INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH

STANDARD PROTOCOL FOR BATCH TESTING OF COMMERCIAL RT-PCR BASED SARS-COV-2 DETECTION KIT

Background: This SOP is for batch testing of RT-PCR 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 notified validation centres before it is released for distribution to depots and labs

Objectives:

1. To determine specificity and sensitivity of the kit using a panel of clinical samples screened with that of the **ICMR-NIV RT-qPCR assay**

Sample Panel

1. SARS-CoV-2 positive samples (n =20) (equal representation of samples with low, medium and high Ct values as per the gold standard)
2. SARS-CoV-2 negative samples (n=30)

Methodology:

1) Extraction of viral RNA from twenty SARS-CoV-2 positive and thirty SARS-CoV-2 negative samples using any validated RNA extraction kit
2) Testing of RNA for detection of SARS-CoV-2 target genes and internal control gene as per the protocol provided by the manufacturer

Results:

Interpretation of results as per the cut off threshold cycle (Ct) values recommended by the manufacturer for-

a. Detection of positive samples as positive
b. Detection of negative samples as negative

Calculation of sensitivity and specificity of the kit based on these results

The kit performance is *satisfactory if-

1. The **sensitivity** of the assay is ≥95% for detection of positive samples (i.e. atleast 19 out of 20 positive samples should come positive)
   AND
2. **Specificity** of the assay is ≥96.5% for detection of negative samples (i.e. atleast 29 samples out of 30 negative samples tested should come negative)

REPORT FORMAT- Report to be sent only to ICMR Hqrs

NAME OF THE VALIDATION CENTRE

PERFORMANCE EVALUATION REPORT FOR BATCH TESTING FOR RT-PCR DIAGNOSTIC KIT

- Name of the kit
- Name of the manufacturer
- Batch number
- Kit components
- Sample Panel
  - Positive samples
  - Negative samples (provide details)
- Results

		RT PCR Results		
		Positive	Negative	Total
Name of RT PCR Kit	Positive			
	Negative			
	Total			

	Estimate (%)	95% CI
Sensitivity		
Specificity		

- Conclusions:
  - Sensitivity, specificity
  - Performance: Satisfactory or Not Satisfactory

(Sensitivity and specificity have been assessed in controlled lab setting using kits provided by the manufacturer from the batch mentioned above)

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.

In addition to the above (1,2,3), the following disclaimer/Limitation needs to be included in all validation reports by all ICMR approved validation centres for SYBR green based real-time PCR assay

Interpretation of the SYBR green based test results requires expertise and experience which may not be available in many routine diagnostic laboratories involved in COVID-19 testing.

Note: This report is exclusively for RT-PCR Kit (Lot No……) manufactured by …… (supplied by …….)

Evaluation Done on ……

Evaluation Done by …….

Signature of Director/ Director-Incharge ……