

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number: K120846

B. Purpose for Submission: New device

C. Measurand: Not applicable (N/A)

D. Type of Test: Transport culture medium device

E. Applicant: Puritan Medical Products LLC

F. Proprietary and Established Names: Puritan® Liquid Amies Collection and
Transport System

G. Regulatory Information:

1. Regulation section: 21 CFR§866.2900; Microbiological specimen collection
and transport device
2. Classification: Class I
3. Product code: LIO: Device, Specimen Collection
JTW: System, Transport, Aerobic
JTX: Transport Systems, Anaerobic

4. Panel: 83 Microbiology

H. Intended Use:

1. Intended use(s):

The Puritan® Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

2. Indication(s) for use:

The Puritan® Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

3. Special conditions for use statement(s): For prescription use

4. Special instrument requirements: None

I. Device Description:

Specialized systems for collecting and transporting bacteriological specimens are commonly used in laboratories to aid in the diagnosis of bacterial infections, especially when there is a delay between specimen collection and processing.

The Puritan® Liquid Amies Collection and Transport System consists of a sterile peel-open pouch containing a pre-scored HydraFlock® flocced swab and a polypropylene screw-cap vial containing 1 ml of modified liquid Amies medium. HydraFlock® multiple split polyester fibers facilitate quick absorption and release of clinical specimens. HydraFlock® flocced swabs are available in various score points and configurations to facilitate specimen collection from various sites on patients' bodies. Modified liquid Amies transport medium is a non-nutritive phosphate-buffered medium capable of maintaining the viability of aerobic, anaerobic, and fastidious bacteria such as *Neisseria*

gonorrhoeae during transport to the laboratory. It also contains thioglycolate salt to provide a reduced environment and chloride salts to help maintain osmotic balance and control permeability of bacterial cells.

Approximate modified liquid Amies medium formulation per liter

Sodium chloride	3.0g
Disodium phosphate	1.2g
Sodium thioglycolate	1.0g
Monopotassium phosphate	0.2g
Potassium chloride	0.2g
Calcium chloride	0.1g
Magnesium chloride	0.1g

J. Substantial Equivalence Information:

1. Predicate device name(s): BD Liquid Amies Elution Swab (ESwab) Collection and Transport System
2. Predicate 510(k) number(s): K061301
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	The Puritan® Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.	BD™ Liquid Amies Elution Swab (ESwab) Collection and Transport System is intended for the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the collection site to the testing laboratory. In the laboratory, BD ESwab specimens are processed using standard clinical laboratory operating

Similarities		
Item	Device	Predicate
Base Medium	Liquid Amies medium	procedures for bacterial culture. Same
Product Configuration	Medium and swab in peel pouch	Same

Differences		
Item	Device	Predicate
Swab Tip	HydraFlock® Swab (Polyester)	Nylon Flock Swab

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

1. Quality Control of Microbiological Transport Systems, M40-A, Clinical Laboratory and Standards Institute (CLSI), Wayne, PA, 2003. [The standard was mentioned for informational purpose only. No claims were made]

L. Test Principle: Not applicable (N/A)

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

The performance characteristics of Puritan® Liquid Amies Collection and Transport System were determined using the procedures outlined in the Clinical Laboratory Standards Institute (CLSI) M40-A document. A variety of aerobic, anaerobic, and fastidious organisms were included in this study. The test organisms comprised of the ten ATCC strains that are recommended in the CLSI M40-A document for determining performance characteristics of swab transport systems. To determine the performance characteristics of the Puritan® Liquid Amies Collection and Transport System, bacterial viability studies were performed. These studies were conducted at two different temperatures to reflect refrigerated (4-8°C) and room temperature (20-25°C) conditions. The swabs from each transport system were inoculated in duplicate with a specified volume of select bacterial concentrations. These swabs were then placed in their respective transport vial and held for 0, 24, and 48 hours; at the designated time intervals the swabs were removed and processed. These studies were conducted using both the Roll-Plate and Swab Elution Methods.

Organisms evaluated:

A. Aerobes and Facultative Anaerobes:

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

B. Anaerobes

1. *Bacteroides fragilis* ATCC 25285,
2. *Peptostreptococcus anaerobius* ATCC 27337,
3. *Fusobacterium nucleatum* ATCC 25586,
4. *Propionibacterium acnes* ATCC 6919,
5. *Prevotella melaninogenica* ATCC 25845.

C. Fastidious

1. *Neisseria gonorrhoeae* ATCC 43069

Acceptance criteria for recovery of bacteria as recommended in the CLSI document M40-A are followed. For Roll-Plate Method viability results to be considered acceptable, there shall be ≥ 5 CFU following the specified holding time from the specific dilution that yielded zero-time plate counts closest to 300 CFU. For results by Swab Elution Method to be considered acceptable there shall be no more than a 3 \log_{10} ($1 \times 10^3 \pm 10\%$) decline in CFU between the zero-time CFU count and the CFU of the swabs that were stored.

The results of the study by Roll-Plate Method and the Swab Elution Method are presented in Tables 1-4. The results demonstrate the ability of Puritan[®] Liquid Amies Collection and Transport System to sustain the viability and recovery of test bacteria within acceptance criteria for at least 48 h at refrigerated (4 -8°C) and room temperatures (20-25°C). *Neisseria gonorrhoeae* results support acceptable recoveries up to 24 h as recommended in the CLSI guidance M40-A.

Viability performance studies also included an assessment of bacterial overgrowth at refrigerated temperature. Overgrowth assessment as defined in CLSI M40-A guideline is greater than 1 \log_{10} increase in CFU between zero-time and the holding time point. There was no increase in bacterial count when the samples were stored at 4-8°C for 48 h and analyzed by the Roll-Plate Method (Table 2) and the Swab Elution Method (Table 4).

Table 1. Bacterial recovery results for the Roll-Plate Method at room temperature.

Organism	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>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 111101	308	310	81
		Puritan - 110907	241	251	111
		Puritan - 111209	267	260	106
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 111101	250	204	77
		Puritan - 110907	194	210	131
		Puritan - 111209	245	191	77
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 111101	134	101	34
		Puritan - 110907	200	88	65
		Puritan - 111209	171	164	74
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 111101	264	254	82
		Puritan - 110907	236	136	48
		Puritan - 111209	250	198	61
<i>Bacteroides fragilis</i> ATCC 25285	Diluted 10 ⁻³	Puritan - 111101	320	265	109
		Puritan - 110907	200	117	64
		Puritan - 111209	270	285	105
<i>Peptostreptococcus anaerobius</i> ATCC 27337	Diluted 10 ⁻³	Puritan - 111101	265	118	41
		Puritan - 110907	260	130	85
		Puritan - 111209	225	150	18
<i>Fusobacterium nucleatum</i> ATCC 25586	Diluted 10 ⁻³	Puritan - 111101	199	105	26
		Puritan - 110907	265	109	40
		Puritan - 111209	213	281	33
<i>Propionibacterium acnes</i> ATCC 6919	Diluted 10 ⁻⁴	Puritan - 111101	280	161	57
		Puritan - 110907	279	96	29
		Puritan - 111209	202	196	65
<i>Prevotella melaninogenica</i> ATCC 25845	Diluted 10 ⁻³	Puritan - 111101	271	121	29
		Puritan - 110907	264	96	21
		Puritan - 111209	289	165	16
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 111101	264	150	
		Puritan - 110907	226	131	
		Puritan - 111209	258	158	

Table 2. Bacterial recovery results for the Roll-Plate Method at refrigerated temperature.

Organism	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>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 111101	308	240	46
		Puritan - 110907	241	113	54
		Puritan - 111209	267	281	128
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 111101	250	200	41
		Puritan - 110907	194	111	78
		Puritan - 111209	245	102	81
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 111101	134	61	16
		Puritan - 110907	200	35	35
		Puritan - 111209	171	122	59
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 111101	264	134	45
		Puritan - 110907	236	83	38
		Puritan - 111209	250	136	47
<i>Bacteroides fragilis</i> ATCC 25285	Diluted 10 ⁻³	Puritan - 111101	320	220	52
		Puritan - 110907	200	103	33
		Puritan - 111209	270	230	96
<i>Peptostreptococcus anaerobius</i> ATCC 27337	Diluted 10 ⁻³	Puritan - 111101	265	101	49
		Puritan - 110907	260	96	39
		Puritan - 111209	225	158	10
<i>Fusobacterium nucleatum</i> ATCC 25586	Diluted 10 ⁻³	Puritan - 111101	199	85	14
		Puritan - 110907	265	67	21
		Puritan - 111209	213	181	41
<i>Propionibacterium acnes</i> ATCC 6919	Diluted 10 ⁻⁴	Puritan - 111101	280	186	23
		Puritan - 110907	279	77	25
		Puritan - 111209	202	164	108
<i>Prevotella melaninogenica</i> ATCC 25845	Diluted 10 ⁻³	Puritan - 111101	271	114	19
		Puritan - 110907	264	121	16
		Puritan - 111209	289	77	46
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 111101	264	119	
		Puritan - 110907	226	90	
		Puritan - 111209	258	160	

Table 3. Bacterial recovery results for the Swab Elution Method at room temperature.

Organism	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	Log ₁₀ Decline
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 111101	1.0x10 ⁶	1.2x10 ⁶	2.1x10 ⁵	-0.68
		Puritan - 110907	1.2x10 ⁶	1.3x10 ⁶	6.1x10 ⁵	-0.29
		Puritan - 111209	2.7x10 ⁶	1.9x10 ⁶	1.8x10 ⁶	-0.18
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 111101	2.1x10 ⁶	2.7x10 ⁶	7.4x10 ⁵	-0.45
		Puritan - 110907	2.6x10 ⁶	9.1x10 ⁵	3.5x10 ⁵	-0.87
		Puritan - 111209	7.6x10 ⁵	1.0x10 ⁶	2.5x10 ⁵	-0.48
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 111101	2.2x10 ⁶	1.8x10 ⁶	5.5x10 ⁵	-0.60
		Puritan - 110907	1.4x10 ⁶	8.8x10 ⁵	3.1x10 ⁵	-0.65
		Puritan - 111209	2.1x10 ⁶	1.1x10 ⁶	9.1x10 ⁵	-0.36
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 111101	2.6x10 ⁶	7.8x10 ⁵	7.1x10 ⁵	-0.56
		Puritan - 110907	2.1x10 ⁶	1.4x10 ⁶	5.1x10 ⁵	-0.61
		Puritan - 111209	3.1x10 ⁶	2.0x10 ⁶	1.5x10 ⁶	-0.32
<i>Bacteroides fragilis</i> ATCC 25285	Diluted 10 ⁻³	Puritan - 111101	1.7x10 ⁶	1.2x10 ⁶	2.1x10 ⁵	-0.91
		Puritan - 110907	9.9x10 ⁵	5.4x10 ⁵	2.8x10 ⁵	-0.55
		Puritan - 111209	2.9x10 ⁶	2.1x10 ⁶	1.3x10 ⁶	-0.35
<i>Peptostreptococcus anaerobius</i> ATCC 27337	Diluted 10 ⁻³	Puritan - 111101	3.1x10 ⁶	1.5x10 ⁶	4.1x10 ⁵	-0.88
		Puritan - 110907	2.0x10 ⁶	1.3x10 ⁶	4.2x10 ⁵	-0.68
		Puritan - 111209	1.9x10 ⁶	7.0x10 ⁵	3.9x10 ⁵	-0.69
<i>Fusobacterium nucleatum</i> ATCC 25586	Diluted 10 ⁻³	Puritan - 111101	2.0x10 ⁶	8.6x10 ⁵	2.5x10 ⁵	-0.90
		Puritan - 110907	1.9x10 ⁶	7.8x10 ⁵	2.1x10 ⁵	-0.96
		Puritan - 111209	2.6x10 ⁶	6.1x10 ⁵	3.0x10 ⁵	-0.94
<i>Propionibacterium acnes</i> ATCC 6919	Diluted 10 ⁻⁴	Puritan - 111101	2.3x10 ⁶	1.2x10 ⁶	7.7x10 ⁵	-0.48
		Puritan - 110907	2.0x10 ⁶	9.9x10 ⁵	6.2x10 ⁵	-0.51
		Puritan - 111209	1.0x10 ⁶	6.2x10 ⁵	2.1x10 ⁵	-0.68
<i>Prevotella melaninogenica</i> ATCC 25845	Diluted 10 ⁻³	Puritan - 111101	1.8x10 ⁶	8.9x10 ⁵	5.6x10 ⁵	-0.51
		Puritan - 110907	1.5x10 ⁶	5.3x10 ⁵	3.5x10 ⁵	-0.63
		Puritan - 111209	1.9x10 ⁶	4.2x10 ⁵	1.7x10 ⁵	-1.05
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 111101	1.1x10 ⁶	1.0x10 ⁵		-1.04
		Puritan - 110907	9.9x10 ⁵	4.6x10 ⁵		-0.33
		Puritan - 111209	1.3x10 ⁶	1.3x10 ⁵		-1.00

Table 4. Bacterial recovery results for the Swab Elution Method at refrigerated temperature.

Organism	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	Log ₁₀ Decline
<i>Pseudomonas aeruginosa</i> ATCC BAA-427	Diluted 10 ⁻⁴	Puritan - 111101	1.0x10 ⁶	9.5x10 ⁵	5.0x10 ⁵	-0.30
		Puritan - 110907	1.2x10 ⁶	9.5x10 ⁵	3.0x10 ⁵	-0.60
		Puritan - 111209	2.7x10 ⁶	4.3x10 ⁵	8.8x10 ⁵	-0.49
<i>Streptococcus pyogenes</i> ATCC 19615	Diluted 10 ⁻⁴	Puritan - 111101	2.1x10 ⁶	7.7x10 ⁵	2.5x10 ⁵	-0.92
		Puritan - 110907	2.6x10 ⁶	5.0x10 ⁵	2.3x10 ⁵	-1.05
		Puritan - 111209	7.6x10 ⁵	1.0x10 ⁶	6.1x10 ⁵	-0.10
<i>Streptococcus pneumoniae</i> ATCC 6305	Diluted 10 ⁻⁴	Puritan - 111101	2.2x10 ⁶	1.1x10 ⁶	1.3x10 ⁵	-1.23
		Puritan - 110907	1.4x10 ⁶	6.8x10 ⁵	1.3x10 ⁵	-1.03
		Puritan - 111209	2.1x10 ⁶	1.1x10 ⁶	1.6x10 ⁶	-0.12
<i>Haemophilus influenzae</i> ATCC 10211	Diluted 10 ⁻⁴	Puritan - 111101	2.6x10 ⁶	4.1x10 ⁵	3.4x10 ⁵	-0.88
		Puritan - 110907	2.1x10 ⁶	1.0x10 ⁶	2.0x10 ⁵	-1.02
		Puritan - 111209	3.1x10 ⁶	3.8x10 ⁵	4.2x10 ⁵	-0.87
<i>Bacteroides fragilis</i> ATCC 25285	Diluted 10 ⁻³	Puritan - 111101	1.7x10 ⁶	8.1x10 ⁵	7.8x10 ⁵	-0.34
		Puritan - 110907	9.9x10 ⁵	6.1x10 ⁵	2.0x10 ⁵	-0.69
		Puritan - 111209	2.9x10 ⁶	7.9x10 ⁵	9.9x10 ⁵	-0.47
<i>Peptostreptococcus anaerobius</i> ATCC 27337	Diluted 10 ⁻³	Puritan - 111101	3.1x10 ⁶	5.5x10 ⁵	1.3x10 ⁵	-1.38
		Puritan - 110907	2.0x10 ⁶	7.7x10 ⁵	1.5x10 ⁵	-1.12
		Puritan - 111209	1.9x10 ⁶	6.1x10 ⁵	9.7x10 ⁵	-0.29
<i>Fusobacterium nucleatum</i> ATCC 25586	Diluted 10 ⁻³	Puritan - 111101	2.0x10 ⁶	2.4x10 ⁵	1.4x10 ⁵	-1.15
		Puritan - 110907	1.9x10 ⁶	3.0x10 ⁵	1.8x10 ⁵	-1.02
		Puritan - 111209	2.6x10 ⁶	5.0x10 ⁵	5.8x10 ⁵	-0.65
<i>Propionibacterium acnes</i> ATCC 6919	Diluted 10 ⁻⁴	Puritan - 111101	2.3x10 ⁶	7.5x10 ⁵	4.4x10 ⁵	-0.72
		Puritan - 110907	2.0x10 ⁶	4.6x10 ⁵	4.9x10 ⁵	-0.61
		Puritan - 111209	1.0x10 ⁶	9.6x10 ⁵	4.5x10 ⁵	-0.35
<i>Prevotella melaninogenica</i> ATCC 25845	Diluted 10 ⁻³	Puritan - 111101	1.8x10 ⁶	3.0x10 ⁵	3.2x10 ⁵	-0.75
		Puritan - 110907	1.5x10 ⁶	3.5x10 ⁵	1.7x10 ⁵	-0.95
		Puritan - 111209	1.9x10 ⁶	3.0x10 ⁵	1.2x10 ⁵	-1.20
<i>Neisseria gonorrhoeae</i> ATCC 43069	Diluted 10 ⁻⁴	Puritan - 111101	1.1x10 ⁶	2.3x10 ⁵		-0.68
		Puritan - 110907	9.9x10 ⁵	6.7x10 ⁵		-0.17
		Puritan - 111209	1.3x10 ⁶	1.6x10 ⁶		-0.09

a. *Precision/Reproducibility*: N/A

b. *Linearity/assay reportable range*: N/A

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

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 Liquid Amies Collection and Transport System. All samples tested were found to maintain pH within the specified range.

Cytotoxicity: Cytotoxicity test was conducted to evaluate glue, shaft and the polyester (flock) swabs for potential cytotoxicity effect following ISO Elution Method-1X MEM Extract. No evidence of cytotoxicity was detected.

Sterilization: Puritan Liquid Amies Transport Systems are sterilized by gamma irradiation and validated following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products - Radiation guidelines.

d. *Detection limit*: N/A

e. *Analytical specificity*: N/A

f. *Assay cut-off*: N/A

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. It is one component or an accessory to the bacterial identification process. Bench testing studies were done to determine the ability of the

Puritan Amies liquid medium to maintain viability of different strains of aerobes, anaerobes and fastidious bacteria. It showed recovery of bacteria within the acceptance criteria recommended in the CLSI M40-A guidelines like the predicate device. (See above under Performance Characteristics)

b. *Matrix comparison:* N/A

3. Clinical studies:

a. *Clinical Sensitivity:* N/A

b. *Clinical specificity:* N/A

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

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

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.