

TMVT 003 – VIRAL TRANSPORT KIT (Double Nylon Flocked Swab)

INTENDED USE

For collection and transport of clinical specimen for recovery of viral agents.

PRODUCT SUMMARY AND EXPLANATION

A Viral Transport kit is intended for the collection and transport of clinical specimens containing viruses, chlamydiae, mycoplasmas or ureaplasmas from the collection site to the testing laboratory. It is ready to use transport swab kit, designed to maintain viral viability and transport viruses in active form for isolation. The peculiar design of the flocked swab ensures optimal elution of the specimen into the transport medium. The viral transport medium contains essential buffers and antibiotics required for maintaining the viability of the viruses during transport. The medium is also recommended by CDC and WHO for collection and transport of Coronavirus.

The kit comprises one Nasopharyngeal and one Oropharyngeal nylon flocked swab with breakpoints, and a tube of Viral Transport Medium. Swab contains short perpendicular nylon fiber strands attached to flexible molded plastic that results in efficient collection and release of particular matter. The flocked specimen yields more sample which helps to maximize sensitivity of cell culture and molecular technique assay. Flexible plastic shaft delivers better patient comfort. Each swab has a molded breakpoint which allows the swab to be broken in to the tube.

KIT INCLUDES

Components	Composition
Viral Transport Medium*	Proprietary
Single Nasopharyngeal Nylon flocked swab with breakpoint	-
Single Oropharyngeal Nylon flocked swab with breakpoint	-

*3ml medium in 10-15 ml tube

PRINCIPLE

The viral transport medium consists of Hanks Balanced Salt Solution modified and enriched with bovine serum albumin, cysteine, gelatin, sucrose and glutamic acid. The pH is quenched with buffer HEPES. Phenol red is used as a pH indicator. Vancomycin, amphotericin B and colistin have been added to the medium to inhibit the proliferation of competing bacteria and yeasts. The medium is isotonic and lacks toxicity to the mammalian host cells. The presence of sucrose acts as a cryoprotectant that facilitates the viruses and chlamydia if samples are frozen (-70 ° C) for long storage.

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Orange-red colour, clear solution
pH (at 25°C)	:	7.3± 0.2
Sterility Check	:	Passes release criteria

INSTRUCTION FOR USE

Collection of Samples:

Samples for research on viruses, chlamydia, mycoplasmas or ureaplasmas should be collected and handled following the reference manuals and guidelines. Probability of successful isolation is increased if the sample is processed immediately after collection. Therefore, once the collection of a sample is done it should immediately be placed in the transport bottle where it will come in contact with the transport medium. To maintain optimum viability, samples should be taken to the laboratory as soon as possible. The better recovery is obtained if samples are refrigerated at 2°C to 8°C or held with ice



pack after collection and during transport. If there is going to be a long delay before they are processed, the samples should be frozen at -70°C or at a lower temperature and transported on dry ice.

Procedure:

1. Open the pouch to remove the swab.
2. Specimen can be collected with the swab in the following manner.

Nasal swab

- A. A nasal swab is used to diagnose upper respiratory tract infections, such as whooping cough. It is quick and painless test.
- B. Insert a small, soft-tipped swab into each nostrils and twirl it a few times until it is covered in secretions. This may be a little uncomfortable but should not be painful.

Nasopharyngeal swab

- A. Place patient with the head tilted slightly back.
- B. With sterile gloved hand, insert suction catheter into the patient's nose to the depth of the nasopharyngeal area (beyond the turbinates). Do not remove catheter until end of procedure.
- C. With the non-sterile gloved hand, instill approximately 1-2 mL normal saline outside the catheter.
- D. Apply suction to aspirate nasopharyngeal secretions.
- E. Above steps may need to be repeated to obtain 1 mL sample in specimen trap.
- F. Remove catheter from patient. With specimen trap still in-line, rinse catheter with remaining saline to clear secretions.
- G. Specimens transported by tube system must be transferred from trap to a leak-proof sterile container (be sure the lid is tightly secured).

Throat swab

A throat swab is a test commonly used to diagnose infections in the throat. These infections can include strep throat, pneumonia, tonsillitis, whooping cough, meningitis, etc.

- A. Ask patient to open his/her mouth. Swab the back of throat near the tonsils thoroughly.
- B. Break the swab near the break point and insert into the tube containing viral transport medium and close the cap tightly.
- C. Label the sample correctly with name of patient, time and date of collection.
- D. Transport the samples immediately to the laboratory for processing.

TRANSPORTATION OF SAMPLE:

To maintain optimum viability, transport the specimen to the laboratory as soon as possible. Best recovery is obtained when specimens are refrigerated at 2-8°C or kept on wet ice following collection and while in transit. If there will be long delay before processing, it is suggested that specimen should be frozen at -70°C.

STORAGE AND SHELF LIFE:

The viral transport kit should be stored at 15-30°C before sample collection and 2-8°C after sample collection. Use before the expiry date.

PRECAUTIONS

1. Isolation of viruses will largely depend on proper specimen collection, timing of sample collection and processing of samples.
2. Do not use the product if, (i) there is change in the color of the medium, (ii) there is evidence of leakage and (iii) there are other signs of deterioration.
3. Specimen collection should be done in the acute phase of illness.
4. Avoid repeated freeze-thaw of collected samples.
5. To maintain infectivity of viruses, it is important that temperature be properly maintained for sample collection to processing.



6. It is recommended to refer to standard procedures and published protocols for sample collection and processing.

QTY.
Quantity

**LOT/
B. NO.**
Lot / Batch Number


Temperature Unit


Manufacturer


Best Before

GMP
Certification of
Good Manufacturing Practices

REF
Catalogue No.

EC REP MediStar GmbH
Buckhorn 10,
49163 Neustadt, Germany
Authorized Representative

CE
European Conformity


Consults Instructions for use :


QR
Code

IVD
For In Vitro Diagnostic Use

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
Revision: 04 March., 2020