

**INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH**

STANDARD PROTOCOL FOR BATCH TESTING OF OF VIRAL TRANSPORT MEDIUM (VTM) AND SWABS

Background: This SOP is for batch testing of VTM and Swabs which have been validated by ICMR approved validation centres and have been procured by ICMR. The kits when supplied by the firm against the purchase order requires to be tested (batch wise) by any of the ICMR validation centres before it is released for distribution to depots and labs

Objectives

To evaluate the performance of viral transport medium (VTM) and swabs for quality assurance

Methodology:

- 1) Collect throat swabs from ten healthy individuals in ten tubes as per sample collection SOP. Swab needs to be collected by a qualified person.
- 2) Spike fifty percent of healthy control VTM tubes (five tubes) with 100 µl of SARS-CoV-2 positive sample of Ct value in the range of 20-25
- 3) Store all the tubes at 4°C for 8-12 hrs
- 4) Extract RNA from all ten samples using viral RNA extraction kit routinely used for detection of SARS-CoV-2 samples.
- 5) 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 using VTM or swabs under evaluation

Results:

- 1) Detection of SARS-CoV-2 in spiked samples
- 2) Detection of IC in all ten tubes

Interpretation of Results:

The kit performance is satisfactory if-

- 1) 100% concordance among spiked positive samples
- 2) 100% concordance among negative samples
- 3) 100% samples showed amplification in internal control

General remarks

Appearance of VTM, pH of VTM, swab quality, quality of tubes and caps should be checked

REPORT FORMAT- Report to be sent only to ICMR Hqrs

NAME OF THE VALIDATION CENTRE

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

- Name of the kit
- Name of the manufacturer
- Batch number
- Kit components
- Methodology

- Results
 1. Viral target amplification was observed in ...VTM tubes spiked with the virus
 2. Amplification of internal control was noted intubes containing swabs collected from healthy individuals

- Conclusions:
 - Percentage concordance among spiked positive samples:
 - Percentage concordance among negative samples:
 - Percentage of samples showing amplification in internal control:.....
 - Performance: Satisfactory or Not 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.....) manufactured by (supplied by)

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

Evaluation Done on

Evaluation Done by

Signature of Director/ Director-Incharge