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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

Date: 15/10/2020

Advisory for use of Cartridge Based Nucleic Acid Amplification Test (CBNAAT)

1. Cartridge Based Nucleic Acid Amplification Test (CBNAAT) platforms like TrueNat and Cepheid Xpert Xpress SARS CoV-2, that employ real time RT PCR technology, are in use for COVID-19 testing in India.
2. TrueNat system has been validated by ICMR and Cepheid Xpert Xpress SARS CoV-2 has been approved by US FDA for use under an emergency use authorization (EUA) only <https://www.fda.gov/media/136314/download>.
3. US FDA has provided EUA to some other CBNAAT based COVID-19 testing platforms which are now available for sale in India. Such manufacturers may approach the DCGI directly for permission.
4. ICMR recommends that any testing with the CBNAAT platforms for SARS CoV-2 is carried under Biosafety 2 level (BSL-2) conditions and with appropriate biosafety precautions.
5. Any laboratory which is already functional for SARS CoV2 testing by real-time PCR with the appropriate BSL-2 setup may initiate testing using CBNAAT platforms for SARS CoV-2 without any further approval from ICMR. The results of the testing need to be entered on the ICMR COVID-19 portal.
6. Specimen collection and transfer of sample for CBNAAT must be performed using appropriate PPE and following all applicable biosafety requirements.
7. Any new Government laboratory seeking to initiate CBNAAT must satisfy the following minimum requirements:
 - a. **Availability of a BSL-2 level laboratory facility including a molecular biology setup for virological diagnosis and a functioning and calibrated Biosafety cabinet type 2A/2B in the laboratory.**
 - b. Staff Requirements:
 - i. Availability of following minimum staff: trained microbiologist for handling Molecular Virology work.
 - ii. Technicians – At least 2-3 with experience of work on respiratory pathogens.
 - iii. Multi-Task Staff – 1 or more for washing / cleaning
 - c. Desired expertise of the staff:
 - i. Good understanding of laboratory biosafety and biosecurity, trained for handling respiratory samples for viral diagnosis



- ii. Experience of work in virology and handling clinical specimens, especially respiratory samples.

d. A robust Institutional policy on biomedical waste management of human origin.

e. Well defined arrangement for segregation and discarding of biomedical waste.

8. In addition to the above, private laboratories which intend to initiate testing using CBNAAT should have NABL accreditation for molecular detection of RNA viruses either by Real Time PCR or by specific CBNAAT platform.
9. ICMR guidelines and testing strategy for testing may be strictly followed.
10. Since the guidance evolves periodically, the latest revised version should be followed. Testing laboratories to ensure immediate/ real-time reporting to State officials of IDSP (Integrated Disease Surveillance Program of Govt. of India) for timely initiation of contact tracing. Additionally, as mandated by PMO, a report should also be uploaded on the online portal of ICMR. Each laboratory initiating COVID-19 testing should essentially register on the ICMR portal and get a username and password. Data entry should be ensured on a daily real-time basis.
11. All applications may be submitted by email at: **salajrana05@icmr.gov.in**