भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

**Date: 22/05/2021**

# Invitation for Expression of Interest for Validation of Rapid Antigen Detection Assays for COVID-19:

ICMR invites applications for validation of rapid antigen detection tests for SARS-CoV-2 from all manufacturers who have developed rapid antigen test (RAT) kits, in the following categories:

1. **First time validation:**

**Requirements:**

i. A minimum of 300 rapid antigen tests from three different batches (100 from each batch) would be required for validation.
ii. A minimum of 3-4 instruments (if the test results are to be interpreted using a specialized equipment such as fluorescence immunoassay readers etc.) will be required.
iii. Kit insert / detailed IFU of test kit to be validated.
iv. In-house performance report of the test kit on a minimum of 50 clinical samples (30 positive & 20 negative) along with the Ct values (<20; 20-30; >30) of their corresponding RT-PCR positives using a nasopharyngeal (NP) or NP + oropharyngeal (OP) swabs.
v. Manufacturers should be able to provide training to technical staff involved in validation of the test kit.
vi. If the kit is approved after validation, the manufacturer should be committed to make adequate supplies of the product (as per National requirement) available to India with immediate effect.
vii. Import / test manufacturing license from CDSCO/DCGI should be provided.

*Kits from indigenous manufacturers with good production capacity will be prioritized for validation, after fulfillment of requisite formalities.*

2. **Revalidation:**

**Requirements:**

a. All the above requirements (i to vii) need to be fulfilled.
b. Detailed changes undertaken by the manufacturer after the kit underperformed in the first validation attempt. These requirements need to be furnished as per the table given below:

| Review Parameters | Earlier Version | Revised Improvised version |
|---|---|---|
| Indigenous and Imported components of the kit | | |
| Source of Antibody (Change in Supplier, Y/N) | | |
| Type of Antibody (mAb /pAbs) | | |
| Concentration of Antibody | | |
| Thickness of Nitrocellulose Membrane | | |
| Runtime | | |
| Other Differences in composition | | |
| Manufacturing capacity | | |

- **Only one revalidation attempt would be given to indigenous manufacturers.**
- **No revalidation will be undertaken for kits manufactured outside India.**

**3. <u>Validation with alternate sample type (nasal swab/ oral swab/ saliva) for already ICMR validated and approved kits (for conversion to self test / home test category)</u>:**

**Requirements:**

i. 100 test strips of the ICMR validated and approved RAT lateral flow assay and 100 test strips of Self test/ home test (to be validated).
ii. In-house performance report of the test kit on a minimum of 50 clinical samples (30 positive & 20 negative) along with the Ct values (<20; 20-30; >30) of their corresponding RT-PCR positives. Please note that the in-house validation should be conducted with the alternate sample type (nasal swab/ oral swab/ saliva) and compared with RTPCR conducted using a nasopharyngeal (NP) or NP + oropharyngeal (OP) swabs.
iii. Kit insert / detailed IFU of test kits to be validated.
iv. DCGI manufacturing license of the already ICMR approved RAT kit.
v. Certificate of registration on the GeM portal of the already ICMR approved RAT kit.

**List of Validation Centres:**

1. All India Institute of Medical Sciences, Delhi
2. SMS Medical College, Jaipur
3. King George Medical University, Lucknow
4. Kasturba Hospital for Infectious Diseases, Mumbai
5. Post Graduate Institute of Medical Education & Research, Chandigarh
6. Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
7. National Institute of Virology, Kerala Unit, Alappuzha
8. Bangalore Medical College & Research Institute, Bengaluru
9. National Institute of Mental Health and Neurosciences, Bengaluru
10. All India Institute of Medical Sciences, Bhopal
11. All India Institute of Medical Sciences, Raipur
12. All India Institute of Medical Sciences, Jodhpur
13. B J Medical College, Ahmedabad
14. Kings Institute for Preventive Medicine & Research, Chennai
15. Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram
16. Maulana Azad Medical College, Delhi
17. Government Medical College, Aurangabad
18. Sri Venkateshwara Institute of Medical Sciences, Tirupati
19. Mysore Medical College and Research Institute, Mysore
20. SN Medical College, Jodhpur
21. King Edward Memorial Hospital and Seth GS Medical College, Mumbai
22. All India Institute of Medical Sciences, Nagpur
23. Government Institute of Medical Sciences, Gr. Noida

**Documents to be submitted with the request:**

All interested manufacturers fulfilling the above essential criteria are requested to send their applications to the following email id:

drneetu.vijay@icmr.gov.in
guptanivedita.hq@icmr.gov.in

**Subject-line of the email should read as: REQUEST FOR VALIDATION OF COVID-19 RAPID ANTIGEN TEST**.