	70
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 140609	172	130	118
		Puritan - 140610	127	96	75
		Puritan -140611	138	99	62
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 10 ⁻⁴	Puritan - 140609	288	254	200
		Puritan - 140610	235	211	187
		Puritan -140611	240	208	172
<i>Bordetella pertussis</i> ATCC 9797	Diluted 10 ⁻⁴	Puritan - 140609	167	100	96
		Puritan - 140610	175	155	128
		Puritan -140611	203	182	142
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 10 ⁻⁴	Puritan - 140609	166	145	120
		Puritan - 140610	286	275	271
		Puritan -140611	115	89	59
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 10 ⁻⁴	Puritan - 140609	223	184	144
		Puritan - 140610	256	207	147
		Puritan -140611	216	188	177
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 10 ⁻⁴	Puritan - 140609	158	127	101
		Puritan - 140610	252	243	132
		Puritan -140611	110	108	83
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 140609	198	83	
		Puritan - 140610	199	124	
		Puritan -140611	280	150	

Table 3. Bacterial recovery results for Puritan Liquid Stuart Medium using HydraFlock swabs and the 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>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 140609	236	49	56
		Puritan - 140610	223	150	79
		Puritan -140611	130	78	77
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 140609	206	136	70
		Puritan - 140610	182	76	54
		Puritan -140611	151	95	59
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 140609	134	113	79
		Puritan - 140610	141	111	88
		Puritan -140611	217	157	116
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 140609	125	64	16
		Puritan - 140610	131	44	31
		Puritan -140611	164	104	46
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 10 ⁻⁴	Puritan - 140609	270	220	150
		Puritan - 140610	294	213	185
		Puritan -140611	256	216	160
<i>Bordetella pertussis</i> ATCC 9797	Diluted 10 ⁻⁴	Puritan - 140609	114	32	13
		Puritan - 140610	136	45	24
		Puritan -140611	152	43	20
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 10 ⁻⁴	Puritan - 140609	137	101	76
		Puritan - 140610	300	184	145
		Puritan -140611	167	133	90
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 10 ⁻⁴	Puritan - 140609	225	134	28
		Puritan - 140610	262	187	43
		Puritan -140611	160	98	49
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 10 ⁻⁴	Puritan - 140609	177	131	81
		Puritan - 140610	117	63	35
		Puritan -140611	183	136	112
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 140609	200	70	
		Puritan - 140610	106	22	
		Puritan -140611	230	83	

Table 4. Bacterial recovery results for Puritan Liquid Stuart Medium using HydraFlock swabs and the 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
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 140609	236	190	164
		Puritan - 140610	223	199	176
		Puritan -140611	130	122	101
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 140609	206	200	125
		Puritan - 140610	182	179	130
		Puritan -140611	151	107	82
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 140609	134	133	123
		Puritan - 140610	141	123	110
		Puritan -140611	217	155	121
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 140609	125	91	44
		Puritan - 140610	131	107	73
		Puritan -140611	164	109	58
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 10 ⁻⁴	Puritan - 140609	270	236	170
		Puritan - 140610	294	259	241
		Puritan -140611	256	232	200
<i>Bordetella pertussis</i> ATCC 9797	Diluted 10 ⁻⁴	Puritan - 140609	114	41	36
		Puritan - 140610	136	92	55
		Puritan -140611	152	119	63
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 10 ⁻⁴	Puritan - 140609	137	122	106
		Puritan - 140610	300	281	223
		Puritan -140611	167	159	139
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 10 ⁻⁴	Puritan - 140609	225	186	90
		Puritan - 140610	262	241	106
		Puritan -140611	160	129	91
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 10 ⁻⁴	Puritan - 140609	177	144	98
		Puritan - 140610	117	92	60
		Puritan -140611	183	160	150
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 140609	200	136	
		Puritan - 140610	106	55	
		Puritan -140611	230	116	

Swab Elution Method:

The results of the study by Swab Elution Method are presented in Tables 5-8 below for 3 lots of Puritan OptiTranz Liquid Stuart Collection and Transport System. The results demonstrate that the swabs from Puritan OptiTranz Liquid Stuart Collection and Transport System were able to maintain acceptable viability levels for all organisms up to 48 hours at room temperature (20-25°C) and under refrigerated (4-8°C) conditions based on the acceptance recovery criteria in CLSI M40-A2 . For viability in the Swab Elution Method to be considered acceptable there shall be no more than a 3 log₁₀ (1 x 10³ +/- 10%) decline in CFU between the zero-time CFU count and the CFU of the swabs that were stored. *Neisseria gonorrhoeae* results support acceptable recoveries up to 24 h, as recommended in the CLSI guidance M40-A2. There is no CLSI M40-A2 interpretation for *N. gonorrhoeae* beyond 24 h of storage using the Swab Elution Method.

Table 5. Bacterial recovery results for Puritan Liquid Stuart Medium using Rayon swabs and the 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 ₁₀ Decline
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 1:10	Puritan - 140609	1.5 x 10 ⁶	6.8 x 10 ⁵	3.3 x 10 ⁵	-0.66
		Puritan - 140610	2.2 x 10 ⁶	5.3 x 10 ⁵	2.8 x 10 ⁵	-0.90
		Puritan -140611	2.0 x 10 ⁶	6.0 x 10 ⁵	1.9 x 10 ⁵	-1.02
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	7.5 x 10 ⁵	6.7 x 10 ⁵	-0.50
		Puritan - 140610	1.8 x 10 ⁶	4.4 x 10 ⁵	3.5 x 10 ⁵	-0.71
		Puritan -140611	2.1 x 10 ⁶	9.7 x 10 ⁵	7.4 x 10 ⁵	-0.45
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 1:10	Puritan - 140609	1.8 x 10 ⁶	6.0 x 10 ⁵	4.4 x 10 ⁵	-0.61
		Puritan - 140610	1.7 x 10 ⁶	8.8 x 10 ⁵	5.0 x 10 ⁵	-0.53
		Puritan -140611	2.0 x 10 ⁶	8.6 x 10 ⁵	4.1 x 10 ⁵	-0.69
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 1:10	Puritan - 140609	1.0 x 10 ⁶	2.4 x 10 ⁵	7.6 x 10 ⁴	-1.12
		Puritan - 140610	9.6 x 10 ⁵	3.9 x 10 ⁵	9.8 x 10 ⁴	-0.99
		Puritan -140611	1.3 x 10 ⁶	3.3 x 10 ⁵	8.8 x 10 ⁴	-1.17
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 1:10	Puritan - 140609	1.1 x 10 ⁶	2.9 x 10 ⁵	9.1 x 10 ⁴	-1.08
		Puritan - 140610	1.4 x 10 ⁶	3.9 x 10 ⁵	1.2 x 10 ⁵	-1.07
		Puritan -140611	1.1 x 10 ⁶	3.8 x 10 ⁵	9.7 x 10 ⁴	-1.05
<i>Bordetella pertussis</i> ATCC 9797	Diluted 1:10	Puritan - 140609	1.4 x 10 ⁶	7.9 x 10 ⁵	5.3 x 10 ⁴	-1.42
		Puritan - 140610	1.6 x 10 ⁶	6.1 x 10 ⁵	8.8 x 10 ⁴	-1.26
		Puritan -140611	1.8 x 10 ⁶	6.2 x 10 ⁵	2.2 x 10 ⁵	-0.91
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 1:10	Puritan - 140609	2.2 x 10 ⁶	5.5 x 10 ⁵	1.7 x 10 ⁵	-1.11
		Puritan - 140610	2.5 x 10 ⁶	5.1 x 10 ⁵	3.9 x 10 ⁵	-0.81
		Puritan -140611	2.4 x 10 ⁶	6.4 x 10 ⁵	1.4 x 10 ⁵	-1.23
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 1:10	Puritan - 140609	2.0 x 10 ⁶	6.0 x 10 ⁵	4.1 x 10 ⁵	-0.69
		Puritan - 140610	2.2 x 10 ⁶	6.3 x 10 ⁵	5.4 x 10 ⁵	-0.61
		Puritan -140611	1.9 x 10 ⁶	5.6 x 10 ⁵	3.3 x 10 ⁵	-0.76
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 1:10	Puritan - 140609	1.4 x 10 ⁶	5.9 x 10 ⁵	1.0 x 10 ⁵	-1.15
		Puritan - 140610	1.2 x 10 ⁶	5.0 x 10 ⁵	7.2 x 10 ⁴	-1.22
		Puritan -140611	9.4 x 10 ⁵	4.5 x 10 ⁵	5.9 x 10 ⁴	-1.20
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	1.1 x 10 ⁵		-1.28
		Puritan - 140610	2.4 x 10 ⁶	9.0 x 10 ⁴		-1.43
		Puritan -140611	2.0 x 10 ⁶	8.3 x 10 ⁴		-1.38

Table 6. Bacterial recovery results for Puritan Liquid Stuart Medium using Rayon swabs and the 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	Log ₁₀ Decline
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 1:10	Puritan - 140609	1.5 x 10 ⁶	1.6 x 10 ⁶	8.5 x 10 ⁵	-0.25
		Puritan - 140610	2.2 x 10 ⁶	2.5 x 10 ⁶	9.2 x 10 ⁵	-0.38
		Puritan -140611	2.0 x 10 ⁶	2.4 x 10 ⁶	7.9 x 10 ⁵	-0.40
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	2.0 x 10 ⁶	5.6 x 10 ⁵	-0.57
		Puritan - 140610	1.8 x 10 ⁶	1.5 x 10 ⁶	7.0 x 10 ⁵	-0.41
		Puritan -140611	2.1 x 10 ⁶	1.7 x 10 ⁶	9.5 x 10 ⁵	-0.34
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 1:10	Puritan - 140609	1.8 x 10 ⁶	1.5 x 10 ⁶	3.0 x 10 ⁵	-0.78
		Puritan - 140610	1.7 x 10 ⁶	1.2 x 10 ⁶	5.8 x 10 ⁵	-0.47
		Puritan -140611	2.0 x 10 ⁶	1.5 x 10 ⁶	9.3 x 10 ⁵	-0.33
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 1:10	Puritan - 140609	1.0 x 10 ⁶	9.9 x 10 ⁵	4.1 x 10 ⁵	-0.39
		Puritan - 140610	9.6 x 10 ⁵	9.0 x 10 ⁵	2.6 x 10 ⁵	-0.57
		Puritan -140611	1.3 x 10 ⁶	1.1 x 10 ⁶	7.8 x 10 ⁵	-0.22
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 1:10	Puritan - 140609	1.1 x 10 ⁶	1.0 x 10 ⁶	7.7 x 10 ⁵	-0.15
		Puritan - 140610	1.4 x 10 ⁶	1.3 x 10 ⁶	6.9 x 10 ⁵	-0.31
		Puritan -140611	1.1 x 10 ⁶	1.1 x 10 ⁶	7.0 x 10 ⁵	-0.20
<i>Bordetella pertussis</i> ATCC 9797	Diluted 1:10	Puritan - 140609	1.4 x 10 ⁶	1.2 x 10 ⁶	8.1 x 10 ⁵	-0.24
		Puritan - 140610	1.6 x 10 ⁶	1.5 x 10 ⁶	6.6 x 10 ⁵	-0.38
		Puritan -140611	1.8 x 10 ⁶	1.4 x 10 ⁶	7.9 x 10 ⁵	-0.36
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 1:10	Puritan - 140609	2.2 x 10 ⁶	2.0 x 10 ⁶	5.5 x 10 ⁵	-0.60
		Puritan - 140610	2.5 x 10 ⁶	2.4 x 10 ⁶	5.1 x 10 ⁵	-0.69
		Puritan -140611	2.4 x 10 ⁶	2.1 x 10 ⁶	8.5 x 10 ⁵	-0.45
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 1:10	Puritan - 140609	2.0 x 10 ⁶	1.7 x 10 ⁶	8.6 x 10 ⁵	-0.37
		Puritan - 140610	2.2 x 10 ⁶	2.0 x 10 ⁶	5.9x 10 ⁵	-0.57
		Puritan -140611	1.9 x 10 ⁶	1.8 x 10 ⁶	3.9 x 10 ⁵	-0.69
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 1:10	Puritan - 140609	1.4 x 10 ⁶	1.3 x 10 ⁶	9.3 x 10 ⁵	-0.18
		Puritan - 140610	1.2 x 10 ⁶	9.7 x 10 ⁵	6.3 x 10 ⁵	-0.28
		Puritan -140611	9.4 x 10 ⁵	8.2 x 10 ⁵	3.9 x 10 ⁵	-0.38
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	8.5 x 10 ⁵		-0.39
		Puritan - 140610	2.4 x 10 ⁶	7.8 x 10 ⁵		-0.49
		Puritan -140611	2.0 x 10 ⁶	1.3 x 10 ⁶		-0.19

Table 7. Bacterial recovery results for Puritan Liquid Stuart Medium using HydraFlock swabs and the 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 ₁₀ Decline
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 1:10	Puritan - 140609	2.7 x 10 ⁶	8.9 x 10 ⁵	3.6 x 10 ⁵	-0.88
		Puritan - 140610	2.4 x 10 ⁶	7.5 x 10 ⁵	1.9 x 10 ⁵	-1.10
		Puritan -140611	2.6 x 10 ⁶	7.4 x 10 ⁵	5.1 x 10 ⁵	-0.71
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	6.9 x 10 ⁵	2.9 x 10 ⁵	-0.86
		Puritan - 140610	2.4 x 10 ⁶	7.4 x 10 ⁵	3.5 x 10 ⁵	-0.84
		Puritan -140611	2.5 x 10 ⁶	8.3 x 10 ⁵	4.1 x 10 ⁵	-0.79
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 1:10	Puritan - 140609	2.3 x 10 ⁶	5.5 x 10 ⁵	1.2 x 10 ⁵	-1.28
		Puritan - 140610	2.2 x 10 ⁶	6.2 x 10 ⁵	2.0 x 10 ⁵	-1.04
		Puritan -140611	2.7 x 10 ⁶	7.3 x 10 ⁵	3.0 x 10 ⁵	-0.95
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	8.1 x 10 ⁵	2.6 x 10 ⁵	-0.91
		Puritan - 140610	2.3 x 10 ⁶	7.8 x 10 ⁵	1.6 x 10 ⁵	-1.16
		Puritan -140611	1.9 x 10 ⁶	7.5 x 10 ⁵	1.2 x 10 ⁵	-1.20
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 1:10	Puritan - 140609	1.8 x 10 ⁶	8.3 x 10 ⁵	6.8 x 10 ⁵	-0.42
		Puritan - 140610	1.9 x 10 ⁶	8.8 x 10 ⁵	5.2 x 10 ⁵	-0.56
		Puritan -140611	2.2 x 10 ⁶	9.8 x 10 ⁵	4.2 x 10 ⁵	-0.72
<i>Bordetella pertussis</i> ATCC 9797	Diluted 1:10	Puritan - 140609	1.7 x 10 ⁶	6.3 x 10 ⁵	1.5 x 10 ⁵	-1.05
		Puritan - 140610	2.0 x 10 ⁶	6.8 x 10 ⁵	2.4 x 10 ⁵	-0.92
		Puritan -140611	1.6 x 10 ⁶	7.2 x 10 ⁵	1.1 x 10 ⁵	-1.16
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 1:10	Puritan - 140609	2.4 x 10 ⁶	5.9 x 10 ⁵	2.0 x 10 ⁵	-1.08
		Puritan - 140610	2.8 x 10 ⁶	6.6 x 10 ⁵	3.1 x 10 ⁵	-0.96
		Puritan -140611	2.8 x 10 ⁶	5.8 x 10 ⁵	2.7 x 10 ⁵	-1.02
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 1:10	Puritan - 140609	2.3 x 10 ⁶	9.3 x 10 ⁵	3.3 x 10 ⁵	-0.84
		Puritan - 140610	2.0 x 10 ⁶	8.8 x 10 ⁵	4.6 x 10 ⁵	-0.64
		Puritan -140611	2.4 x 10 ⁶	7.8 x 10 ⁵	2.9 x 10 ⁵	-0.92
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 1:10	Puritan - 140609	1.7 x 10 ⁶	3.0 x 10 ⁵	1.0 x 10 ⁵	-1.23
		Puritan - 140610	1.9 x 10 ⁶	4.6 x 10 ⁵	2.5 x 10 ⁵	-0.88
		Puritan -140611	1.6 x 10 ⁶	4.9 x 10 ⁵	2.8 x 10 ⁵	-0.76
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 1:10	Puritan - 140609	1.3 x 10 ⁶	2.8 x 10 ⁵		-0.67
		Puritan - 140610	1.2 x 10 ⁶	1.8 x 10 ⁵		-0.82
		Puritan -140611	1.6 x 10 ⁶	1.0 x 10 ⁵		-1.20

Table 8. Bacterial recovery results for Puritan Liquid Stuart Medium using HydraFlock swabs and the 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	Log ₁₀ Decline
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 1:10	Puritan - 140609	2.7 x 10 ⁶	1.9 x 10 ⁶	1.2 x 10 ⁶	-0.35
		Puritan - 140610	2.4 x 10 ⁶	9.5 x 10 ⁵	8.3 x 10 ⁵	-0.46
		Puritan -140611	2.6 x 10 ⁶	9.9 x 10 ⁵	8.1 x 10 ⁵	-0.51
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	9.3 x 10 ⁵	5.3 x 10 ⁵	-0.60
		Puritan - 140610	2.4 x 10 ⁶	8.9 x 10 ⁵	7.8 x 10 ⁵	-0.49
		Puritan -140611	2.5 x 10 ⁶	8.3 x 10 ⁵	6.0 x 10 ⁵	-0.62
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 1:10	Puritan - 140609	2.3 x 10 ⁶	8.5 x 10 ⁵	4.3 x 10 ⁵	-0.73
		Puritan - 140610	2.2 x 10 ⁶	8.8 x 10 ⁵	6.1 x 10 ⁵	-0.56
		Puritan -140611	2.7 x 10 ⁶	9.0 x 10 ⁵	6.0 x 10 ⁵	-0.65
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 1:10	Puritan - 140609	2.1 x 10 ⁶	1.8 x 10 ⁶	5.9 x 10 ⁵	-0.55
		Puritan - 140610	2.3 x 10 ⁶	1.7 x 10 ⁶	3.8 x 10 ⁵	-0.78
		Puritan -140611	1.9 x 10 ⁶	1.9 x 10 ⁶	6.5 x 10 ⁵	-0.47
<i>Bordetella parapertussis</i> ATCC 15311	Diluted 1:10	Puritan - 140609	1.8 x 10 ⁶	9.8 x 10 ⁵	8.3 x 10 ⁵	-0.34
		Puritan - 140610	1.9 x 10 ⁶	9.6 x 10 ⁵	8.0 x 10 ⁵	-0.38
		Puritan -140611	2.2 x 10 ⁶	1.3 x 10 ⁶	7.6 x 10 ⁵	-0.46
<i>Bordetella pertussis</i> ATCC 9797	Diluted 1:10	Puritan - 140609	1.7 x 10 ⁶	9.4 x 10 ⁵	6.9x 10 ⁵	-0.39
		Puritan - 140610	2.0 x 10 ⁶	8.8 x 10 ⁵	7.4 x 10 ⁵	-0.43
		Puritan -140611	1.6 x 10 ⁶	9.0 x 10 ⁵	7.5 x 10 ⁵	-0.33
<i>Staphylococcus aureus</i> (MRSA) ATCC 43300	Diluted 1:10	Puritan - 140609	2.4 x 10 ⁶	1.5 x 10 ⁶	9.2 x 10 ⁵	-0.42
		Puritan - 140610	2.8 x 10 ⁶	1.8 x 10 ⁶	7.0 x 10 ⁵	-0.60
		Puritan -140611	2.8 x 10 ⁶	2.0 x 10 ⁶	8.7 x 10 ⁵	-0.51
<i>Enterococcus faecalis</i> (VRE) ATCC 51299	Diluted 1:10	Puritan - 140609	2.3 x 10 ⁶	9.9 x 10 ⁵	8.9 x 10 ⁵	-0.41
		Puritan - 140610	2.0 x 10 ⁶	9.2 x 10 ⁵	6.5 x 10 ⁵	-0.49
		Puritan -140611	2.4 x 10 ⁶	1.1 x 10 ⁶	5.4 x 10 ⁵	-0.65
<i>Streptococcus agalactiae</i> (Group B Strep) ATCC 13813	Diluted 1:10	Puritan - 140609	1.7 x 10 ⁶	9.3 x 10 ⁵	7.9 x 10 ⁵	-0.33
		Puritan - 140610	1.9 x 10 ⁶	8.7 x 10 ⁵	5.3 x 10 ⁵	-0.55
		Puritan -140611	1.6 x 10 ⁶	8.1 x 10 ⁵	5.9 x 10 ⁵	-0.43
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 1:10	Puritan - 140609	1.3 x 10 ⁶	4.9 x 10 ⁵		-0.42
		Puritan - 140610	1.2 x 10 ⁶	6.5 x 10 ⁵		-0.27
		Puritan -140611	1.6 x 10 ⁶	6.8 x 10 ⁵		-0.37

Overgrowth Evaluation:

Viability performance studies on all of the organisms above also included an assessment of performance evaluation and overgrowth per CLSI M40-A2 8.12.4 for roll plate method. Overgrowth assessment as defined in CLSI M40-A2 guideline is greater than one-log₁₀ increase in CFU between zero-time and the holding time point. There was no increase in bacterial count for all organisms tested when the samples were stored at room temperature. The data provided is in conformance with the guidelines in CLSI M40-A2 at room temperature.

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

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

Accelerated shelf life stability test were performed successfully on 3 lots of product demonstrating stability for up to 18 months at room temperature.

pH Stability: The pH of the test device was measured at predetermined time intervals up to 18 month after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan OptiTranz liquid Stuart Medium. All samples tested were found to maintain pH within the specified range of 7.3+/- 0.2.

Cytotoxicity: Cytotoxicity test was conducted to evaluate glue, shaft, rayon or flock tipped swabs for potential cytotoxicity effect following ISO Elution Method-1X MEM Extract. Historically the ISO Elution method is used for cytotoxicity because cytotoxicity is not addressed in CLSI M40-A2 for swab transport devices. No evidence of cytotoxicity was detected as no cell lysis and no reduction in cell growth were observed.

Sterilization: Puritan OptiTranz liquid Stuart Medium 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:

Method comparison is not applicable for a bacterial transport medium. The device itself does not provide a result that can be used in making a clinical decision.

Bench testing studies were done to determine the ability of the Puritan OptiTranz Liquid Stuart Collection and Transport System to maintain viability of different strains of aerobic bacteria. It showed recovery of bacteria within the acceptance criteria recommended in the CLSI M40-A2 and similar to the predicate device. (See above under Performance Characteristics).

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.