

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

**STANDARD PROTOCOL FOR VALIDATION OF COMMERCIAL RNA
EXTRACTION KIT FOR SARS-COV-2 DETECTION**

Objectives

To evaluate the performance of RNA extraction kit using a panel of SARS-CoV-2 positive and negative nasopharyngeal/ oropharyngeal clinical samples and to assess its practicality in a laboratory having minimal facility for molecular diagnosis

Panel details: Forty (40) SARS-CoV-2 positive samples (with equal representation of samples with high, medium and low Ct values) and Ten (10) SARS-CoV-2 negative samples

Methodology:

- 1) Extraction of viral RNA from forty SARS-CoV-2 positive and ten SARS-CoV-2 negative samples according to the manufacturer's instructions
- 2) Testing of extracted RNA by targeting SARS CoV-2 genes along with human RNaseP or any other human housekeeping gene as an internal control (IC) in real time PCR to assess overall RNA extraction efficiency and consistency

Results:

- 1) Detection of positive samples as positive
- 2) Detection of negative samples as negative
- 3) Detection of IC in all samples in the panel

Interpretation of Results

1. The kit performance is satisfactory if-
 - Atleast 95% concordance among positive samples (concordance in atleast 38 out of 40 for positive samples) and atleast 90% concordance among negative samples (concordance in atleast 9 out of 10 for negative samples)
 - More than 95 % samples showed amplification in internal control

General comments

1. Important requirements to have optimal kit performance such as any specific equipment, specific temperature requirements, intermittent shaking, time etc.
2. Mention practical difficulties experienced during the extraction
3. Any specific tips which you feel may improve the kit performance

REPORT FORMAT

NAME OF THE VALIDATION CENTRE

PERFORMANCE EVALUATION REPORT FOR RNA EXTRACTION KIT

- Name of the kit
- Name of the manufacturer
- Batch number
- Kit components
- Sample Panel
 - Positive samples
 - Negative samples
- Methodology

- Results

Among the positive samples, showed positive result. Among the negative samples, RNA fromsamples gave negative results. Amplification of Internal Control (_____) was seen in RNA extracted fromsamples

- Conclusions:
 - Percentage concordance among positive and 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 RNA Extraction Kit (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