

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Criteria for initiation of additional COVID-19 testing laboratories

Currently, the Indian Council of Medical Research (ICMR) has approved the COVID-19 testing in more than 200 laboratories across the country. Based on the new requests from several districts of India for initiation of COVID-19 testing, ICMR has formulated the following guidelines for establishment of a new testing laboratory for COVID-19 testing in any district.

In areas with no operational COVID-19 testing facility, a new facility will be considered subject to fulfillment of the following criteria (applicable from 5th April, 2020):

- i) The number of suspected cases in that particular district should be more than 100 per day.
- ii) The nearest testing laboratory for COVID-19 is more than:
 - a. Plain areas- 250 kms (4-5 hrs @ 60 Km/hr)
 - b. Hilly areas- 150 kms (5 hrs @ 30Km/hr)
- iii) In case there are testing laboratories within the above mentioned distance, each of the existing testing laboratories should be testing at least 100 samples per day.
- iv) If the nearest testing laboratory is within the above mentioned distance, and not testing 100 samples per day, and does not agree to test the samples from the affected district, then the existing laboratory will be closed down, and permission will be given to the new laboratory.
- v) The district should have a government laboratory with the following:
 - Availability of BSL-2 level laboratory including a molecular biology setup for virological diagnosis.
 - Availability of a functioning and calibrated Biosafety cabinet type 2A/2B in the laboratory.
 - Availability of cold centrifuge/microfuge for RNA extraction
 - Availability of a functioning and calibrated real-time PCR machine.
 - Availability of staff with good understanding of laboratory biosafety and biosecurity, trained for handling respiratory samples for viral diagnosis, RNA extraction and realtime PCR.
 - Available staff with experience of work in virology and handling clinical specimens, especially respiratory samples.
 - A robust Institutional policy on biomedical waste management of human origin.
 - Well defined arrangement for segregation and discarding of biomedical waste.

(Proofs of the above mentioned requirements need to be submitted to ICMR while applying for a new testing laboratory, which will include documents and photographs of the laboratory)

- vi) If the district has no government laboratory, but has a private laboratory which can apply for COVID-19 testing, the laboratory should have NABL accreditation, and the scope of accreditation must include real-time PCR for respiratory viruses.

(All the required documentations which needs to be provided by the private laboratory to ICMR is available in the official website of ICMR)