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: 25/06/2020

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

Context:

As India is lifting lockdowns in various parts of the country in a phased manner, it is expected to see 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 interms of widespread availability. In view of this, there is urgent requirement of reliable and convenient rapid point of care antigen detection assays with high sensitivity and specificity. Such assays could be used as potential diagnostic tests in all possible public and private healthcare settings and made available for mass testing.

So far, ICMR has validated and approved only one rapid antigen detection assay from SD Biosensor.

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

Essential criteria for validation:

1. A minimum of 300 rapid antigen tests 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.

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

guptanivedita.hq@icmr.gov.in

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