3DVTM01-3.0ml

Viral Transport Media

For collection and transport of clinical specimens for recovery of viral agents such as SARS-CoV-2

Instructions for Use (IFU)

INTENDED USE

THIS PRODUCT IS A VIRAL TRANSPORT MEDIA AND IS INTENDED FOR *IN VITRO* RECOVERY OF VIRAL AGENTS. FOR TRANSPORT OF SPECIMENS[1] ONLY. NOT TO BE TAKEN INTERNALLY. INSTRUCTIONS MUST BE CAREFULLY FOLLOWED.

3DVTM01-3.0ml contains a Non-Propagating Viral Transport Medium intended to be inoculated with specimens collected with an FDA approved sterile swab, transported, and analyzed per standard molecular diagnostic practices to detect the presence of viral infection in humans.

3DVTM01-3.0ml is to be used (1) to stabilize and transport clinical specimens obtained from swabs (2) with molecular or antigen assays for measuring various viral markers (e.g., nucleic acids, antigens, etc.) and (3) with molecular or antigen assays conducted on various test platforms.

3DVTM01-3.0ml is produced per cGMP requirements by qualified and trained clinical laboratory personnel specifically instructed and trained on the 3DVTM01-3.0ml SOP per the CDC Preparation of viral transport medium, 2020 DSR-052-05.

DESCRIPTION

3DVTM01-3.0ml is a Viral Transport Media to collect, maintain, and transport viruses in their active form to the laboratory for isolate detection. The media is a slightly yellow transparent liquid and has a consistency of water.

3DVTM01-3.0ml is produced in support of the Centers for Disease Control and Prevention (CDC) Coronavirus 2019 (COVID-19) outbreak response. The special formula ensures the best possible recovery for viral samples and the addition of the antibiotic reliably inhibits the contaminating growth of bacteria and fungi.

COMPOSITION 3DVTM01-3.0ml

3DVTM01-3.0ml Media
- 1X Hanks balanced salt solution
- 2% Fetal Bovine Serum
- 100ug/mL Gentamicin Sulfate
- 0.5ug/ml - Amphotericin B

[1] In this document the word specimen(s) and sample(s) are synonymous and used interchangeably.

3DVTM01-3.0ml

Viral Transport Media

For collection and transport of clinical specimens for recovery of viral agents such as SARS-CoV-2

Instructions for Use (IFU)

3DVTM01-3.0ml Tube and Container Closure

Standard 16mm x 93mm 10ml sterile screw cap specimen tube with conical bottom with 3.0ml of Media.

Name	Component	Volume of Media	Dimensions	SKU Code	Working Volume
3DVTM01-3.0ml	Sterile VTM Vial	3.0ml per vial x 50	H: 16 mm (Capped Height) W: 93 mm	3DVTM01-3.0ml	20ml

SPECIMEN TYPES

Oropharyngeal (OP) collected by Health Care Professional via FDA approved Sterile Swab.

Nasopharyngeal (NP) collected by Health Care Professional via FDA approved Sterile Swab.

Anterior Nares (AN) collected by Health Care Professional via FDA approved Sterile Swab.

Mid-turbinate (MT) collected by Health Care Professional via FDA approved Sterile Swab.

STORAGE CONDITIONS

Do not freeze tube. Store at 2-8°C and keep away from a direct light source. Do not use product beyond its expiry date on the label or if product shows any contamination or signs of deterioration. Tubes can also be stored for up to 120 days at room temperature without inhibiting the performance 3DVTM01-3.0ml. After collection store specimens at 2-8°C for up to 72 hours to yield the best results.

SHELF LIFE

12-month shelf life at 2-8°C.

3DVTM01-3.0ml

Viral Transport Media

For collection and transport of clinical specimens for recovery of viral agents such as SARS-CoV-2

Instructions for Use (IFU)

SPECIMEN COLLECTION PROCEDURE

IMPORTANT: Please ensure that a lab operator and trained authorized personnel read these Instructions for Use for 3DVTM01-3.0ml. Specimen should be collected according to the healthcare institutional guidelines.

Step 1: Collection of Sample

For a complete diagnostic analysis of viral diseases, it is important that the infectivity of the viruses is preserved after sample collection. Stability of samples is enhanced by cooling; therefore, samples should be kept at 2-8°C after collection. The probability of a successful isolation is increased when the samples are processed immediately after collection. Viral load is maximized if the samples are collected immediately after the onset of clinical symptoms and before the administration of antiviral medications.

Step 2: Directions for Swab and 3DVTM01-3.0ml Deployment

1) Cut and open the pouch to remove the swab.

2) Specimen can be collected with the swab in accordance with healthcare institutional guidelines.

3) Break the swab near the break point or cut the swab with scissor and insert into the tube containing viral transport medium and close the cap tightly.

4) Label the sample correctly with the name of the patient and time and date of collection.

5) Transport the samples immediately to the laboratory for processing.

Step 3: Transportation of Samples

Samples should be transported to the laboratory as soon as possible. Samples can be refrigerated at 2-8°C after collection or can be transported at 2-8°C on ice packs within 72 hours.

WARNING AND LIMITATIONS

- **3DVTM01-3.0ml has not been reviewed by the FDA**
- *FOR IN VITRO USE ONLY.*

3DVTM01-3.0ml

Viral Transport Media

For collection and transport of clinical specimens for recovery of viral agents such as SARS-CoV-2

Instructions for Use (IFU)

- Do not freeze tube. Store at 2-8°C and keep away from a direct light source.

- Specimen stability for this media was not validated for recovery of viral infectious particles using a culture-based assay.
- Follow standard precautions and handle using proper PPE and safe laboratory practices.
- Do not ingest media.
- Not suitable for any other application than intended use.
- Tubes may be impacted by elevated temperature.
- Repeat freeze and thaw cycles is not recommended.
- This product does not contain hazardous substances in concentrations exceeding limits therefore it is classified as dangerous.
- This product is intended for professional use only and must be used by properly trained personnel.

3DVTM01-3.0ml

Viral Transport Media

For collection and transport of clinical specimens for recovery of viral agents such as SARS-CoV-2

Instructions for Use (IFU)

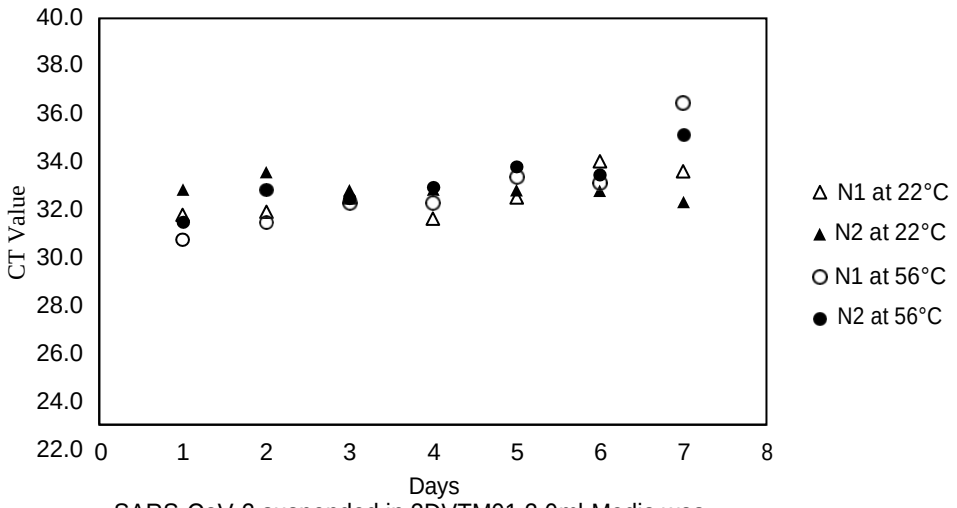
QUALITY CONTROL

Sterility Check 1 ml of 3DVTM01-3.0ml Media is aseptically plated on chocolate agar plates and incubated for 48 hours at 37°C +/- 2°C to monitor growth.

Randomly selected & 3DVTM01-3.0ml tubes were examined for appropriate media volume, color, optical clarity, and integrity of the tubes and caps.

3DVTM01-3.0ml Media was tested for its support of SARS-COV-2 RNA amplification target which was spiked into samples at 2x limit of detection (LoD) of the SARS-CoV-2 RT-PCR assay (1.5 copies/uL) to assess amplification of SARS-CoV-2.

PERFORMANCE CHARACTERISTICS



SARS-CoV-2 suspended in 3DVTM01 3.0ml Media was detected up to 7 days after incubating at 22°C and 56°C.
CT values of 3DVTM01-3.0ml Media spiked at 2X LoD incubated at 22°C and 56°C.
PCR efficiency SARS-CoV-2 was not affected when samples were kept at 22°C and 56°C for 7 days.
In addition, the suitability of aged 3DVTM01-3.0ml Media for RT-PCR testing and that PCR efficiency was not affected by elevated temperatures.

3DVTM01-3.0ml

Viral Transport Media

For collection and transport of clinical specimens for recovery of viral agents such as SARS-CoV-2

Instructions for Use (IFU)

INDEX OF SYMBOLS

Index of Symbols			
Symbol	**Description**	**Symbol**	**Description**
	In vitro diagnostic medical device		Do not re-use
	Expiry date		Consult instructions for use
	Warning, please refer to the instruction		Manufacturer
	Store at 2-8℃	LOT	Lot number
	Keep away from sunlight		Don't use the product when the package is damaged
	Date of manufacture		Biological risk
STERILE	Sterile		

REFERENCES

1. Interim guidelines for collecting, handling, and testing clinical specimens for COVID-19. US Centers for Disease Control and Prevention. Updated October 8, 2020. [Accessed June 2021]
2. FAQs on Viral Transport Media During COVID-19 | FDA.
3. Preparation of viral transport medium. [PDF] US Centers for Disease Control and Prevention.(2020) [Accessed June 2021]
4. Smith, K.P., Cheng, A., Chopelas, A., DuBois-Coyne, S., Mezghani, I., Rodriguez, S., Talay, M.and Kirby, J.E., 2020. Large-scale, in-house production of viral transport media to support SARS-CoV-2 PCR testing in a multihospital health care network during the COVID-19 pandemic. *Journal of clinical microbiology*, *58*(8), pp.e00913-20.

3DVTM01-3.0ml

Viral Transport Media

For collection and transport of clinical specimens for recovery of viral agents such as SARS-CoV-2

Instructions for Use (IFU)

3D MedSupply & Manufacturing, LLC

General Information Requests: info@3dmedicalsupply.com

Manufacturing Contact:
Claudia Gonzalez
Claudia.Gonzalez@3DMedicalSupply.com

David Carter, Esq
dcarter@carterlaw.com

4303 Vineland Rd.
Suite F 8
Orlando, FL 32811
Office / Fax: (866) 30-3D-MED / (866) 303-3633
http://www.3DMedicalSupply.com