510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number: K113249

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 UTM-RT Collection and Transport System

G. Regulatory Information:

1. Regulation section: 21 CFR 866.2390, Transport culture medium

2. Product code(s): JSM; Culture media, non-propagating transport
   LIO; Device, specimen collection

3. Classification: Class: I

4. Panel: 83 Microbiology

H. Intended Use:

Puritan UTM – RT Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing laboratory. The specimen transported in the Puritan UTM - RT can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture.

2. Indication(s) for use:

Puritan UTM – RT Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the collection site to the testing laboratory. The specimen transported in the Puritan UTM - RT can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture.

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

4. Special instrument requirements: None

I. Device Description:

Each tube of Puritan UTM – RT consists of modified Hank's balanced salt solution, gelatin and bovine serum albumin as stabilizers, sucrose, glutamic acid and (4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid)(HEPES). The presence of buffered salts in the medium protects pathogens that are sensitive to pH changes. Gelatin and bovine serum albumin are source of nutrition to support viability of fastidious bacteria during storage and transport. Sucrose aids in the preservation of viruses and chlamydiae when specimens are frozen for prolonged storage. Antimicrobial agents are incorporated to minimize commensal bacterial and fungal contamination. Phenol red is added to act as a pH indicator. Puritan UTM-RT is comprised of a conical polypropylene vial filled with three 3-mm glass beads and 1.5ml or 3 mL of the transport medium, affixed with a high density polyethylene cap. Each unit of Puritan UTM-RT is provided in a peel pouch containing one of the following swab combinations:

- 1ml UTM with ultrafine tip HydraFlock® Swab
- 3ml UTM with one elongated tip HydraFlock® and one ultrafine tip swab
- 3ml UTM with elongated tip HydraFlock®® swab
- 3ml UTM with mini-tip HydraFlock® swab, scored shaft
- 3ml UTM with ultrafine HydraFlock® tip swab
- 3ml UTM vial with 2 regular polyester tip swabs, scored shaft
- 3ml UTM vial with regular polyester tip and one wire/plastic shaft with polyester tip

J. Substantial Equivalence Information:

1. Predicate device name(s): Copan (BD) UTM-RT System

2. Predicate 510(k) number(s): K042970

1. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Puritan UTM – RT is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas and ureaplasmas from the	BD™ Universal Viral Transport System **is** intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasmas and ureaplasmas

	collection site to the testing laboratory. The specimen transported in the Puritan UTM - RT can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture.	from the collection site to the testing laboratory. This system can be processed using standard clinical laboratory operating procedures for viral, chlamydial, mycoplasmal, and ureaplasmal culture.
Medium	Hank's balanced salt solution with additives	Same
Product Configuration	Medium in vial with cap	Same
	System including Medium and swab in peel pouch option	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

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Recovery studies: The following viruses were chosen for recovery study:

Adenovirus
Cytomegalovirus
Echovirus Type 30
Herpes Simplex Virus Type I
Herpes Simplex Virus Type II
Influenza A
Parainfluenza Type 3
Respiratory Syncytial Virus

Varicella Zoster Virus

Among bacteria, *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Mycoplasma pneumoniae*, *Mycoplasma hominis*, and *Ureaplasma urealyticum* were used for testing.

The survival and recovery of viruses, chlamydiae, mycoplasmas and ureaplasmas was tested to determine the performance characteristics of Puritan Universal Transport Medium (UTM-RT). Neat stocks of the above microorganisms were prepared for testing. Two different dilutions of the neat stock suspensions were prepared and, from these, 100 µl were directly inoculated onto swabs in triplicate. The swabs were transferred into the transport medium and held at both 4^{o} C and room temperature (20-25^{o} C) for the required amount of time. At key time points following inoculation (0, 24, and 48 h), each sample was vortexed after which an aliquot of the suspension was inoculated into shell vials or suitable culture media. Viability of viruses and chlamydiae was determined by shell vial assay followed by immunostaining and enumeration of fluorescent foci. The viability of mycoplasmas and ureaplasmas was determined using direct culture methods onto appropriate growth media followed by enumeration of colony forming units (CFU). Cultures were processed by standard laboratory techniques and examined following optimal incubation periods.

The results of the study are presented in Tables 1-3. The results demonstrate the ability of Puritan Medical Products UTM-RT to sustain the viability and recovery of test bacteria and viruses for at least 48 h at 4^{o} C and room temperature (20-25^{o}C). Viability of microorganisms in the Puritan UTM - RT transport system other than the ones listed above was not tested and is not known. It should be validated by the user.

Table 1- Recovery of Viruses

Organism	Dilution of Neat Stock[a]	Percent Infectivity of Host Cells	Storage Time	Incubation Time Prior to Reading	Mean Viability of Test Organism Using Test (Puritan) Device: Foci Counts[b] with SD	
		(% Infectivity)	(Hours)	(Hours)	4°C	RT
Adenovirus	1:100	2%	0		343 ± 72	343 ± 72
			24	24	550 ± 77	434 ± 66
			48		652 ± 143	408 ± 89
	1:500	3%	0		118 ± 78	118 ± 78
			24	24	192 ± 37	161 ± 28
			48		145 ± 57	47 ± 17
Cytomegalovirus	1:10	100%	0		751 ± 71	751 ± 71
			24	24	209 ± 26	47 ± 3
			48		269 ± 58	319 ± 34
	1:100	100%	0		242 ±7	242 ± 7
			24	24	134 ± 13	47 ± 5
			48		86 ± 35	207 ± 110
Echovirus Type 30	1:100	64%	0		95 ± 52	95 ± 52
			24	24	337 ± 178	332 ± 221
			48		454 ± 210	605 ± 194
	1:500	100%	0		63 ± 48	63 ± 48
			24	24	194 ± 134	214 ± 108
			48		252 ± 31	151 ± 41
Herpes Simplex Type 1	1:10	6%	0		207 ± 78	207 ± 78
			24	24	665 ± 189	325 ± 107
			48		609 ± 238	772 ± 243
	1:100	48%	0		167 ± 101	167 ± 101
			24	24	89 ± 38	72 ± 17
			48		96 ± 14	107 ± 35
Herpes Simplex Type 2	1:10	47%	0		126 ± 13	126 ± 13
			24	24	51 ± 21	85 ± 25
			48		108 ± 32	6 ± 3
	1:100	97%	0		26 ± 6	26 ± 6
			24	24	25 ± 15	37 ± 13
			48		17 ± 6	8 ± 6

Table 1 Recovery of Viruses (continued)

Organism	Dilution of Neat Stock[a]	Percent Infectivity of Host Cells	Storage Time	Incubation Time Prior to Reading	Mean Viability of Test Organism Using Test (Puritan) Device: Foci Counts[b] with SD	
		(% Infectivity)	(Hours)	(Hours)	4°C	RT
Influenza A	1:50	10%	0	24	298 ± 86	289 ± 86
			24		470 ± 96	250 ± 89
			48		173 ± 95	93 ± 41
	1:100	12%	0	24	186 ± 130	186 ± 130
			24		109 ± 56	181 ± 117
			48		82 ± 36	30 ± 13
Parainfluenza A	1:10	3%	0	48	501 ± 116	501 ± 116
			24		30 ± 10	628 ± 208
			48		101 ± 26	107 ± 56
	1:100	25%	0	48	358 ± 87	358 ± 87
			24		24 ± 10	292 ± 60
			48		47 ± 13	54 ± 23
Respiratory Syncytial Virus	1:10	76%	0	24	140 ± 19	140 ± 19
			24		176 ± 20	170 ± 14
			48		78 ± 24	131 ± 26
	1:100	100%	0	24	25 ± 6	25 ± 6
			24		74 ± 15	62 ± 5
			48		59 ± 19	74 ± 4
Varicella-Zoster Virus	1:10	100%	0	24	325 ± 91	325 ± 91
			24		253 ± 51	212 ± 43
			48		33 ± 13	117 ± 47
	1:100	100%	0	24	132 ± 45	132 ± 45
			24		97 ± 12	97 ± 3
			48		87 ± 69	94 ± 49

[a]From each dilution, 100 µL were inoculated onto test swab tip followed by placement of the swab into the test device containing 3 mL of transport medium

[b]Average of triplicate tests (± standard deviation) performed on 200 µL of test device medium at each time point; RT, room temperature

Table 2- Recovery of Chlamydia

Organism	Dilution of Neat Stock[a]	Percent Infectivity of Host Cells	Storage Time	Incubation Time Prior to Reading	Mean Viability of Test Organism Using Test (Puritan) Device: Foci Counts[b] with SD	
		(% Infectivity)	(Hours)	(Hours)	4°C	RT
Chlamydia pneumoniae	1:10	100%	0	48	169 ± 33	169 ± 33
			24		356 ± 70	456 ± 68
			48		301 ± 121	345 ± 66
	1:100	100%	0	48	65 ± 6	65 ± 6
			24		163 ± 25	134 ± 35
			48		110 ± 24	131 ± 33
Chlamydia trachomatis	1:10	100%	0	48	227 ± 63	227 ± 63
			24		204 ± 79	627 ± 197
			48		184 ± 62	234 ± 102
	1:100	100%	0	48	73 ± 10	73 ± 10
			24		60 ± 12	138 ± 50
			48		57 ± 19	92 ± 32

[a]From each dilution, 100 µL were inoculated onto test swab tip followed by placement of the swab into the test device containing 3 mL of transport medium

[b]Average of triplicate tests (± standard deviation) performed on 200 µL of test device medium at each time point; RT, room temperature

Table 3- Recovery of Mycoplasma and Ureaplasma

Organism	Dilution of Neat Stock[a]	Storage Time	Incubation Time Prior to Reading	Mean Viability of Test Organism Using Test (Puritan) Device: CFU Counts[b] with SD	
		(Hours)	(Days)	4°C	RT
Mycoplasma hominis	1:500	0	3	TNTC	TNTC
		24		TNTC	34 ± 5
		48		TNTC	75 ± 11
	1:1000	0	3	171 ± 42	171 ± 42
		24		136 ± 9	28 ± 7
		48		160 ± 19	9 ± 5
Mycoplasma	Neat	0	6	TNTC	TNTC

pneumoniae		24		TNTC	TNTC
		48		TNTC	1116 ± 119
		0		887 ± 334	887 ± 334
	1:10	24	6	416 ± 177	275 ± 62
		48		600 ± 303	144 ± 53
		0		TNTC	TNTC
	1:500	24	5	TNTC	TNTC
		48		TNTC	TNTC
Ureaplasma urealyticum		0		811 ± 311	811 ± 311
	1:1000	24	5	893 ± 486	775 ± 306
		48		611 ± 89	486 ± 134

[a]From each dilution, 100 µL were inoculated onto test swab tip followed by placement of the swab into the test device containing 3 mL of transport medium

[b]Average of triplicate tests (± standard deviation) performed on 100 µL of test device medium at each time point; RT, room temperature; TNTC, too numerous to count, defined as 1,000 CFU for *M. hominis* and 2,000 CFU for *M. pneumoniae* and *U. urealyticum*

a. *Precision/Reproducibility*: Not applicable

b. Linearity/assay reportable range: Not applicable

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 the manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan UTM-RT. All samples tested were found to maintain pH within the specified target range.

Antibiotics Stability Test: Antibiotics stability of test device was evaluated using three expired lots and a new lot of test device and compared to the predicate device. All products tested demonstrated the ability to control bacterial activities up to 72 hours.

Cytotoxicity: Cytotoxicity testing using an MRC-5 cell line in conjunction with a standard Sulforhodamine B assay demonstrated no cellular toxicity associated with three lots of test devices when statistically compared to negative controls.

Sterilization: All plastic components of Puritan UTM-RT are validated and sterilized following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products-Radiation or by ANSI/AAMI/ISO11135:2007, Sterilization of health care products-ethylene oxide. Puritan UTM-RT tubes are filled aseptically under

control conditions. Representative samples from each lot of Puritan UTM-RT are tested according to the USP 34 NF, 29:2011, <71>, Sterility Tests.

d. Detection limit: Not applicable

e. Analytical specificity: Not applicable

f. Interfering Substances: Not applicable

g. Assay cut-off: Not applicable

2. Comparison studies:

a. Method comparison with predicate device: Method comparison is not applicable for a transport medium. The performance of the test device is compared to the predicate by analytical studies or bench testing concerning viral and bacterial recovery.

Recovery comparison: For both transport systems, test viruses and bacteria were quantified during 48 hours at the two storage temperatures as described above for tables 1 to 3. Culture recovery data between the test and predicate devices were statistically analyzed and compared. One-way ANOVA demonstrated statistically significant differences ($P<0.05$) between the two devices under certain conditions. The differences were considered to be the result of normal microbiological variability and thus not significant from a clinical stand point. Qualitative and not quantitative results are most often the critical endpoint in the clinical diagnosis of an infectious agent.

It is concluded that under the conditions of testing the test organisms could be recovered from the new device just as with the comparator thus making it a valid system for the collection, storage, and transport of clinical specimens.

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.