



State Level Virus Research and Diagnostic Laboratory
Bangalore Medical College & Research Institute
Department of Microbiology
Victoria Hospital Campus,
K.R. Road, Fort, Bengaluru – 560002. India.



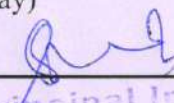
Ph: +91-8026705331; Fax: +91-8026704342; E-mail:vrdblmcric@gmail.com

Validation report of COVID-19 rapid antigen test kits

1. Name of the Validation Centre: State Level VRDL, BMCRI, Bengaluru
2. Name of the kit: ImmunoQuick COVID- 19 Ag Rapid Card Test
3. Country of origin: India
4. Recommended temperature of storage of the kit: 4-30 ° C
5. Details of kit components: Rapid COVID-Ag Test Device (1 pouch with desiccant), Lysis Buffer for COVID-19 Antigen test, Sample extraction tubes for COVID-19 Antigen Test, Package insert Nylon flocked Nasopharyngeal swab – Each box contains materials for 25 tests.
6. Details of the KIT:

Sl.No	Lot NO	Mfg. Date	Expiry Date
01	E 146001	09/2020	08/2022
02	E 146002	09/2020	08/2022
03	E 146003	09/2020	08/2022

7. Details of additional equipment required: NIL
8. Date of receipt of the kit: 23/09/2020;
9. Number of patients recruited: 231
10. Type of Specimen: Nasopharyngeal Swab in Lysis Buffer
11. Gold standard used: NIV Multiplex RT-PCR Kit(Single Tube Assay)


Principal Investigator
State Level VRDL
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12. Details of 2X2 table

Rapid antigen test	RT-PCR test (Gold standard)		Total
	Positive	Negative	
Positive	40	0	40
Negative	35	156	191
Total	75	156	231

13. Sensitivity: 53.33%

14. Specificity: 100%

15. Positive Predictive Value: 100%

16. Negative Predictive Value: 81.68%

17. Comments on kit performance: The sensitivity of the validated ImmunoQuick COVID-Ag Rapid Card Test kit is 53.33%, and is in the range of ICMR recommended sensitivity of 50-84% for rapid antigen detection tests.

18. Comments on quality of kit packaging: Satisfactory

19. Signature of the In-charge with name and date :

[Signature]
10/11/20
[Dr. Shantala G.R.]
Principal Investigator
State Level VRDL
BMCRI
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