VIRAL TRANSPORT MEDIUM IVD

Cat. no. R99	Viral Transport Medium, 14ml polypropylene tube, 3ml fill	20 tubes/box
Cat. no. R64BX	Viral Transport Medium, 5ml polypropylene tube, 3ml fill	100 tubes/box

INTENDED USE

Hardy Diagnostics Viral Transport Medium is recommended for the collection and transport of clinical specimens for the preservation of viral agents including, but not limited to, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV), Adenovirus, Herpes Simplex Type I, Herpes Simplex Type II, Cytomegalovirus (CMV), and Echovirus for the purpose of molecular analysis, such as PCR (Polymerase Chain Reaction).

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 detection. Hardy Diagnostics Viral Transport Medium complies with the CDC formulation and consists of Hank's Balanced Salt Solution and Fetal Bovine Serum, along with Amphotericin B and Gentamicin Sulfate to inhibit bacterial and fungal contaminants. The medium also acts as a cryo-protectant to ensure virus stabilization through freezing and thawing.

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

Final pH 7.3 +/- 0.2 at 25ºC.

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

MATERIALS PROVIDED

Cat. no. R99 - Twenty tubes containing 3.0ml of Viral Transport Media.

Cat. no. R64BX – One hundred tubes containing 3.0ml of Viral Transport Media.

STORAGE AND SHELF LIFE

Storage: Upon receipt, store at 2-30ºC 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 on the product label and incubated for the recommended quality control incubation times.

Refer to the document "Storage" for more information.

PRECAUTIONS

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 handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." The "Guidelines for Isolation Precautions" is available from the Centers for Disease Control and Prevention at https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf.

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.

Refer to the document SDS Search instructions on the Hardy Diagnostics' website for more information.

MICROBIAL LOAD

Sample units are evaluated for microbial load (contamination) based upon lot size using an American National Standards Institute/American Society for Quality statistical sampling plan (ANSI/ASQ Z1.4-2008. See the lot Certificate of Analysis or Limitations section below for more information.

PROCEDURE

Aseptically collect specimen. Use swabs and shafts (plastic or flexible wire) that are non-toxic to viral agents, such as polyester (Dacron®), rayon, or flocked nylon swabs. Do not use cotton or calcium alginate swabs or swabs with a wooden shaft for collection of specimens, as these may contain agents that inactivate some viruses and inhibit PCR or RT-PCR testing. Be sure to comply with the requirements of the test method to be used. Swabs with a scored break point at or less than 100mm are preferred. Swab options are shown below, but other validated swabs may also be used.

Cat. no.	Swab Type	Description
106CC	Mini-tip	Traditional Dry Rayon Swab (no calcium) w/Flexible Aluminum Shaft
501CS01	Mini-tip	Flocked Swab w/80mm breakpoint
502CS01	Regular tip	Flocked Swab w/80mm breakpoint
503CS01	Flexible Mini-Tip	Flocked Swab w/100mm Breakpoint
518CS01	Minitip	Flocked swab w/100mm Breakpoint
519CS01	Regular	Flocked Swab w/100mm Breakpoint

Note: If the scored breakpoint on the swab and the top of the tube do not match, then scissors may be used to cut the swab shaft in order to fit into the tube.

Nasopharyngeal swabs: Insert swab into the nostril parallel to the palate. Leave the swab in place for a few seconds to absorb secretions.

Oropharyngeal swabs (e.g. throat swabs): Swab the posterior pharynx, avoiding the tongue.

After collection of specimen, remove cap from the tube, insert swab. Submerge the tip of the swab into the media. Cut the shaft with scissors or break off the swab by bending the shaft (for swabs with a scored break point) against the rim of the tube. For scored swabs, 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 for aerosol formation. Ensure the top of the swab shaft is below the rim of the tube to facilitate closure. Re-cap the tube securely. Label the sample. Transport immediately to the lab at 2-30ºC within 24 hours after collection. If time to testing is greater than 24 hours, but less than 72 hours, then store at 2-8ºC. If storing specimen more than 72 hours, then freeze at -70ºC. Use of ice will help preserve the integrity of the sample during shipment to public health laboratories. Place the tube into a biohazard specimen bag and seal securely.

For long-term storage, freeze at -70ºC. Do not freeze at temperatures warmer than -70ºC. For more information, consult listed references [2-5,8]

More than one tube may be submitted if more than one sample type of culture is requested to ensure adequate specimen for testing. If necessary, a nasopharyngeal swab and oropharyngeal swab (NP/OP swab) may be combined at collection into a single tube.[8]

All specimens should be shipped in compliance with all federal, state, hospital, or public health laboratory guidelines. Check for information from The Centers for Disease Control and Prevention (CDC) or with state and county public health laboratories for information that must be included with the specimen for testing.[8]

INTERPRETATION OF RESULTS

Consult listed references for isolation and identification procedures for specific organisms recovered from transport media.[2-5,8]

LIMITATIONS

1. This media contains selective agents and is manufactured in an environmentally controlled area and has been validated to an SAL of 10^{-3} with an AQL of 0.10.
2. Viral Transport Media is classified as a culture media, non-propagating transport.
3. Hardy Diagnostics Viral Transport Media has not been reviewed by the FDA.
4. Inspect tubes of Viral Transport Medium prior to use for the correct broth appearance. Discard tubes prior to use if the medium has changed from the original clear and light peach color to a yellow color, which would indicate bacterial contamination.
5. Do not submerge the swab in the Viral Transport Medium prior to sampling. Inoculate specimens as soon after collection as possible.
6. If there is a delay of more than 48 hours before testing, store at 2-8ºC. Specimens shipped to public health laboratories should be shipped on ice with appropriate paper work.[8]
7. For long-term storage of specimens for the recovery of viruses, freeze at -70ºC. Do not freeze at temperatures warmer than -70ºC.
8. Repeated freezing or thawing of frozen specimens may reduce the chance of viral recovery.
9. Polyester (Dacron®), rayon, or flocked nylon tipped swabs with plastic shafts are recommended. Calcium alginate, cotton swabs, or swabs with wooden shafts should not be used.
10. Data represented in the Performance Characteristics section is for culture only, and not molecular analysis. It is recommended that each laboratory establish performance characteristics of this product in conjunction with its viral testing methods.
11. Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, nasopharyngeal swabs, oropharyngeal swabs, biohazard bags, applicator sticks, PCR or RT-PCR kits, incinerators, incubators, refrigerators, shipping containers, ice, etc., as well as serological and biochemical reagents, 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). The following organism is routinely used for testing at Hardy Diagnostics:

For Quality Control, the test virus is inoculated into the Viral Transport Medium (VTM) and then held for 48 hours at 2-8°C. Then 0.3ml of the VTM is transferred to the shell vial of rabbit kidney cells. After 12-24 hours at 35°C., the shell vial is read under the microscope at 100X magnification to observe for cytopathic effects.

Test Organisms	Time	Reaction
Herpes Simplex Type I McIntyre ATCC® VR-539	48 hours	Viability maintained by examining for cytopathic effects on rabbit kidney cells

* Refer to the document "Inoculation Procedures for Media QC" for more information.

Toxicity Study: A further test is performed to ensure the VTM is not toxic to animal tissue cells. A 0.3ml aliquot of the Viral Transport 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 a 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.

PHYSICAL APPEARANCE

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

PERFORMANCE CHARACTERISTICS

All viruses were recovered (showed cytopathic effects in appropriate cell lines) after 72 hours at room temperature (15-30°C) and refrigerated storage (2-8°C). The table below shows the viral species that were tested.

Organism (Wild-type strains: One isolate/organism)
Influenza A
Influenza B
Respiratory Syncytial Virus (RSV)
Adenovirus
Herpes Simplex Type I
Herpes Simplex Type II
Cytomegalovirus (CMV)
Echovirus

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. Clyde, W.A. et al. 1984. *Cumitech 19; Laboratory Diagnosis of Chlamydial and Mycoplasmal Infections*, Coordinating ed. W.L. Drew. American Society for Microbiology, Washington D.C.

5. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

6. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

7. Centers for Medicare & Medicaid Services (CMS). Individualized Quality Control Plan (IQCP).

8. The Centers for Disease Control and Prevention (CDC). *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019(COVID-19)*. Accessed March 13, 2020.

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

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