UniTranz-RT®

Puritan®
Quality since 1919

Puritan UniTranz-RT® Transport System

Puritan Medical Products Company LLC

P.O. Box 149, 31 School Street
Guilford, Maine, USA 04443-0149

Tel: 800-321-2313 (US and Canada)
207-876-3311

Fax: 800-323-4153 (US and Canada)
207-876-3130

sales@puritanmedproducts.com
www.puritanmedproducts.com

EC REP

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

CE

Puritan UniTranz-RT®*

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INTENDED USE
Puritan UniTranz-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 UniTranz-RT** can be used in the laboratory to perform viral, chlamydial, mycoplasmal and ureaplasmal culture.

SUMMARY AND EXPLANATION
Proper specimen collection and transport plays a critical role in laboratory diagnosis of infectious diseases associated with viruses, chlamydiae, mycoplasmas and ureaplasmas. **Puritan UniTranz-RT** is a self-contained, ready-to-use system that allows for the collection and safe transport of clinical samples from the collection site to the testing laboratory. **Puritan UniTranz-RT** transport medium is stable at room temperature, and consists of a balanced buffer solution to maintain neutral pH, antimicrobial agents, a source of protein, and sucrose as a preservative.

The system is offered with a self-centering cap and vial to safely contain and transport biological specimens and a single or double scored plastic shaft swab to collect the specimens.

PRINCIPLES OF THE PROCEDURE
Each vial of **Puritan UniTranz-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.

REAGENTS

Hank's Balanced Salts	L-Glutamic Acid
Bovine Serum Albumin	Phenol Red
Gelatin	Colistin
Sucrose	Amphotericin B
L-Cysteine	Vancomycin
HEPES	pH: 7.3 ± 0.2

PRECAUTIONS
For *in vitro* diagnostic use only.
- To be used by trained and qualified professionals.
- Read the information in this package insert and follow directions carefully.
- Follow standard microbiological aseptic techniques.
- There is always a potential for the presence of blood borne viruses including human immunodeficiency virus and hepatitis viruses in the specimens. Special precautions should be taken when handling specimens that may have come in contact with blood and other bodily fluids. Follow state, local and institutional guidelines for the handling and disposition of this and all biohazard waste.[1–6]
- This product is not intended to be used for the collection and transport of general bacterial and fungal specimens. Carefully read and follow the instructions outlined in the package insert.
- Do not ingest the medium inside the vial.
- Do not re-pack.
- Do not bend flocked swab prior to specimen collection.
- Do not premoisten the applicator before use.
- Do not re-sterilize swabs.
- Do not use if the swab is damaged or broken.
- Do not use if the package is damaged.
- Do not use if the medium is contaminated (medium change color from pink to yellow or turn turbid).

STORAGE
Optimum storage temperature is 36-77°F (2-25°C) until used.

SPECIMEN COLLECTION PROCEDURES
Proper specimen collection is critical for successful isolation and identification of infectious organisms. Specimens should be collected soon after the onset of symptoms when microorganism titers are at their highest.[7–12] Specimens should be placed in the transport medium immediately following collection and promptly transferred to the laboratory for processing. For optimum recovery, specimens should be refrigerated during transport. For long term storage, specimens should be frozen at -70°C or colder.[13,14,16] Refer to the recommended guidelines, referenced standards and manuals for additional information on specimen collection procedures.[5,10,15,16]

*Room Temperature

MATERIALS PROVIDED

Puritan UniTranz-RT is comprised of one polypropylene vial affixed with a polyethylene cap, filled with 1 or 3 ml of transport medium and 3 glass beads. The system is offered with one of the following configurations:

Puritan Part #	Description	Pack
UT-100	Vial with 1ml universal transport medium	6/50
UT-106	Vial with 1ml universal transport medium, large PurFlock Ultra® swab	6/50
UT-116	Vial with 1ml universal transport medium, mini-tip PurFlock Ultra® swab	6/50
UT-117	Vial with 1ml universal transport medium, ultrafine PurFlock Ultra® swab	6/50
UT-300	Vial with 3ml universal transport medium	6/50
UT-302	Vial with 3ml universal transport medium, regular and mini-tip polyester swabs	6/50
UT-306	Vial with 3ml universal transport medium, elongated PurFlock Ultra® swab	6/50
UT-316	Vial with 3ml universal transport medium, mini-tip PurFlock Ultra® swab	6/50
UT-317	Vial with 3ml universal transport medium, ultrafine PurFlock Ultra® swab	6/50
UT-361	Vial with 3ml universal transport medium, regular polyester tipped swab	6/50
UT-362	Vial with 3ml universal transport medium, two regular polyester tipped swabs	6/50
UT-366	Vial with 3ml universal transport medium, mini-tip and regular polyester swabs	6/50
UT-367	Vial with 3ml universal transport medium, elongated and ultrafine PurFlock Ultra® swabs	6/50

MATERIAL REQUIRED BUT NOT PROVIDED

Materials required for the isolation, culturing and identification of viruses, chlamydiae, mycoplasmas and ureaplasmas. Tissue culture medium, cell lines, instruments for incubation and enumeration.
Refer to the corresponding standards, guidelines and references for optimum recovery and identification results.[8,10,12]

TEST PROCEDURE

Puritan UniTranz-RT system

1. Peel open the sealed pouch pack.
2. Remove one swab from the pouch and collect the specimen **without** bending the swab.
3. Aseptically remove the cap from the vial.
4. Insert the swab into the vial containing medium.
5. Break the swab shaft by bending the swab against the vial rim at the scored point.
6. Replace the cap and secure the lid tight.
7. Record the patient's information on the label.
8. Transfer the vial containing the specimen to laboratory for analysis.

Puritan UniTranz-RT vial only (for specimen collection by aspiration, scraping, small tissues and stool samples)

1. Aseptically remove the cap from the vial.
2. Transfer the specimen into the vial containing medium.
3. Replace the cap and secure the lid tight.
4. Record the patient's information on the label.
5. Transfer the vial containing the specimen to laboratory for analysis.

Antibacterial and antifungal agents have been added to the **Puritan UniTranz-RT** medium to inhibit bacterial and fungal growth. To further control the potential for microbial overgrowth, it is also recommended that specimens be refrigerated and processed as soon as possible. Refer to recommended laboratory referenced standards for proper specimen processing and cultivation.[10]

Quality Control

Each lot of **Puritan UniTranz-RT** is tested for bacterial and fungal contamination and medium pH. Refer to CLSI, Journals of Clinical Microbiology and ASM publications for detailed quality control procedures of Universal Viral Transport Medium.[10,17,18]

RESULTS

Accuracy of culture results largely depends on proper specimen collection and transportation time, as well as specimen handling in the testing laboratory.

LIMITATIONS

Conditions such as extreme temperature fluctuation and prolonged specimen transit time could impact reliability of the culture results.

1. **Puritan UniTranz-RT** is only recommended for collection and transport of viruses, chlamydiae, mycoplasmas and ureaplasmas.
2. Do not use **Puritan UniTranz-RT** as a replacement for tissue culture medium for isolation of viruses and chlamydiae.
3. Repeated freezing and thawing of specimens may reduce the recovery of organisms
4. Calcium alginate fiber and wooden shaft swabs are not recommended for use with **Puritan UniTranz-RT** transport systems as they may affect organism viability.
5. **Puritan UniTranz-RT** transport system is validated solely with the use of Puritan polyester flocked swabs. Swabs and transport medium from other sources have not been validated and could adversely affect the performance characteristics of the product.
6. Any usage of this product in conjunction with a rapid diagnostic test or instrument should be validated by the user.
7. The performance of the **Puritan UniTranz-RT** for storage time over 48 hrs has not been evaluated.

PERFORMANCE CHARACTERISTICS

The survival and recovery of viruses, chlamydiae, mycoplasmas and ureaplasmas was tested to determine the performance characteristics of **Puritan UniTranz-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°C and room temperature (20-25°C) for the required amount of time. At key time points following inoculation (0, 24 and 48h), 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. Test viruses used for evaluation of the transport medium were adenovirus, cytomegalovirus, echovirus type 30, herpes simplex virus type 1, herpes simplex virus type 2, influenza A, parainfluenza 3, respiratory syncytial virus, and varicella-zoster virus . Among bacteria, *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Mycoplasma pneumoniae*, *Mycoplasma hominis*, and *Ureaplasma urealyticum* were used for testing.

The results of the study are presented in Tables 1-3. The results demonstrate the ability of **Puritan UniTranz-RT** to sustain the viability and recovery of test bacteria and viruses, namely adenovirus, cytomegalovirus, echovirus type 30, herpes simplex virus type 1, herpes simplex virus type 2, influenza A, parainfluenza 3, respiratory syncytial virus, and varicella-zoster virus, *Chlamydia pneumoniae*, *Chlamydia trachomatis*, *Mycoplasma pneumoniae*, *Mycoplasma hominis*, and *Ureaplasma urealyticum* for at least 48 h at 4°C and room temperature (20-25°C). **Caution**: Viability of microorganisms in the **Puritan UniTranz-RT** transport system other than the ones tested here is not known and 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	24	343 ± 72	343 ± 72
			24		550 ± 77	434 ± 66
			48		652 ± 143	408 ± 89
	1:500	3%	0	24	118 ± 78	118 ± 78
			24		192 ± 37	161 ± 28
			48		145 ± 57	47 ± 17
Cytomegalovirus	1:10	100%	0	24	751 ± 71	751 ± 71
			24		209 ± 26	47 ± 3
			48		269 ± 58	319 ± 34
	1:100	100%	0	24	242 ±7	242 ± 7
			24		134 ± 13	47 ± 5
			48		86 ± 35	207 ± 110
Echovirus Type 30	1:100	64%	0	24	95 ± 52	95 ± 52
			24		337 ± 178	332 ± 221
			48		454 ± 210	605 ± 194
	1:500	2.91%	0	24	63 ± 48	63 ± 48
			24		194 ± 134	214 ± 108
			48		252 ± 31	151 ± 41
Herpes Simplex Type 1	1:10	6%	0	24	207 ± 78	207 ± 78
			24		665 ± 189	325 ± 107
			48		609 ± 238	772 ± 243
	1:100	48%	0	24	167 ± 101	167 ± 101
			24		89 ± 38	72 ± 17
			48		96 ± 14	107 ± 35
Herpes Simplex Type 2	1:10	47%	0	24	126 ± 13	126 ± 13
			24		51 ± 21	85 ± 25
			48		108 ± 32	6 ± 3
	1:100	97%	0	24	26 ± 6	26 ± 6
			24		25 ± 15	37 ± 13
			48		17 ± 6	8 ± 6
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

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
Parainfluenza 3	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 pneumoniae	Neat	0	6	TNTC	TNTC
		24		TNTC	TNTC
		48		TNTC	1116 ± 119
	1:10	0	6	887 ± 334	887 ± 334
		24		416 ± 177	275 ± 62
		48		600 ± 303	144 ± 53
Ureaplasma urealyticum	1:500	0	5	TNTC	TNTC
		24		TNTC	TNTC
		48		TNTC	TNTC
	1:1000	0	5	811 ± 311	811 ± 311
		24		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*

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