References

1. Centers for Disease Control and Prevention (CDC) Laboratory Outreach Communication System SOP post on 3-21-20:
   cdc.gov/coronavirus/2019-ncov/downloads/Viral-Transport-Medium.pdf
2. FAQs on Viral Transport Media During COVID-19
   fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-viral-transport-media-during-covid-19
3. CDC preventing transmission of infectious agents in healthcare settings guidelines;
   cdc.gov/infectioncontrol/guidelines/isolation

Symbol glossary

biomeddiagnostics.com/l/symbol-glossary

Technical Information

For technical information or questions, please contact Biomed Diagnostics, Inc.: 800-964-6466.

Document Revision History

Rev. B, September 2020
Added statement about room-temperature storage.

Rev. A, July 2020
Changed reference 2 to refer to FAQs; changed wording about FDA enforcement policy; added statement about including copy of IFU for labs processing the tubes; added statement about room-temperature incubation.

Rev. NEW, July 2020
New Document

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100-607 IFU VTM-C19 Transit Tube Rev. B (09/2020)

BIOMED DIAGNOSTICS

VTM-C19 Transit Tube

A premium transport device for use with clinical material for nucleic acid testing of SARS-CoV-2 specimens

REF	11-602-001	Σ 1
REF	11-602-002	Σ 50
REF	11-602-003	Σ 300

For In Vitro Diagnostic Use
Instructions must be carefully followed.

IVD

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Certificate of Analysis

Introduction

Intended Use

The VTM-C19 Transit Tube contains a viral transport medium (VTM; Culture Media, Non-Propagating, Transport) intended to be inoculated with nasopharyngeal (NP) or oropharyngeal (OP) synthetic fiber swab specimens (Not provided, see "Key Notes Regarding Specimen Collection" section for details), transported appropriately to the lab and analyzed with validated qRT-PCR assays for the detection of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that causes COVID-19 disease in humans.[1,2]

Description and Principle

When used according to the instructions for use, the VTM-C19 Transit Tube ensures a non-replicating competent status of SARS-CoV-2 (COVID-19) thereby preserving viral RNA genome integrity of the virus. VTM-C19 medium also suppresses the growth of other bacteria and fungi that may be present in clinical samples from the human respiratory system. From the site of collection to downstream laboratory nucleic acid testing (e.g., qRT-PCR), the VTM-C19 Transit Tube is intended to be used in the collection and transport process of human clinical samples that contain the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The VTM-C19 Transit Tube aids laboratory professionals in the diagnosis of the infectious human coronavirus disease-2019 (COVID-19) that is caused by the virus, SARS-CoV-2.

The VTM-C19 Transit Tube is designed to facilitate the identification of SARS-CoV-2 with qRT-PCR technology by providing:

- Safe transport and preservation of the specimen
- Compatible with approved nucleic acid extraction and qRT-PCR tests

The VTM-C19 Transit Tube is available for use in the USA under the FDA guidance "Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19)Public Health Emergency" (July 2020). The VTM-C19 Transit Tube has completed the notification process.

Reagents and Appearance

The VTM-C19 medium appears clear and is formulated using the CDC prescribed recipe[1] including the following reagents: heat-inactivated fetal bovine serum, Hanks balanced salt solution with calcium and magnesium ions, Gentamycin sulfate and Amphotericin B. Post-production pH of the media is 7.2 ± 0.2 at 25°C.

Precautions, Safety and Disposal

Read the Safety Data Sheet (SDS) and follow the handling instructions. Wear appropriate protective eyewear, clothing and gloves.

All specimens should be handled according to the CDC preventing transmission of infectious agents in healthcare settings guidelines.[3]
cdc.gov/infectioncontrol/guidelines/isolation

Once the tube has been inoculated and resealed, re-open only in a biological safety cabinet. Prior to disposal, sterilize tubes by autoclaving at 121°C for 20 minutes or through another suitable means of sterilization.

The VTM-C19 Transit Tube does not contain guanidine thiocyanate. It is however recommended that the user test the compatibility of the media with their disinfecting reagent before general/routine use.

Authorized laboratories will collect information on the performance of the VTM-C19 Transit Tube and report to Biomed Diagnostics, Inc. (via email: **medicalsafety@biomeddiagnostics.com**) any suspected occurrence of false positive or false negative results linked to use of the VTM-C19 Transit Tube and significant deviations from the established performance characteristics of the VTM-C19 Transit Tube of which they become aware.

Storage

Do not freeze the VTM-C19 Transit Tube. Upon receipt, store at 2-8°C, and keep away from direct light exposure. Do not use expired tubes. Do not use a tube if it appears to be damaged, leaking or the media appears to be cloudy.

After receipt or removal from refrigerated temperature (2-8°C), the VTM-C19 Transit Tube can be stored at room temperature (18-25°C) for up to 30 days without deterioration of performance , but not past the expiration date on the tube. Do not use expired tubes.

Shelf Life

The VTM-C19 Transit Tube is based on the CDC formulation which has a shelf-life of twelve-months when stored at 2–8°C. However, due to the ongoing COVID-19 emergency, shelf-life testing is currently on-going. The product label reflects the expiry date relative to current internal data acquired for product stored at 2–8°C. Please contact us for any further information.

Procedure

Key Notes Regarding Specimen Collection

IMPORTANT: Please ensure that a copy of these Instructions for Use (IFU) is provided to all labs processing VTM-C19 Transit Tubes.

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

Materials Provided

- VTM-C19 Transit Tube(s)

Materials Required but Not Provided

- **Swabs:** Use synthetic fiber nylon or Dacron® swab tips with plastic or aluminum shafts only, as recommended.[2] To be used with Nasopharyngeal (NP) or Oropharyngeal (OP) specimens.
- **Sample:** Please see Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) **cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html**

1. Aseptically remove red screw top of a VTM-C19 Transit Tube containing a clinical swab specimen.
2. Gently swirl the swab to the left (6 times) and to the right (6 times) to release the viral particles into the media.

   Gently press the swab to the inside of the tube above the media and rotate to the left or right to remove excess media and prevent dripping.
3. Carefully remove and discard the swab aseptically according to your institutional guidelines.
4. Secure the red screw top of the tube and store the inoculated VTM-C19 Transit Tube upright in a place holder.
5. Complete the label with patient information in accordance with your laboratory requirements and store or transport the tubes at 2-8 °C in upright position. The Viral particles are expected to remain in a non-replicating viable status for up to 72 hours at 2-8 °C.

   It is suggested that storage beyond 72 hours should be at -70°C. However, the effectiveness of the tube performance at this temperature (-70°C) has not been tested.

Transportation

The VTM-C19 Transit Tube is designed for safe transport. Inoculated tubes should be transported within 72 hours after inoculation and maintained at 2-8°C [2].

Quality Control

This product has been tested and meets the CLSI (formerly NCCLS) Approved Standard for commercially prepared media (M22-A3). At the time of manufacture, quality control testing is performed on each lot of VTM-C19 Transit Tubes for verification of sterility.

Limitations

- Performance of the VTM-C19 Transit Tube may be impacted by extreme temperatures and repeated freeze and thaw cycles.
- The use of VTM-C19 Transit Tubes for uses other than described here shall be evaluated by the end user.
- The use of swabs with wooden or calcium alginate components has not been tested with the VTM-C19 Transit Tube and should not be used.
- 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.

Performance Characteristics

This test was performed to evaluate the Biomed COVID-19 Viral Transport Media (VTM-19 Transit Tube) by detection of gamma-irradiated cell lysate from SARS-Cov-2 (BEI Resources) infected cells, after RNA was isolated using the QIAamp® DSP Viral RNA Mini Kit (QIAGEN®). Detection of the isolated SARS-Cov-2 RNA was by qRT-PCR using New England Biolabs® OneTaq® One-Step RT-PCR kit and run on a Roche® Lightcycler® 96 with EvaGreen® (Biotium) detection from samples after storage of viral lysates in VTM-C19 at 24, 48 and 72 hours at 4-8°C. Synthetic RNA standard (BEI Resources) at 2.9 x 10^8 was serially (10-fold) diluted for the standard (STD) in the amplification reaction.

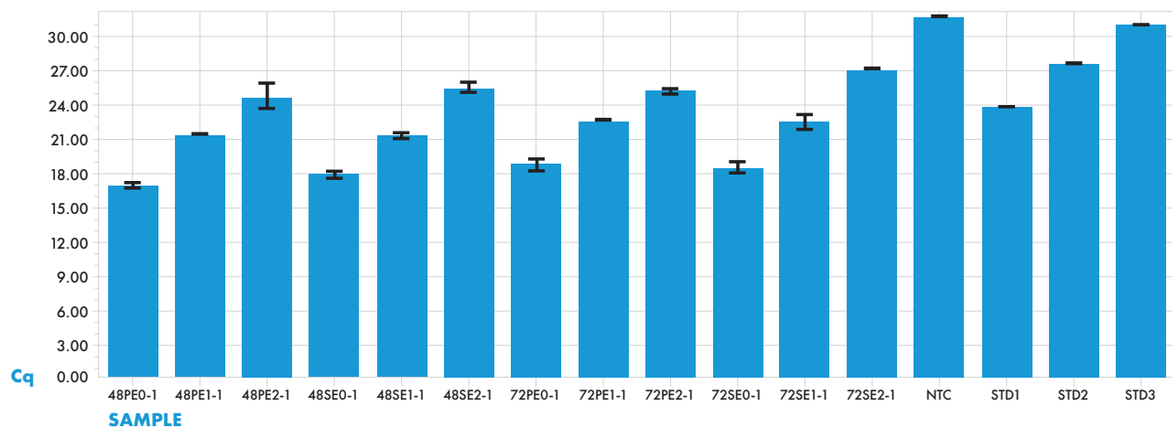
The assay results demonstrate consistent amplification and Cq quantification of the N1 gene (using CDC primer) in the media after incubations. In addition, excellent dilution linearity is demonstrated across all samples and replicates (See Fig. 1) indicating consistency in the performance of the media across replicate samples and incubation time. This data indicates that the Biomed ISO 13845 manufactured VTM-C19 Transit Tube does not negatively interfere with the qRT-PCR detection of Sars-Cov-2 viral nucleic acid materials after incubation at 4-8°C for 72 hours.

Further evaluation indicated that the VTM-C19 was compatible with viral RNA recovery and qRT-PCR assay post-inoculation and incubation at 25°C for up to 1 week.

For further information or queries, please contact us.

Figure 1: Cq values for three concentrations of 48 and 72 h samples

(24 h result not shown)



All samples shown are means from triplicate assays, with error bars indicating the arithmetic error for Cq shown. Slope -3.58; Efficiency 90.25%; Amplification 1.9; R^2 1.0

Note:

48P or 72P : Polypropylene tubes sampled at 48 or 72 hours post-inoculation.

48S or 72S : Polystyrene tubes sampled at 48 or 72 hours post-inoculation.