

Viral Transport Medium

Product Information Sheet

Indications for Use

Nephron's Viral Transport Medium is intended for the collection and transport of clinical specimens containing viruses, from the collection site to the testing laboratory. The Viral Transport Medium can be processed using standard clinical laboratory operating procedures for viral culture.

General Information

The Viral Transport Medium allows the safe transfer of viruses for further research including classical cell culture methods, diagnostics testing, as well as molecular biology techniques (including PCR). The special formulation ensures the best possible recovery of the samples and the addition of antibiotics reliably inhibits the contaminating growth of bacteria and fungi.

The composition and the manufacturing of the Viral Transport Medium follows the recommendations outlined in the CDC's standard operating procedure for preparation of Viral Transport Medium. Nephron's Viral Transport Medium is formulated under a laminar flow hood using sterile ingredients. The product is then filled aseptically under the laminar flow hood into pre-sterilized conical sample tubes. The formulation of Viral Transport Medium is a completely aseptic process from start to finish with in-process and finished product sterility checks as outlined in the CDC's standard operating procedure.

Contents and Storage

Product	Item No.	Volume
Viral Transport Medium, Formula CDC	0487-0872-19	3 mL
Nasopharyngeal swab/Oropharyngeal (Throat) swab	IC-2323	N/A

Appearance

Clear liquid
Transparent

Shelf life and storage

12 months from the manufacture date when stored at 2°C to 8°C.
Do NOT freeze. Protect from light. Store and transfer in upright position.

Shipping Conditions

Ambient

Working Conditions

Ready to use

Materials Provided

25 pre-filled 3 mL vials
25 Nasopharyngeal swab/Oropharyngeal (Throat) swab

Materials Not Provided

Materials for the microscopic examination, cultivation, differentiation, and isolation of bacteria from clinical specimens are not provided.

For lot specific data (Certificate of Analysis) please refer to our website: www.nephronpharm.com

Formulation

Our Viral Transport Medium is based on Hanks Balanced Salt Solution (HBSS) with Calcium and Magnesium and contains heat-inactivated Fetal Bovine Serum, Gentamicin and Amphotericin B.

Instructions for Use: Specimen Handling, and Storage

The Viral Transport Medium is suitable for the transfer of various types of viruses. Use the viral transport medium as it is most suitable for your application.

Inadequate or inappropriate specimen collection, storage, and transport will likely yield false test results.

Training in specimen collection is highly recommended due to the importance of specimen quality.

- Transporting Specimens
 - Specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation.
 - Store specimens at +2°C to +8°C and ship overnight on ice pack. If a specimen is frozen at -70°C or lower, ship overnight on dry ice.
- Storing Specimens
 - Specimens can be stored at +2°C to +8°C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -70°C or lower.

Performance Characteristics

Patient samples were collected in Nephron Pharmaceutical Corporation (NPC) viral transport media (VTM). Specimen transport devices were evaluated by counting cells collected in nasopharyngeal swab (NP) samples from patients in NPC VTM to assess cell viability after 24 hours. Cells were then re-suspended in phosphate buffered saline, diluted in viability dye, vortexed to mix, then loaded onto a hemacytometer and counted.

Specimen Stability was evaluated by spiking NPC VTM with a concentration of 100 viral copies per mL (cp/mL) of the non-replicating, full SARS-CoV-2 viral genome. Spiked NPC VTM was refrigerated or stored at room temperature for 0, 24, 48 and 72 hours, then tested on a Real Time PCR (RT-PCR) system.

VTM Validation Data Summary

Specimen	Component Validated	Method	Time Period	Acceptance Criteria	Results
Nasopharyngeal Swabs	Specimen Transport Device	Viability	24 hrs	20 live cells/20 µL	3,466.7 live cells/20 µL
SARS-CoV-2 (100 cp/mL)	Specimen Stability at 4°C	RT-PCR	0 hrs	Detection of viral genes (Ct≤35)	Positive
			24 hrs		Positive
			48 hrs		Positive
	Specimen Stability at RT		72 hrs		Positive
			24 hrs		Positive
			48 hrs		Positive
SARS-CoV-2 (Reporter)	Specimen Preservation	Fluorescence	72 hrs	No fluorescence difference vs standard culture media (McCoys)	N/A (invalid)
			24 hrs		No difference
			48 hrs		No difference
			72 hrs		No difference

Precautions and Disclaimer

For transport of specimens only. Not to be taken internally. For in vitro diagnostic use.

This device is to only be used by trained and qualified professionals.

Specimen stability for this media was not validated for recovery of viral infectious particles using a culture-based assay.

The solution is a transport medium that serves as culture media, nonpropagating transport. The medium is not intended for therapeutic use.

This product has not been reviewed by the FDA.

Do not use if a visible precipitate is observed in the medium.

Use of Viral Transport Medium does not guarantee the successful outcome of testing.

Do not use Viral Transport Medium beyond the expiration date indicated on the product label.

Handle all specimens as if infectious using safe laboratory procedures.

Signs and Symbols

IVD – In vitro diagnostics **ⓧ** – Do not reuse **STERILE A** – Aseptic filling

Additional Inquires

If you have any further questions regarding this product please do contact us by email (clinicallabscheduling@nephronpharm.com) or phone (+1 (803) 381-1045).