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: 02/12/2020

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

Context:

There is an upsurge in cases of COVID-19 due to increased transmission of SARS-CoV-2 virus. In view of this, it is important to scale up testing capacity to the maximum possible levels.

The gold standard RT-PCR diagnostic test for COVID-19 has limitations in terms of widespread availability and long turnaround time . In view of this, there is urgent requirement of reliable and convenient rapid point of care antigen detection assays with high sensitivity and specificity. Though these antigen detection RDTs (Ag-RDTs) are substantially less sensitive than RT-PCR, they offer the possibility of rapid, inexpensive and early detection of the most infectious COVID-19 cases in appropriate settings. Such assays could be used as potential diagnostic tests in all possible public and private healthcare settings and made available for mass testing.

ICMR invites applications for validation of rapid antigen detection tests for COVID-19 from all manufacturers who have developed such test.

ICMR has identified the following sites for validation of the rapid point-of-care antigen detection tests for COVID-19:

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

Essential criteria for validation:

1. A minimum of 300 rapid antigen tests from three different batches (100 from each batch) would be required for each validation.
2. 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.
3. Ability to provide training to technical staff involved in validation of the test.
4. If the kit is approved after validation, the manufacturers should be committed to make adequate supplies of the product available to India with immediate effect.
5. Import / test license from CDSCO/DCGI wherever applicable.

Documents to be submitted with the request:

1. Kit Insert / Detailed IFU of test kits to be validated.
2. An **inhouse performance report** of the test kit on a minimum 30 clinical specimens (20 positives & 10 negatives) along with the Ct values (<20; 20-30; >30) of their corresponding RT-PCR positives.

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

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

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