



Validation Report of Rapid Antigen Test Kits

1. Name of the Validation Centre - Advance Research Lab, Dept. of Microbiology SMS Medical College, Jaipur.
2. Name of the kit -CoviRAT COVID-19 Rapid Antigen test kit
3. Manufactured by Zephyr Biomedicals (Tulip Diagnostics) Goa
4. Country of origin - India
5. Batch Tested: ZRD/20/K-64, ZRD/20/K-65, ZRD/20/K-66
6. Recommended temperature of storage of the kit: 4° to 30°C.
7. Details of kit components: -Test Device, Disposable container, Extraction buffer tubes, Nozzle for extraction tubes, extraction buffer
8. Details of additional equipment required - Nil
9. Date of receipt of the kit: - 16/01/2021
10. Number of patients recruited - 218, sample type: Nasopharyngeal Swab
11. Gold standard used - RT-PCR (Kits received from NIV, Pune)
12. Details of 2X2 table

**A:- Overall Result:-**

CoviRAT COVID-19 Ag test	RT-PCR test (Gold standard)		Total
	Positive	Negative	
Positive	95	04	99
Negative	13	106	119
Total	108	110	218

13. Sensitivity -87.96%
14. Specificity - 96.36%
15. Positive Predictive Value - 95.9%
16. Negative Predictive Value -89.83%

Continued page 2....

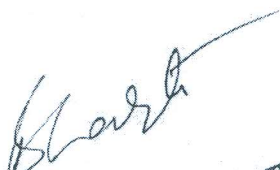
जीवाणु विज्ञान विभाग  
स.मा.सि.सि. जयपुर  
जीवाणु विभाग


डॉ. सिल्विया थ्यास,  
वरिष्ठ आचार्य एवं विभागाध्यक्ष  
सूक्ष्म जीवाणु विज्ञान विभाग  
एस.एम.एस. मेडिकल कॉलेज, जयपुर

**B:-Result of RTPCR positives with Ct < 30**

CoviRAT COVID-19 Ag test	RT-PCR test (Gold standard)		Total
	Positive	Negative	
Positive	83	04	87
Negative	04	106	110
Total	87	110	197

16. Sensitivity –95.4 %
17. Specificity – 96.36 %
18. Positive Predictive Value – 95.4 %
19. Negative Predictive Value –96.36 %
20. Comments on kit performance - Performance is satisfactory
21. Comments on quality of kit packaging - Satisfactory

  
Dr. Bharti Malhotra  
Sr. Prof. & Nodal officer  
ADRL, Dept of Microbiology  
जीवाणु विज्ञान विभाग  
स.ना.सि.चि.  
जयपुर

  
Dr. Nitya Vyas  
Sr. Professor & Head  
Dept of Microbiology  
वरिष्ठ आचार्य  
सूक्ष्म जीवाणु विज्ञान विभाग  
एस.एम.एस. मेडिकल, कॉलेज, जयपुर