IFU

Instructions for Use

VIRAL TRANSPORT MEDIUM

IVD Rx only

Cat. no. R99	Viral Transport Medium, 16x100mm polypropylene tube, 3ml fill	20 tubes/box
Cat. no. TPV50	TransPRO Viral Transport Medium System, single 16x100mm polypropylene tube, 3ml fill with individually wrapped, sterile, mini-tip, flocked swab with 80mm breakpoint.	50 each/box

INTENDED USE

Hardy Diagnostics' Viral Transport Medium (VTM) is intended for the collection and transport of clinical specimens for the preservation of viral agents including, Influenza A, Influenza B, Adenovirus, and Echovirus from the collection site to the testing laboratory. Hardy Diagnostics' VTM is a culture-based media that is intended to be used in standard laboratory procedures for virus culture and diagnostic assays that utilize stable recoverable infectious viral particles.

SUMMARY

Hardy Diagnostics' Viral Transport Medium is a non-propagating transport media used for the collection and transport of clinical specimens suspected of containing viruses for viral culture and detection. Hardy Diagnostics' Viral Transport Medium consists of Hank's Balanced Salt Solution, fetal bovine serum, sucrose to stabilize viral agents, along with amphotericin B and gentamicin sulfate to inhibit bacterial and fungal contaminants. Hardy Diagnostics' VTM also contains a pH indicator (phenol red) to provide a visual indicator of the medium's pH. When clinical samples are properly collected and stored in Hardy Diagnostics' Viral Transport Medium (R99, TPV50) at 2-8°C and 20-25°C, recovery of Influenza A, Influenza B, Adenovirus, and Echovirus can be accomplished for up to 48 hours.

FORMULA

The formulation is made up of the following ingredients per liter.*

Fetal Bovine Serum	20ml
Hank's Balanced Salt Solution	980ml
Amphotericin B	0.5mg
Gentamicin Sulfate	100mg
Phenol Red	10mg
Sucrose	68.46g

Final pH 7.3 +/- 0.2 at 25ºC.

*Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-25ºC away from direct light. Media should not be used if there are any signs of deterioration, leakage, appearance change, or contamination, or if the expiration date has passed.

The expiration dating on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date, which is for up to 12 months from the date of manufacture when stored at 2-25ºC.

Refer to the document "Storage" for more information. If reviewing this document in print form, the link reference is at the end of the package insert.

WARNINGS AND PRECAUTIONS

Please read the instructions carefully.

Not suitable for any application other than the intended use.

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious and handled observing the usual universal blood precautions.

Do not ingest, inhale, or allow to come into contact with skin.

Viral Transport Media is classified as a non-propagating transport culture media.

This product is for *in vitro* diagnostic use only.

This product is for prescription use only,

It must be used only by adequately trained and qualified laboratory personnel.

This product is for single use.

Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention. For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M-29: *Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information. If reviewing this document in print form, the link reference is at the end of the package insert.

Do not use the product beyond the expiration date.

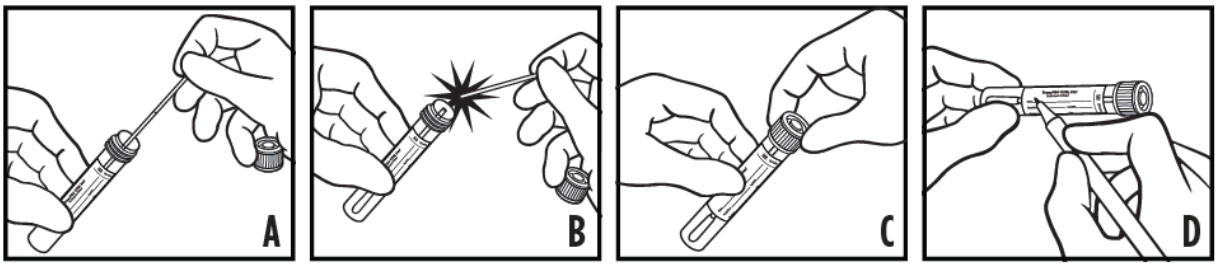
Inspect tubes of Viral Transport Medium prior to use to ensure the correct broth appearance. Discard tubes prior to use if the medium has changed from the original translucent and light peach color to a yellow color and/or cloudy, which could indicate microbial contamination.

Do not submerge the swab in the Viral Transport Medium prior to sampling. Inoculate specimens to Viral Transport Medium as soon as possible after collection. The use of this product in combination with diagnostic kits or instruments must be validated by the user prior to use.

When opening the TransPRO VTM System pouch, inspect the swab wrapper seals prior to use. Swab sterility is only guaranteed when the swab wrapper seals are not compromised.

Refer to the document "Limitations of Procedures and Warranty" for more information. If reviewing this document in print form, the link reference is at the end of the package insert.

SAMPLE COLLECTION PROCEDURE



1. Open the swab peel pouch and collect the clinical specimen. Refer to CDC's current guidelines for the appropriate specimen collection procedure.[7]

2. After specimen collection, remove the cap from the tube and insert the swab. Submerge the tip of the swab into the viral transport medium. (step A of the diagram above)

3. For swabs with a breakpoint, gently bend the swab shaft to break it off at the breakpoint. Gently rotate the swab shaft to complete the breakage and remove the upper part of the swab shaft. (step B of the diagram above) For swabs without a breakpoint, use sterile scissors to cut the swab shaft to fit into the tube.

   Note: Position the tube and swab shaft in the medium in front of the user and break the shaft facing away from the body to reduce the chance of aerosol formation. Ensure the top of the swab shaft is below the rim of the tube to facilitate closure.

4. Screw the cap back onto the tube securely. (step C of the diagram above)

5. Label the sample. (step D of the diagram above) Transport immediately to the lab at 2-25ºC within 24 hours after collection.

6. Perform culture or diagnostic testing within 48 hours of specimen collection.

LIMITATIONS

1. This media is not sterile and may contain selective agents, is manufactured in an environmentally controlled area, and has been validated to have a SAL of 10^{-3} with an AQL of 0.10.

2. Polyester (Dacron®), rayon, or flocked nylon tipped swabs with plastic shafts or flexible wire are recommended. Calcium alginate, cotton swabs, or swabs with wooden shafts should not be used.

3. Data represented in the Performance Characteristics section is for laboratory diagnostics that utilize stable recoverable infectious viral particles.

4. Hardy Diagnostics' VTM was also tested for viral recovery of Respiratory Syncytial Virus. However, due to unquantifiable recovery, the data was insufficient to support the use of this medium for collection and storage of specimens for Respiratory Syncytial Virus culture or testing.

5. The recovery performance of other viruses beyond the ones listed in the recovery study are not known.

6. Freezing and thawing of specimens has not been validated.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs (except for Cat. No. TPV50), biohazard bags, incinerators, incubators, refrigerators, shipping containers, ice, etc. which may be needed, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CofA).

Sample units are evaluated for microbial load (contamination) based upon lot size. See the lot Certificate of Analysis or Limitations section for more information.

Refer to the document "Inoculation Procedures for Media QC" for more information. If reviewing this document in print form, the link reference is at the end of the package insert.

Toxicity test: Another test is performed to ensure that the Viral Transport Medium is not toxic to animal tissue-culture cells. A 0.3ml aliquot of Viral Transport Medium is inoculated into MRC-5 shell vials. The vials are incubated for 18-24 hours at 35°C. The result is recorded as normal or abnormal as observed by visual determination of the cells under an optical microscope at 100X.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificates of analysis (CofA) available from Hardy Diagnostics Certificates of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see reference(s) for more specific information. If reviewing this document in print form, each link reference is at the end of the package insert.

PHYSICAL APPEARANCE

Viral Transport Media should appear translucent and light peach in color. Discard tubes prior to use if the medium has changed from the original translucent and light peach color to a cloudy and or yellow color.

PERFORMANCE CHARACTERISTICS

The performance of Hardy Diagnostics' Viral Transport Medium was evaluated for virus viability across different incubation temperatures and times. The viral recovery study was conducted by spiking a known virus concentration into pooled negative clinical matrix. The contrived viral samples were then inoculated to a minimum of three lots of Viral Transport Medium and held at 2-8°C and 20-25°C for 0, 24, and 48 hours.

Aliquots of each lot were pulled at 0, 24, and 48 hours, serially diluted, and inoculated in triplicate into the susceptible host cell line. Host cells were plated at a suitable density in culture medium in microwell plates prior to testing. Virus-induced cytopathic effect (CPE) was observed and the viral titer was determined by calculating the fifty-percent tissue culture infective dose ($TCID_{50}$/mL) using the Reed-Muench method. Results were considered

acceptable if the average viral recovery for each time point and storage condition demonstrated any percent changes within ±90% (i.e., 1 log change) from baseline (T=0).

The results of the study are presented in Tables 1 and 2 and demonstrate the ability of Hardy Diagnostics' VTM to maintain the viability and recovery of diverse viruses for at least 48 hours at refrigerated condition (2-8°C) and at room temperature (20-25°C).

Table 1: Viral recovery performance of Viral Transport Medium at 20-25°C

Test Strain	Viral recovery ($TCID_{50}$/mL) at T=0 hrs.	Percent changes in viral recovery from the baseline (T= 0 hr.) (-ve indicates reduction)	
		24 hrs.	48 hrs.
Influenza A	$2.12x10^3$	-92.24*	-59.76
Influenza B	$7.23x10^2$	-23.86	-3.45
Echovirus	$1.40x10^5$	-20.55	-25.23
Adenovirus	$1.92x10^3$	18.11	-7.71

* Considered acceptable because subsequent time points, i.e., 48 hrs. time point showed < 90% increase.

Table 2: Viral recovery performance of Viral Transport Medium at 2-8°C

Test Strain	Viral recovery ($TCID_{50}$/mL) at T=0 hrs.	Percent Changes in viral recovery from the baseline (T= 0 hr.) (-ve indicates reduction)	
		24 hrs.	48 hrs.
Influenza A	$1.32x10^3$	-5.98	-58.59
Influenza B	$8.05x10^2$	-36.32	-44.27
Echovirus	$1.27x10^5$	21.91	-3.98
Adenovirus	$1.47x10^3$	-20.19	23.11

REFERENCES

1. Anderson, N.L., et al. Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.
2. Jorgensen et al. Manual of Clinical Microbiology. American Society for Microbiology, Washington, D.C.
3. Tille, P.M., et al. Bailey and Scott's Diagnostic Microbiology, C.V. Mosby Company, St. Louis, MO.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook, Vol. I, II & III. American Society for Microbiology, Washington, D.C.
5. Quality Assurance for Commercially Prepared Microbiological Culture Media, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.
6. Centers for Medicare & Medicaid Services (CMS). Individualized Quality Control Plan (IQCP).
7. The Centers for Disease Control and Prevention (CDC). Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. Accessed July 16, 2024.

If reviewing the document in print form, below are relevant links listed throughout the package insert:
Storage:
https://hardydiagnostics.com/pub/media/assets/product/documents/Storage.pdf

Precautions When Using Media:
https://hardydiagnostics.com/pub/media/assets/product/documents/PrecautionsWhenUsingMedia.pdf
Limitations of Procedure and Warranty:
https://hardydiagnostics.com/pub/media/assets/product/documents/LimitsOfProceduresWarranty.pdf
Inoculation Procedures for Media QC:
https://hardydiagnostics.com/pub/media/assets/product/documents/InocProced4MediaQC.pdf
Certificates of Analysis:
https://hardydiagnostics.com/searchdocuments/coa/search
Finished Product Quality Control Procedures:
https://hardydiagnostics.com/pub/media/assets/product/documents/FinishedProductQC.pdf
Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing:
https://www.cdc.gov/covid/hcp/clinical-care/clinical-specimen-guidelines.html

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Ordering Information

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California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207F [C]