INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH

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

Objectives

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

Methodology:

1) Collect throat and nasal swabs from 10 healthy individuals in ten tubes as per sample collection SOP.
2) To evaluate performance of swabs, use validated VTM (e.g. HiMedia) tubes and collect throat and nasal swabs from ten healthy individuals
3) Spike ten VTM tubes with 100 µl of SARS-CoV-2 positive sample of Ct value in the range of 20-25
4) Store all the tubes at 4°C for 8-12 hrs.
5) Extract RNA from all 20 samples using viral RNA extraction kit routinely used for detection of SARS-CoV-2 samples in the laboratory
6) 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 performance of VTM or swabs under evaluation

Results:

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

The kit performance is satisfactory if-

1) 100% concordance among spiked 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, preferably should be threaded tubes with properly fitting caps (must be leak proof)

REPORT FORMAT

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 in …..tubes 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 ……