

INTENDED USE

VTM (Viral Transport Medium) is a culture medium designed for the non-propagating transport of viruses from clinical patient specimens for the measurement of viral particles using molecular or antigen assays.

SUMMARY

Routine procedures in the diagnosis of infections caused by viruses involves the collection and refrigeration of biological specimens.

VTM (Viral Transport Medium) contains:

- Hanks' Balanced Salt Solution
- Fetal bovine serum
- Gentamicin
- Amphotericin B

VTM is manufactured according to CDC (Centers for Disease Control and Prevention) SOP#: DSR-052-03.

FOR IN VITRO DIAGNOSTIC USE ONLY

PRECAUTIONS

VTM is a single-use device for trained and qualified professional use only. VTM is not hazardous and does not require special methods of disposal and handling. Take appropriate precautions for infected material if necessary. For transport use only, not to be taken internally.

STABILITY AND STORAGE

VTM has a shelf life of 12 months from the date of manufacture when stored at the refrigerator temperatures (2–8°C). Alternatively, VTM can be stored at room temperature (15–28°C) for up to 6 months. Do not freeze or overheat.

QUALITY CONTROL

VTM is tested for pH and sterility. Sterility is assessed by applying the solution to the surface of sheep blood agar plates and incubating for 48 hours at 35 ± 2°C checking for growth daily.

USER QUALITY CONTROL

This product should not be used beyond the expiration date. Any product showing excessive cloudiness, unusual turbidity, or discoloration should be discarded. Validation for use of this product in combination with diagnostic kits or instruments is recommended.

SPECIMEN COLLECTION AND PREPARATION

1. Specimens should be collected and handled using protective equipment against biological risk according to published manuals and guidelines.
2. Proper collection of the specimen from the patient is crucial for the successful isolation and identification of infectious viruses.
3. In order to maintain optimal microorganism viability, transport the specimens to the laboratory as soon as possible.

PROCEDURE

Materials Provided: Each vial contains the volume of VTM as stated on the label.

Materials Not Provided: Collection devices or swabs, materials or devices for the identification of viruses.

SPECIMEN PROCESSING

Due to the hazardous nature of patient specimens, all standard laboratory safety procedures should be observed during all phases of collection.

1. After collecting the specimen, unscrew and remove the cap from the VTM vial, taking care not to spill the medium.
2. Insert the swab into the vials until the swab breakpoint (if present) is level with the vial opening.
3. Bend and break the swab at the breakpoint holding the vial away from your face. If the swab does not have a breakpoint, cut the excess shaft and discard.

4. Replace cap and tighten.
5. Process the specimen contained in the VTM within 48 hours of collection, following local laboratory guidelines regarding transportation and storage temperatures.

PERFORMANCE

Viral recovery was assessed by adding T7 Bacteriophage to VTM that was either refrigerated (2-8° C) or held at room temperature (25° C) for up to 6 months. Once inoculated, the VTM was then stored at -80° C, 2-8° C, 25° C, and 37° C for up to 4 weeks. At each timepoint, phage viability was tested with a viral plaque assay.

	VTM (Stored @ 2-8° C)	VTM (Stored @ 25° C)
-80° C: 24 hours	Viable	Viable
2-8° C: 4 weeks	Viable	Viable
25° C: 4 weeks	Viable	Viable
37° C: 24 hours	Viable	Viable

This transport media has not been reviewed by the FDA.

BIBLIOGRAPHY

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4. Biosafety in Microbiological and Biomedical Laboratories (BMBL), current edition.
5. CLSI Standard, M40-A2: Quality Control of Microbiological Transport Systems; Approved Standard, 2nd Ed.
6. Kirby, J. et al. Large-scale, in-house production of viral transport media to support the SARS-CoV-2 PRC testing in a multi-hospital healthcare network during the COVID-19 pandemic. 2020. J. Clin Mic.

CONTACT

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WARRANTY

Alpha-Tec Systems, Inc. warrants this product to perform as described in the labeling and literature supplied. Alpha-Tec Systems, Inc. disclaims any implied warranty or merchantability or fitness for any other purpose, and in no event shall Alpha-Tec Systems, Inc. be liable for any consequential damages arising out of aforesaid express warranty.

PRODUCT CODES

0003730 VTM (Viral Transport Medium), 64 vials/pk



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GLOSSARY OF SYMBOLS

LOT Batch code / Numéro de lot / Número de Lote / Numero di lotto / Lot Nummer / Lotnummer / Lotnummer / Šaržna številka / Número de lote

REF Catalog number / Référence du catalogue / Número de catálogo / Numero di catalogo / Katalognummer / Catalog number / Het aantal van de catalogus / Kataloška številka / Número de catálogo

IVD In vitro diagnostic medical device / Pour usage diagnostique in vitro / Para uso diagnóstico in vitro solamente / Solo per uso diagnostico in vitro / Nur zur Verwendung als in vitro-Diagnostikum / Alleen voor in vitro diagnostisch gebruik / För invitrodiagnostik enbart / Samo za invitro diagnostiko / Apenas para uso em diagnóstico in vitro

EC REP Authorized representative in the European Community / Représentant européen autorisé / Representante Europeo Autorizado / Rappresentante europeo autorizzato / Autorisierter Europäischer Repräsentant / Gemachtigde Europese vertegenwoordiger / Auktoriserad europeisk representant / Pooblaščen evropski predstavnik / Representante Europeo Autorizado



Use-by date / Utiliser avant la date de péremption indiquée / Use antes de la fecha indicada / Utilizzare entro la data indicata / Bis zum angegebenen datum verbrauchen / Gebruik door vermelde datum / Använd innan angivet datum / Porabiti do navadenega datuma / Usar até à data indicada



Manufacturer / Fabricant / Fabricante / Produttore / Hersteller / Fabrikant / Fabrikant / Proizvajalec / Fabricante



Caution / Attention / Cuidado / Attenzione / Achtung / Voorzichtig / laktag försiktighet / Previdno / Atenção



Temperature limit / Conserver aux températures indiquées / Almacene entre las temperaturas indicadas / Conservare a temperatura comprese fra quelle indicate / Im angegebenen temperaturbereich aufbewahren / Opslaan bij een temperatuur tussen / Förvara mellan angivna temperaturer / Shranjevati med navedenimi temperaturami / Armazene entre as temperaturas indicadas



Contains sufficient for <n> tests / Contenu suffisant pour <n> tests / Contiene suficiente para <n> pruebas / Contenido suficiente per <n> tests / Enthält ausreichend für <n> untersuchungen / Inhoud voldoende voor <n> testen / Innehåller tillräckligt för <n> tester / Vsebinsa zadostuje za <n> testov / Contém quantidade suficiente para <n> testes



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