INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH

STANDARD PROTOCOL FOR <u>BATCH TESTING OF COMMERCIAL RNA EXTRACTION KIT</u> FOR SARS-COV-2 DETECTION

Background: This SOP is for batch testing of RNA Extraction kits which are either US-FDA approved or 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 performance of RNA extraction kit for quality assurance using a panel of SARS-CoV-2 positive and negative nasopharyngeal/ oropharyngeal samples

Panel details: Twenty (20) 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 twenty 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
   - There is ≥95% concordance for SARS-CoV-2 among positive samples (concordance in atleast 19 out of 20 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

REPORT FORMAT- Report to be sent only to ICMR Hqrs

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
  o Positive samples
  o Negative samples

- Methodology

- Results

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

- Conclusions:

  o Percentage concordance among positive and negative samples: ……….
  o Percentage of samples showing amplification in internal control:……….
  o 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 ……………………