

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Date: 09/05/2020

Advisory for use of Cartridge Based Nucleic Acid Amplification Test (CBNAAT) using Cepheid Xpert Xpress SARS-CoV2

1. Cepheid Xpert Xpress SARS-CoV2 is a FDA approved Cartridge Based Nucleic Acid Amplification Test (CBNAAT) for use under an emergency use authorization (EUA) only
<https://www.fda.gov/media/136314/download>.
2. Specimen collection and transfer of sample for CBNAAT must be performed using appropriate PPE and following all applicable biosafety requirements.
3. ICMR recommends that any testing with the Cepheid Xpert Xpress SARS CoV-2 is carried under Biosafety 2 level (BSL-2) conditions and with appropriate biosafety precautions.
4. Any laboratory which is already functional for SARS CoV2 testing by real-time PCR with the appropriate BSL-2 setup may initiate testing using Cepheid Xpert Xpress SARS- CoV2 without any further approval from ICMR. The results of the testing need to be entered on the ICMR COVID-19 portal.
5. 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.**
6. 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 CBNAAT.
7. ICMR guidelines and testing strategy for testing may be strictly followed.
8. 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.
9. All applications may be submitted by email at: arvind.nccs@gmail.com