TransPRO CVM™ Transport System

Headquarters:
1430 West McCoy Lane
Santa Maria, CA 93455
800.266.2222 : phone
805.346.2760 : fax
Sales@HardyDiagnostics.com
www. HardyDiagnostics.com

032014ss

TransPRO CVM™

INTENDED USE
TransPRO CVM™ Collection and Transport System is intended for the collection and transport of clinical samples containing viruses, chlamydiae, mycoplasmas, and ureaplasmas from the patient to the testing laboratory. The specimen transported in the **TransPRO CVM**™ can be used in the laboratory to perform viral, chlamydial, mycoplasmal, and ureaplasmal cultures.

SUMMARY AND EXPLANATION
Proper specimen collection and transport play a critical role in laboratory diagnosis of infectious diseases associated with viruses, chlamydiae, mycoplasmas, and ureaplasmas. **TransPRO CVM™** 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. **TransPRO CVM™** transport medium is stable at room temperature and consists of a balanced buffer solution to maintain neutral pH, selective 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 plastic shaft, polyester-flocked swab to collect the specimens.

PRINCIPLES OF THE PROCEDURE
Each vial of **TransPRO CVM™** 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 buffer). The presence of buffered salts in the medium protects pathogens that are sensitive to pH changes. Gelatin and bovine serum albumin are sources 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 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 pathogens, including human immunodeficiency virus (HIV) and hepatitis viruses in specimens. Special precautions should be taken when handling specimens that may have come in contact with blood and/or other bodily fluids. Follow state, local, and institutional guidelines for the handling and disposal of this and all biohazard waste.[1–6]
- This product contains selective agents and 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 changes color from pink to yellow or turns turbid).

STORAGE
Optimum storage temperature is 2 – 25 °C (36 – 77 °F) 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 be promptly transferred to the laboratory for processing. For optimum recovery, specimens should be refrigerated during transport. For longterm 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]

MATERIALS PROVIDED

TransPRO CVM™ is comprised of one polypropylene vial affixed with a polyethylene "swab capture" cap, filled with 3 mL of transport medium and 3 glass beads, and one flocked PurFlock™ swab on a scored, plastic shaft.

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.
Corresponding standards, guidelines, and references for optimum recovery and identification results.[8,10,12]

TEST PROCEDURE

TransPRO CVM™ system with swab

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 tightly. The swab shaft will automatically affix itself to the cap.
7. Record the patient's information on the label.
8. Transfer the vial containing the specimen to laboratory for analysis.

TransPRO CVM™ vial only (for specimen collection by aspiration, scraping, small tissues, and stool samples)

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

Antibacterial and antifungal agents have been added to the **TransPRO CVM™** 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 **TransPRO CVM™** is tested for bacterial and fungal contamination, medium pH, and ability to maintain viability of selected microbial agents of clinical significance. 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, transportation time, and temperature, as well as specimen handling in the testing laboratory.

LIMITATIONS

1. Conditions such as extreme temperature fluctuation and prolonged specimen transit time could impact microorganism viability and reliability of the culture results.
2. **TransPRO CVM™** is only recommended for collection and transport of viruses, chlamydiae, mycoplasmas and ureaplasmas. It is not to be used for other bacteria or fungi.
3 Do not use **TransPRO CVM™** as a replacement for tissue culture medium for isolation of viruses and chlamydiae.
4 Repeated freezing and thawing of specimens may reduce the recovery of organisms.
5 Calcium alginate, cotton fiber, and wooden shaft swabs are not recommended for use with **TransPRO CVM™** transport systems, as they may affect organism viability.
6. **TransPRO CVM™** 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.
7 Any usage of this product in conjunction with a rapid diagnostic test or instrument should be validated by the user.
8 The performance of the **TransPRO CVM™** for storage or transit time over 48 hours has not been evaluated.

PERFORMANCE CHARACTERISTICS

The survival and recovery of viruses, chlamydiae, mycoplasmas, and ureaplasmas were tested to determine the performance characteristics of **TransPRO CVM™**. Neat stocks of the microorganisms below 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 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. 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 **TransPRO CVM™** 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, 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 **TransPRO CVM™** 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 (TransPRO) 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	100%	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 (TransPRO) Device: Foci Counts[b] with SD	
		% Infectivity	Hours	Hours	4°C	RT
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 mL 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 mL 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 (TransPRO) 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 mL 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 mL 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 (TransPRO) Device: CFU Counts[b] with SD	
		Hours	Day	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 mL 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 mL 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*

REFERENCES

1. Sewell, D.L. Laboratory-Associated Infections and Biosafety. Clinical Microbiology Reviews. July 1995. P. 398-405. American Society for Microbiology, Washington, D.C.
2. International Civil Aviation Organization. Technical Instructions for Safe Transport of Dangerous Goods by Air, 2003-2004 Edition.
3. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work, Official Journal of European Communities L262, 17/10/2000 P. 021-045.
4. Garner, J.S. 1996. Hospital Infection Control Practices Advisory Committee, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Guideline for Isolation Precautions in Hospitals. Infect. Control Hospital Epidemiol.17:53-80.
5. Clinical and Laboratory Standard Institute. 2005. Approved Guideline M29-A3. Protection of Laboratory Workers from Occupationally Acquired Infections, 3rd ed. CLSI, Wayne, PA.
6. U.S. Department of Health and Human Services. 2007. Biosafety in Microbiology and Biomedical Laboratories, HHS Publication (CDC), 5th ed. Government Printing Office, Washington, D.C.
7. Walsh, P., C.L. Overmyer, K. Pham, S. Michaelson, L. Gofman, L. De Salvia, T. Tron, D. Gonzalez, J. Pusvat, M. Feola, K.T. Iacona, E. Mordechai, M.E. Adleson. 2008. Comparison of Respiratory Virus Detection Rates for Infants and Toddlers by Use of Flocked Swab. J. Clin. Microbiol. 46: 2374-2376.
8. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.L. Landry and M.A. Pfaller. 2007. Manual of Clinical Microbiology. 9th ed. American Society of Microbiology, Washington, D.C.
9. Miller, J.M. 1999. A Guide to Specimen Management in Clinical Microbiology, 2nd ed. ASM, Washington, D.C.
10. Isenberg, HD., 1998. Essential Procedures for Clinical Microbiology. Chapter 14.12, Page 787. Packaging and Shipping Infectious Substances. ASM, Washington, D.C.
11. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 2002. Bailey and Scott's Diagnostic Microbiology. 11th ed. Mosby, St. Louis, MO.
12. Maass, M. and U. Harig. 1995. Evaluation of Culture Conditions Used for Isolation of *Chlamydia pneumoniae*. Am. J. Clin. Pathol. 103:141-148.
13. Maass, M and K. Dalhoff. 1995. Transport and Storage Conditions for Cultural Recovery of *Chlamydia pneumoniae*. J. Clin. Microbiol. 33: 1793-1796.
14. Bettoli, E. J., P.M. Brewer, M.J. Oxtoby, A.A. Zaidi, M. E. Guinan. 1982. The Role of Temperature and Swab Materials in the Recovery of Herpes Simplex Virus from Lesions. J. Infect. Dis. 145:399.
15. 42CFR72. Code of Federal Regulations, Title 42, Volume 1, Part 72. Interstate Shipment of Etiologic Agents.
16. Johnson, F.B. 1990. Transport of Viral Specimens. Clin. Microbiol. Rev 3: 120-131.
17. Clinical and Laboratory Standards Institute. 2003. Quality Control of Microbiological Transport Systems. Approved Standard M40-A, CLSI, Wayne, PA.
18. Clinical and Laboratory Standards Institute. 2006. Viral Culture; Approved Guideline M41-A, CLSI, Wayne, PA.

Chlamydia, Viral, Mycoplasma Collection & Transport

TransPRO™ CVM Transport System is a specimen collection kit featuring PurFlock® Ultra swab and room temperature stability.

- Ready-to-use transport system
- Advanced kit design for reliability and ease-of-use
- Soft tip for patient comfort
- Flexible shaft
- Premium medical grade plastic components to improve product shelf life
- Stable medium at room temperature
- Economically priced

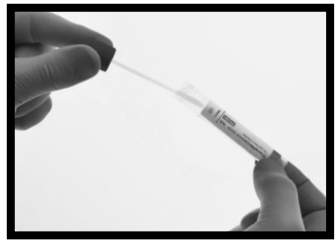
Ordering Information

Specimen Collection Kit with PurFlock® Ultra Swab

Adult/Pediatric,
3ml, 50/pk.....TPCVM1

TransPRO™ CVM Transport System is a specimen collection kit featuring the PurFlock Ultra® swab and transport system. It is the ideal choice with excellent absorption and elution of specimens. For collection and preservation of Virus, Chlamydia, Mycoplasma, and Ureaplasma.

The PurFlock Ultra® swab is the optimal swab for various rapid diagnostic tests including specimen collection, buccal cell collection, DNA testing, forensic evidence collection, and more.



A Comparison of Features

Main Competitive Advantages in Favor of TransPRO™ CVM

	TransPRO™ CVM	UTM™
Pack Size	50/pk	300/pk
Intended Use	Viruses, chlamydia, mycoplasma, ureaplasma	Viruses, chlamydia, mycoplasma, ureaplasma
Storage Temperature	2-25 °C	2-25 °C
Transport Temperature	4-25 °C for 48 hours	4-25 °C for 48 hours
Swab Type:	Naso-pharyngeal	Naso-pharyngeal
Swab-Cap Capture	Yes	Standard tip only
Swab Tip	PurFlock® Ultra (Patented New Technology)	Nylon Flocked (Patented)
Swab Tip Color	White	Yellow tinge
Cap Color	Red	Red
Contains Gelatin	Yes	Yes
Manufacture Location	USA	Italy
Shelf Life	18 months	12 months
Fill Volume	3ml	3ml
Cat. no.	TPCVM1	346C

* UTM is a Trademark of Copan

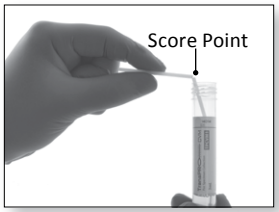
Swab-Cap Capture Feature:
After the sample is collected, the swab is placed into the CVM Medium and the shaft is snapped at the score point. The lid is then screwed on. When the lid is unscrewed, the swab is connected to the lid.

Polystyrene Shaft

PurFlock® Ultra Swab Tip Technology for maximum specimen recovery. Clean, white, effective!

Vial:
Overall Length
16 x 100 mm

TransPRO™ CVM Medium



Compatible with most automated systems.

Packaging includes:
Vial with 3ml CVM Medium
and one PurFlock® Ultra swab,
individually wrapped.

Call 800.266.2222 for a free evaluation sample!

Made in the USA