



विकास शील
संयुक्त सचिव
VIKAS SHEEL
Joint Secretary



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D.O. letter no. 05/2020/COVID-19-ERHSPP

Dated: 14th April 2020

Dear Sir/Madam,

As you are aware, Central TB Division, MoHFW, GOI has placed purchase orders for Truenat COVID-19 chips (*Truenat beta COV*) and CBNAAT COVID-19 cartridges (*Xpert Xpress SARS-CoV-2*) to help ramping up the COVID-19 testing capacity across the country, using CBNAAT as well as Truenat platforms available under National Tuberculosis Elimination Programme.

CBNAAT COVID-19 cartridges (*Xpert Xpress SARS-CoV-2*)

This is to inform that as per the guidance issued by ICMR since *Xpert Xpress SARS-CoV-2* test is US FDA (EUA) approved, it does not require further approval from ICMR. Sample processing for COVID-19 testing requires Biosafety Level 2 (BSL 2) or higher facility. Currently, under NTEP there are about 135 GeneXpert machines collocated with BSL 2 facilities. These sites can be used for COVID-19 testing. A list of such sites is enclosed at Annexure 1. The tranche wise consignee list and quantity of cartridges (*Xpert Xpress SARS-CoV-2*) ordered by CTD is enclosed at Annexure 2. Technical specifications and kit content of *Xpert Xpress SARS-CoV-2* is enclosed at Annexure 3

Truenat COVID-19 Chips (*Truenat beta COV*)

1. *Truenat beta COV* test on *Truelab* workstation has been validated and recommended by ICMR as a screening test. Guidance on the use of *Truenat beta COV* provided by ICMR is available on ICMR website <https://icmr.nic.in/content/covid-19> (copy enclosed at Annexure 4). Technical specifications and kit content of *Truenat beta COV* is enclosed at Annexure 5.
2. As indicated in the guidance document provided by ICMR, States may appoint a core team of experts for assessing facilities with the *Truelab* workstations for feasibility of initiating the COVID-19 testing. State-wise numbers of existing 367 Truenat machines and tranche wise numbers of additional 500 Truenat machines is enclosed at Annexure 6. The State wise distribution of the 500 additional Truenat machines has been worked out in consultation with ICMR.
3. Tranche wise quantity of chips (*Truenat beta COV*) for existing 367 and additional 500 Truenat machines is enclosed at Annexure 7.
4. The State Government is requested to provide the necessary logistics support for transportation of machines and chips up to the testing sites, especially during the lockdown period.

5. It may also be noted that though the new Truenat machines are being procured based on the needs identified for TB testing in the States/UTs, in view of the COVID-19 emergency, the States have full flexibility in deciding the deployment of the new machines as per testing needs for COVID-19. The Truenat machines can subsequently be redeployed according to the plans prepared for TB testing.

Supply of CBNAAT cartridges and Truenat Chips

The supply of CBNAAT cartridges is likely to start from 18th April 2020 and Truenat chips for existing machines is likely to start from 25th April 2020. Accordingly, it is requested that the CBNAAT and Truenat sites identified for COVID-19 testing may be prepared with the laboratory staff of these sites suitably trained.

Training of Laboratory staff

Virtual training schedule of lab staff on Zoom platform for conducting the COVID-19 Testing on CBNAAT machine has been communicated to the States (copy enclosed at Annexure 8). Training schedule for COVID-19 Testing on Truenat machine will also be shared shortly.

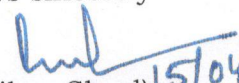
Mandatory Registration in ICMR Portal

1. Registration of all the CBNAAT\Truenat testing sites may be ensured on ICMR Portal before the Truenat chips and CBNAAT cartridges supplies start. States may contact ICMR focal points for registration and uploading the results in the ICMR portal. Each laboratory initiating COVID-19 testing must register on the ICMR portal and get a username and password. Data entry should be ensured daily on a real-time basis.
2. As the details of sample collection centers sending the samples for RTPCR testing are being collected by you to enable the App of Samples Reference Form (SRF), I request you to also map the collection Centres to these CBNAAT / Truenat testing Centres so as to capture the results in ICMR portal.
3. Contact point for registration and technical issues at ICMR is Dr. Harpreet Singh (hsingh@bmi.icmr.org.in) and Dr. Ira Praharaj (praharaj.ira@icmr.gov.in). For logistics related issues, you may contact Dr. Nishant Kumar (kumarn@rntcp.org) at CTD.

warm regards and best wishes

Encl: As above

Yours sincerely



(Vikas Sheel) 15/04/20

To,

Additional Chief Secretary/Pr. Secretary/Secretary – Health, All States/UTs

Copy to:

1. Secretary DHR & DG (ICMR)
2. Mission Director, National Health Mission – All States/UTs
3. Chairman & Managing Director – HLL Lifecare Ltd.
4. DG&CEO – Central Medical Services Society
5. Dr Harpreet Singh, ICMR
6. Dr Ira Praharaj, ICMR
7. PPS to Secretary, HFW
8. PPS to SS(SK)/SS(AS)/AS&FA/AS&MD
9. All JSs - DoHFW


15.04.2020