Sub: Regarding expedited approval of TrueNat / CBNAAT for COVID-19 testing in private labs /hospitals

Dear Sir/Madam,

This is in continuation to the earlier letter dated 1st July 2020, requesting you all to ramp up testing for COVID-19 in your state.

1. So far, ICMR has included a mandatory criterion for obtaining NABL accreditation for all COVID-19 testing private laboratories including those with TrueNat/CBNAAT platform. This is primarily to ensure high quality testing and ensure correct interpretation of test results. Many of the labs are doing this test for the first time. In view of this, it is prudent to comply with NABL norms and obtain accreditation of private labs. This will also help in improving the overall quality of private labs in your state.

2. I also wish to emphasize that in the backdrop of the COVID crisis, NABL has established expedited approval mechanisms with fast-track approvals being granted within 7 days. However, the need to augment testing for COVID-19 in the current situation is well understood. ICMR is committed to support all states in ramping up testing. In view of this, all private laboratories in your state who intend to initiate TrueNat/CBNAAT based testing for COVID-19 should be encouraged to immediately apply for NABL accreditation. All the labs who have applied can reach out to ICMR (at aggarwal.n@icmr.gov.in) with a copy of their NABL application, ICMR will provide expedited approval for TrueNat/CBNAAT subject to NABL approval, which can be submitted within a maximum time span of four weeks from the date of approval.

3. I request you direct the concerned private labs / hospitals in your state who intend to initiate COVID testing using TrueNat/CBNAAT, to adopt the above mechanism for obtaining approval for COVID testing from ICMR. This will further enable you to ramp up testing in your state with immediate effect.

With regards,

Yours sincerely,

(Dr. G. S. Toteja)

All Chief Secretaries (States)/Addl.Chief Secretaries/Secretaries/Commissioners/Principal Secretaries (Health & Family Welfare)

CC:

1. Ms. Preeti Sudan, Secretary, Health & F.W., Nirman Bhawan, New Delhi.
2. Shri Rajesh Bhushan, OSD, Ministry of Health & F.W., Nirman Bhawan, New Delhi.