

PATHKITS

Product Information Sheet

PK Viral Lysis Transport Medium Kit



With 1.5 ml or 3 ml Viral Lysis Transport Medium in a 10 or 15 mL tube and 2 sterile Nylon Flocked swabs with breakpoint recommended for collection and transport of viruses

Product Code: MDS300

Product Description:

PK Viral Lysis Transport medium Kits (VLTM Kits) is a specially formulated medium for collection and transport of viruses. It is designed to lyse as well as maintain optimum conditions for the transport of the viral sample.

PK Viral Lysis Transport Medium (VLTM) is made of Tris-HCl Buffer and contains surfactant and chelating agent, antimicrobial agents (Antibiotic & Anti-fungal) to control microbial contamination, buffers to control the pH.

The sterile Nylon Flocked swabs on a plastic shaft with a breakpoint can be used for collecting nasal and throat samples.

Precautions:

1. Isolation of viruses will largely depend on proper specimen collection, timing of sample collection and processing of samples.
2. Specimen collection should be done in the acute phase of illness.
3. Do not use the product if,
 - There is change in the opacity of the medium.
 - There is evidence of leakage and
 - There are other signs of deterioration.

- To maintain infectivity of viruses, it is important that temperature be properly maintained for sample collection to processing.
- Avoid repeated freeze-thaw of collected samples.
- It is recommended to refer to standard procedures and published protocols for sample collection and processing.

Kit Content:

Description	Qty.	Storage
PK Viral Lysis Transport Medium	1.5 or 3 ml	Room Temperature
Sterile Nylon Swab with breakpoint for Nasal sampling	1	Room Temperature
Sterile Nylon Swab with breakpoint for Oral sampling	1	Room Temperature

Composition: Proprietary

Quality Control:

Appearance

Transparent Clear solution.

pH at 25°C

6.7 ± 0.2

Sterility

No bacterial or fungal growth was observed after 14 days of incubation.

Storage and Shelf Life:

PK Viral Lysis Transport medium should be stored at 15–30°C. Use before expiry date given on the product label.

Shelf life of the product is 15 months.

Packaging:

50/100 pcs per box.

Instruction for use:

- Open the zip lock pack and take out the swab. Get sampling with swab from right body parts.
- Place the swab into the virus specimen tube all the way to the bottom of the tube.
- Cut the plastic shaft to fit swab in the tube.
- Tighten the cap, shake it several times and complete the sampling.

Transport:

After collection, the specimen should be transported to the laboratory within 72 hours with recommended storage temperature of 2–8 degree Celsius. If the delivery and processing exceed 72 hours, specimens should be transported in dry ice and once in laboratory frozen at -70 degree Celsius or colder. The specimens should avoid repeated freezing and thawing.

Accreditations



Product Pictures



Swab Options

Polyester Swabs



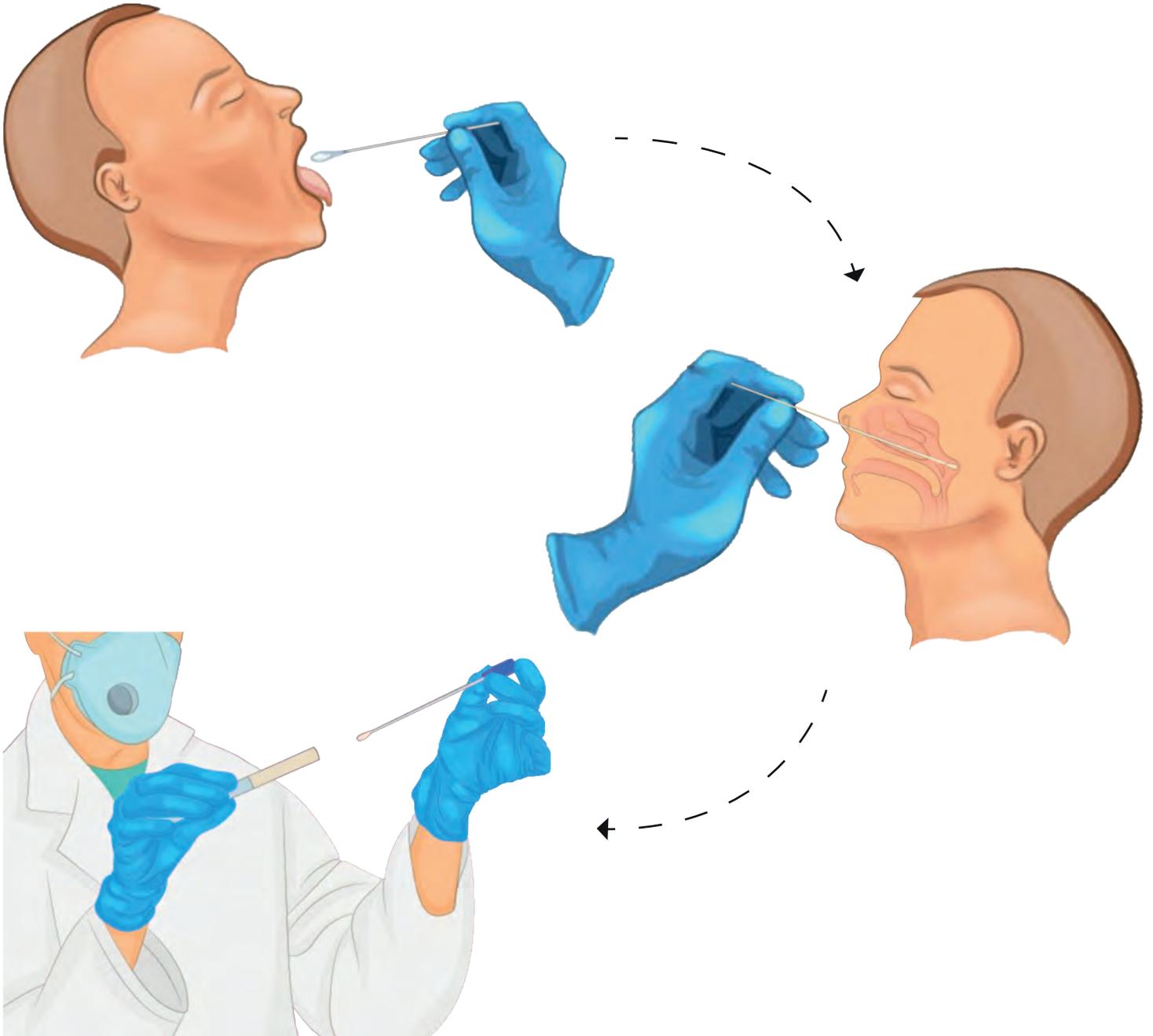
Nylon Flocked Nasal Swabs



Nylon Flocked Oral Swab



Usage



Disclaimer:

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this kit insert. The information contained in this kit insert is based on our research and development work and is to the best of our knowledge true and accurate. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.



20 - ए. डा. आंबेडकर मार्ग, पोस्ट बॉक्स संख्या 11, पुणे - 411 001, भारत.

20-A. Dr. Ambedkar Road, Post Box No. 11, Pune 411 001, India.

Tel. : NIV Camp +91-020-26127301, 26006290, Fax : 26122669, 26126643 / NIV Pashan +91-020-26006390 Fax : No. 25871895 / 25870640

E-mail : director.niv@icmr.gov.in Website : www.niv.co.in

No: Inf/Covid-19/Evaluation/2020-320

1st August 2020

Ms. MetaDesign Solutions Pvt Ltd

Subject: Performance Evaluation Report of PK Viral Lysis Transport Medium Kit (Lot No 07-01/2020) manufactured by MetaDesign Solutions Pvt Ltd (Supplied by Pathkits).

Sir

We have evaluated PK Viral Lysis Transport Medium Kit (Lot No 07-01/2020) manufactured by MetaDesign Solutions Pvt Ltd (Supplied by Pathkits).

Yours sincerely

Prof. Priya Abraham

Director



**PERFORMANCE EVALUATION REPORT FOR VIRAL TRANSPORT MEDIUM
(VTM) AND SWABS**

- Name of the kit PK Viral Lysis Transport Medium Kit
- Name of the manufacturer MetaDesign Solutions Pvt. Ltd.
- Lot number 07-01/2020
- Kit components 1.5 ml media in 15 ml conical tubes with two sterile nylon flocked swabs (Nasopharyngeal and Oropharyngeal)
- Methodology Throat and nasal swabs were collected from ten healthy individuals and swabs were transferred into virus transport medium (VTM) tubes. Another set of ten VTM tubes with swabs were spiked with 100 µl of a strong SARS-CoV-2 positive sample. All tubes were kept at 4°C for 12 hrs. RNA was extracted from all tubes and tested for viral targets (E and ORF1b genes) and human actin gene (internal control) using ICMR-NIV RT-qPCR assay
- Results
 1. Viral target amplification was observed in all VTM tubes spiked with the virus
 2. Amplification of internal control was noted in all tubes containing swabs collected from healthy individuals
 3. Swabbed individuals did not report any discomfort or irritation during or after swabbing
- Conclusions:
 - Percentage concordance among spiked positive samples: 100%
 - Percentage concordance among negative samples: 100%
 - Percentage of samples showing amplification in internal control: 100%
 - Performance: **SATISFACTORY**

Disclaimers

1. ICMR's validation process does not approve/ disapprove the kit design
2. ICMR's validation process does not certify user friendliness of the kit / assay

ICMR-National Institute of Virology

3. Validation of a kit by ICMR is not an assurance that the kit specifications would be included in the tendering process

Note: This report is exclusively for PK Viral Lysis Transport Medium Kit (Lot No 07-01/2020) manufactured by MetaDesign Solutions Pvt. Ltd. (Supplied by Pathkits).

- Packing material of the VTM kit needs to be sturdier. The box was completely collapsed when received.

The company shall not use or publish information or report for advertising or promotional purposes

Evaluation Done on 31-07-2020



Prof. Priya Abraham

Director

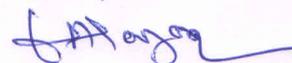
ICMR-NIV

For kit evaluation team

Dr. K. S. Lole



Dr. K. Alagarasu



Dr. V. A. Potdar

