

CM 22784 – MOLECULAR TRANSPORT KIT (Nasal and Throat Flocked Swab)

INTENDED USE

For the stabilization, transportation and inactivation of infectious viral agents.

PRODUCT SUMMARY AND EXPLANATION

Molecular Transport Kit is intended for the safe collection, stabilization, transportation and inactivation of infectious viral agents from the collection site to the testing laboratory. This ready to use kit contains a Molecular Transport Medium (Viral Lysis Transport Medium) and a nasopharyngeal nylon flocked swab with breakpoint & one Oropharyngeal viscose throat swab without breakpoint. The peculiar design of the flocked swab ensures optimal elution of the specimen into the transport medium.

Molecular Transport Medium (Viral Lysis Transport Medium) is a self-contained, ready-to-use system designed for stabilization, inactivation and transportation of potentially infectious, unprocessed nasal and throat swab samples suspected of containing infectious viruses. It is designed to kill the viruses whilst preserving the released intact nucleic acids for molecular diagnostics. The composition of the medium has been optimized in such a way that it disturbs/lyse lipid membranes, destroy proteins including enzymes and nucleases which helps in keeping the naked RNA stable and well preserved within the sample.

Molecular Transport Medium (Viral Lysis Transport Medium) makes the sample safe for transportation, shipment and processing at ambient temperature and allows accurate detection of microbial DNA/RNA using molecular method. Unlike traditional transport medium, molecular transport medium do not keep the viruses viable, rather only maintain the integrity of viral genome. This leads to improved test performance with better turn-around time, sensitivity, specificity, precision and reproducibility as compared to traditional tests. Moreover, considering potential infectivity of the suspected samples and risk involved in handling them during collection and transport, sample inactivation is desired for ensuring safety. This kit has been customized for inactivation of potentially infectious biological pathogens ensuring safety during handling, transport and processing. Thereby, assuring safe and risk-free handling of suspected samples.

The Swab provided, 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. The nylon nasopharyngeal swab has a molded breakpoint which allows the swab to be broken in to the tube and viscose swab is a tipped swab on a polypropylene shaft, which can be used for collecting throat samples. It does not have a breakpoint.

KIT INCLUDES

Components	Composition
Molecular Transport Medium (Viral Lysis Transport Medium)*	Proprietary
Single Sterile Nasopharyngeal Nylon Swab with breakpoint	-
Single Sterile Oropharyngeal Viscose Throat Swab without breakpoint	-

*1.5ml medium in 10-15 ml tube

QUALITY CONTROL SPECIFICATIONS

Appearance	:	Colorless
pH (at 25°C)	:	8.0
Sterility Check	:	Passes release criteria

INSTRUCTION FOR USE

1. Open the pouch to remove the nylon flocked swab & Viscose throat swab.
2. Collect throat or nasopharyngeal secretion using the sterile nylon and viscose swab respectively with prescribed method.
3. After collection, insert the swab containing collected sample directly into Molecular Transport Medium (Viral Lysis Transport Medium).
4. Break-off or cut-off excess swab handle at the scored mark.
5. Alternatively upto 0.5 ml of clinical material (nasal wash/ sputum sample or other bodily fluids including blood) can be pipetted directly into a Molecular Transport Medium (Viral Lysis Transport Medium).
6. Place cap back on the tube and close tightly.
7. Label the samples and transport as specified.

STORAGE AND SHELF LIFE:

Store at room temperature, away from bright light. Use before the expiry date. Sample collected can be stored at ambient temperature for 7 days, 2-8°C for 15 days, -20°C for 1 month and -80°C for 1 year.

QTY.
Quantity

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


Temperature Unit


Manufacturer


Best Before

GMP
Certification of
Good Manufacturing Practices

REF
Catalogue No.

EC REP MedNet GmbH
Buckenhof 10,
49113 Hameln, 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.