

Validation report of Rapid antigen test kits

- Name of the Validation Centre:** VRDL, B. J. Medical College, Ahmedabad
- Name of the kit:** YBIO RAPITESTCOVID -19 Antigen Test Kit (Mfg by Yuvraj Biobiz Incubator India Pvt. Ltd.), Lot no: L20CV01, L20CV02, L20CV03
- Country of origin:** India
- Recommended temperature of storage of the kit:** 2-30°C
- Details of kit components:**
 1. Test Cassette sealed pouch with dropper and silica gel
 2. Buffer bottle – 5ml
 3. Extraction buffer tube
 4. Instruction manual
 5. Swab
- Details of additional equipment required:** Nil
- Date of receipt of the kit:** 11/01/2021
- Number of patients recruited:** 202
- Type of the sample tested:** Nasopharyngeal swab
- Gold standard used:** rRT PCR (NIV Single Tube assay)
- A. Details of 2X2 table (Overall sensitivity and specificity with all RTPCR positives)**

Rapid antigen test	RT-PCR test (Gold standard)		Total
	Positive	Negative	
Positive	58 ** (a)	0 (b)	58
Negative	33 (c)	111 (d)	144
Total	91	111	202*

*Out of 202 samples tested by Rapid Ag detection test; no band found in control region (invalid result) in 9 samples but after repeat of tests on new device, control bands appear with eight negative and one positive result.

** Out of 58 Positive by Rapid Ag detection test, 8 samples showed very faint band.

- B. Details of 2X2 table (Overall sensitivity and specificity among RTPCR positives with Ct value ≤ 30)**

Rapid antigen test	RT-PCR test (Gold standard)		Total
	Positive	Negative	
Positive	57 (a)	0 (b)	57
Negative	29 (c)	111(d)	140
Total	86	111	197

- Sensitivity** $[a/(a+c)] \times 100\%$:
A) 63.74 %
B) 66.28%

13. Specificity $[d/(b+d)] \times 100\%$: A) 100.00%
B) 100.00%
14. Positive Predictive Value $[a/(a+b)] \times 100\%$: A) 100.00%
B) 100.00%
15. Negative Predictive Value $[d/(c+d)] \times 100\%$: A) 77.08 %
B) 79.29%
16. Comments on kit performance: Easy to perform
17. Comments on quality of kit packaging: Good
18. Signature of the In-charge with name and date:

Dmk
Dr. Dipa.

Microbiology Department
B. J. Medical College,
Ahmedabad-16.

Disha
Dr. Disha

Microbiology Department
B. J. Medical College,
Ahmedabad-16.

I
Dr. Paraney K. Shah

PROFESSOR & HEAD
DEPT. OF MICROBIOLOGY
B. J. MEDICAL COLLEGE,
AHMEDABAD,