



15.04.2021

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

- Name of the kit PK Viral Transport Media Kit
- Name of the manufacturer Pathkits Healthcare Private Limited
- Batch number TM/001/03/21- 01
- Kit components
 - 3 ml VTM in 10 ml tubes (30 nos)
 - Sterile Oro-pharyngeal & Naso-pharyngeal swabs (30 nos each)
- Methodology
 - Collect throat & nasal swabs from ten healthy individuals in ten tubes as per sample collection SOP.
 - Spike ten VTM tubes with 100 µl of SARS-CoV-2 positive sample of Ct value in the range of 20-25.
 - Store all the tubes at 4°C for 8-12 hrs.
 - Extract RNA from all 20 samples using viral RNA extraction kit routinely used for detection of SARS-CoV-2 samples.
 - Test for SARS CoV-2 target genes by real time PCR along with human RNaseP or any other human housekeeping gene as an internal control (IC) to assess overall efficiency and consistency of extracted RNA.

- Results
 1. Viral target amplification was observed in 10 VTM tubes spiked with the virus.
 2. Amplification of internal control was noted in 20 tubes containing swabs.
- Conclusions:
 - Concordance among spiked positive samples: 100%
 - Concordance among negative samples: 100%
 - 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
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 VTM Kit and Swabs
Lot No. TM/001/03/21- 01
Manufactured by Pathkits Healthcare Private Limited
The company shall not use or publish information or report for advertising or promotional purposes.

Evaluation Done on 15.04.2021

Evaluation Done by Dr. Dhanashree Jagtap

Signature of Director

Dr. Geetanjali Sachdeva
Director
National Institute for Research
In Reproductive Health (ICMR)
J.M. Street, Parel, Mumbai - 400 012.

