

**ICMR-National Institute for Implementation Research on  
Non-Communicable Diseases (NIIRNCD), Jodhpur  
Performance evaluation report for RT-PCR diagnostic kit**

**Name of the kit** : Microbio-InfectID-SARS-COV-19 (Cat#: MB-1)

**Name of the manufacturer** : Microbio PTY Ltd.

**Lot / batch number** : MB-INF00001

**Date of expiry** : N/A

**Application** : In Vitro Testing kit for detection of novel corona virus infection (COVID-19) by qualitatively detecting E gene, N gene and ORF1ab gene of SARS-CoV-2 virus along with Internal Control(RNase P).

**Kit components** : qPCR Mastermix (R), qPCR Mastermix (D), qPCR Mastermix (IPC), Positive Control (R), Positive Control (D), Positive Control (IPC), Reverse Transcriptase (XLT-RT).

**Sample Panel**

1. SARS CoV-2 Positive samples (n=75)(25 High, 25 Med, 25 Low Ct values as per ICMR-NIV Kit)
2. SARS CoV-2 Negative samples (n=85)

**Results**

		ICMR NIV RT-PCR Kit Results (as Gold Standard)		
		Positive	Negative	Total
<b>Microbio kit</b>	Positive	72	0	72
	Negative	3	85	88
	Total	75	85	160

Parameter	Estimate (%)	95% CI
Sensitivity	96%	88.8% to 99.2%
Specificity	100%	95.7% to 100%

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**Conclusion:**

**Sensitivity for detection of SARS-CoV-2 : 96%**  
**Specificity for detection of SARS-CoV-2 : 100 %**  
**Performance : 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.

**Note:**

- This report is exclusively for RT-PCR Kit (Lot No MB-INF00001) manufactured by Microbio PTY Ltd. (supplied by BIZSOCH CONSULTANTS LLP)
- This report is based on the 'Detection' component of this kit and the 'replicating virus' component is beyond the scope of the current validation protocol.

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

Evaluation Done on ...29/01/2021.....

Evaluation Done by ...Dr Elantamilan D....



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