Instructions For Use

VTM

Transport medium for SARS-CoV-2 specimens.

This transport medium has not been reviewed by FDA.

The specimen stability for this medium was not validated for recovery of viral infectious particles using a culture-based assay.

INTENDED USE

Liofilchem® VTM is a non-propagating transport culture medium intended for transport of clinical material from the collection site to the laboratory for testing. This medium is designed to sustain the viability of viruses and can be used for storage of specimens as well.

DESCRIPTION

When used according to the instructions for use, VTM ensures proper collection, transport and storage of clinical specimens containing upper respiratory viruses, in particular of SARS-CoV-2, the virus responsible for COVID-19 (See PERFORMANCE for the details on compatibility with molecular diagnostic assays).

The medium is formulated to preserve genome (RNA) integrity of the virus while suppressing growth of bacteria and fungi that may be present in clinical samples from the human respiratory system.

COMPOSITION

Sucrose
Hanks Balanced Salt Solution (HBSS)
Bovine Serum Albumin (BSA)
HEPES Buffer
Gelatin
L-Glutamic Acid
Vancomycin
Colistin
Amphotericin B
Phenol Red
Final pH 7.3 ± 0.2 at 25°C

VTM does not contain guanidium thiocyanate.

METHOD PRINCIPLE

Sucrose acts as cryoprotectant ensuring organism viability during freeze-thaw. HBSS provides essential inorganic ions and along with HEPES buffer maintains pH and osmotic balance. BSA, gelatin and glutamic acid help to stabilise virus particles. Vancomycin, colistin and amphoteric B are antimicrobial agents included to inhibit growth of bacteria and fungi. Phenol red is the pH indicator ensuring medium integrity at the time of specimen collection.

DIRECTIONS FOR USE

IMPORTANT: Please ensure that a copy of these Instructions for Use (IFU) is provided to all labs processing Liofilchem® VTM Tubes.

Specimen should be collected by trained authorized personnel according to the healthcare institutional guidelines.

1. Collect swab specimens according to standard technique using a swab with a synthetic tip and a plastic shaft.
2. After collection, immediately place the swab specimen into a VTM tube.
3. Identify the tube containing the specimen.
4. Send promptly to the laboratory.

Specimens may be dispatched at ambient (10-25°C) or refrigerated temperature (2-8°C) to arrive at the laboratory for processing within 96 hours.

APPEARANCE

Clear, light orange-red.

STORAGE

Store at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

6 months.

QUALITY CONTROL

Quality control testing is performed on each lot of VTM for appearance, pH and sterility.

Sterility check is performed by spreading 100 µL of medium onto the surface of a blood agar plate and incubating for 48 hours at 37 ± 2°C as recommended in the CDC's SOP: Preparation of Viral Transport Media. The plate is checked for growth daily.

Please refer to the actual batch related Certificate of Analysis (CoA) available on Liofilchem's website.

PERFORMANCE

The ability of VTM to maintain viral vitality was tested and successfully validated using the DiaSorin Molecular Simplexa™ COVID-19 Direct assay system, a real-time RT-PCR system that enables the direct amplification of Coronavirus SARS-CoV-2 RNA from nasopharyngeal swabs (NPS), nasal swabs (NS), nasal wash/aspirate (NW) or bronchoalveolar lavage (BAL) specimens.

In the Simplexa™ COVID-19 Direct assay, fluorescent probes are used together with corresponding forward and reverse primers to amplify SARS-CoV-2 viral RNA and internal control RNA. The assay targets two different regions of the SARS-CoV-2 genome, ORF1ab and S gene. The S gene encodes the spike glycoprotein of the SARS-CoV-2 (COVID-19 virus) and is also targeted to specifically detect the presence of SARS-CoV-2. The ORF1ab region encodes well-conserved non-structural proteins and therefore is less susceptible to recombination. An RNA internal control is used to detect RT-PCR failure and/or inhibition. This test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, to perform high or moderate complexity tests.

VTM tubes were inoculated with a suspension of the virus and either held at room temperature (20–25°C) or immediately refrigerated (2–8°C) until time of testing. Viral recovery was assessed at 0, 24, 48, 72, and 96 hours. At each time point, RNA was quantified by real-time PCR.

Test results demonstrated that the Liofilchem VTM is compatible with the qRT-PCR detection of SARS-Cov-2 viral nucleic acid materials and that it does not negatively affect viral RNA recovery when the inoculated tubes are maintained at controlled room temperature (RT) and 2-8°C for up to 96 hours.

LIMITATIONS

- VTM is intended for transport of specimens only and must not be taken internally.
- VTM must not be used for premoistening or prewetting the swab prior to collecting the sample or for rinsing or irrigating the sampling sites.
- SWABS are NOT PROVIDED with this device.
- When choosing the collection swab, it is important to know that certain swab components may reduce recovery of some microorganisms or interfere with molecular detection methods. For example, calcium alginate swabs and wooden shaft swabs should not be used.
- All specimens collected for laboratory investigations should be regarded as potentially infectious.
- Condition, timing, and site of sampling as well as the type and volume of specimen are significant variables in obtaining reliable culture results. Refer to appropriate guidelines for detailed explanation of test procedure and sample collection.
- Performance of the VTM may be impacted by extreme temperatures and repeated freeze and thaw cycles.
- The use of this product for uses other than described here shall be evaluated by the end user.
- The use of this product with any diagnostic test should be evaluated and tested by the end user.
- This product is not a replacement for viral cell culture medium.

WARNING AND PRECAUTIONS

Read the Safety Data Sheet (SDS) and follow the handling instructions.

For *In Vitro* Diagnostic use.

For professional use only.

The product is intended for use by trained and qualified professionals following standard precautions. Samples should be handled with care, as they may be infectious, using proper personal protective equipment and safe laboratory procedures.

Do not ingest the medium. Not suitable for any other application than the intended use.

Do not use if it is broken or if any foreign matter is found. Do not use if container contents have leaked out.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

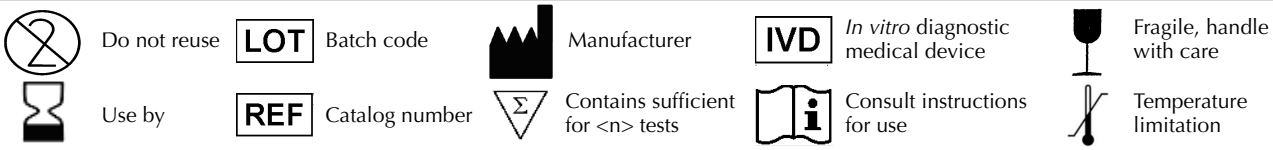
REFERENCES

1. Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency - Guidance for Commercial Manufacturers, Clinical Laboratories, and Food and Drug Administration Staff (July 2020). https://www.fda.gov/media/140300/download
2. Centers for Disease Control and Prevention (CDC's) Standard Operating Procedure (SOP): Preparation of Viral Transport Media. https://www.cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf
3. Centers for Disease Control and Prevention (2020). Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19).https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
4. Clinical and Laboratory Standards Institute (2014). Quality Control of Microbiological Transport Systems; Approved Standard - Second Edition. CLSI document M40-A2.

Product	Format	Packaging	Ref.
VTM	16 x 100 mm Tube with internal shaped conical bottom and screw cap	100 x 3 mL tubes	26490U

For all inquiries please fill out the form at https://www.liofilchem.com/contact-us.html

SYMBOL GLOSSARY



This document is available from the online Support Center:
liofilchem.com/ifu-sds

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