



GOVERNMENT OF KARNATAKA

No: HFW 89 CGM 2020

Karnataka Government Secretariat,
Vikasa Soudha,
Bengaluru, Date: 8th May 2020.

CIRCULAR

Sub: External Quality Assurance plan for COVID 19 Testing Laboratories of Karnataka

Karnataka State started testing for COVID 19 in February 2020. At present there are a total of 33 labs (22 Government and 11 Private) COVID testing labs in the state. In order to ensure quality in COVID testing the State proposes to implement a Quality Assurance (QA) plan. The broad outline of the QA plan is presented below. In the initial phase QA will be restricted to confirmation of test results of all laboratories doing CoVid 19 testing through a Reverse Flow mechanism detailed below. At a later date, the QA will include distribution of Proficiency Test (PT) panels which shall comprise of five coded clinical samples (1 to 2 positives and the remaining negatives) to all participating laboratories.

1. Who will participate in the QA program?

All the Government and Private CoVid 19 testing laboratories in the State shall participate in the QA Program.

2. How will QA be organized?

BMCRI, NIV (Bangalore Unit) and NIMHANS will be the three referral labs verifying test results of participating labs. All participating labs shall be linked to one of these QA centres. The State shall prepare a detailed list of participating labs and allocate them to one of these three referral labs.

3. What is the frequency of the QA program?

The frequency to begin with shall be once every month on a fixed date. Eg. First Monday of every month. On the fixed date all participating labs shall send 500ul of VTM (original samples) as per the details provided below.

4. How many samples should be sent by the participating labs every month?

All participating labs shall send the following categories of samples :

(a) Positive Samples :All participating shall choose four representative positive samples, ideally one from every week during the preceding month. If they have less than four positive samples send all of them to the designated referral lab.

(b) Negative Samples:All participating shall choose one Negative sample from every alternate testing day (maximum of 15 per month) and send these to the designated referral lab.

- (c) Positive and negative samples shall be sent in the cold chain to the respective referral lab so as to reach within 24 hours.
- (d) All samples shall be accompanied by the form enclosed with all details as requested in the form appended as **Annexure 1**.
5. The referral labs at BMCRI, NIV and NIMHANS shall provide QA results in a tabular form of concordance/discordance to the participating labs within 5 working days. If there is any discordance with respect to a sample that is reported negative at the participating lab but positive by the referral lab all efforts must be made to trace the patient and his/her contacts by the surveillance team and the samples will also be sent for umpire testing to a different referral lab. In the event a positive sample from the participating lab yields a negative result at the referral laboratory, the sample may be sent for umpire testing to a different referral lab. The result at the second referral lab after umpire testing shall be considered as the final result.


(JAWAID AKHTAR)

Additional Chief Secretary to Government
Health and Family Welfare Department

To:

- 1) All Private Laboratories testing COVID.
- 2) Commissioner, Health & Family Welfare Services, Bengaluru.
- 3) Mission Director, National Health Mission, Bengaluru.
- 4) All Deputy Commissioners.
- 5) All Director cum Dean of Medical Colleges.
- 6) Director of Health & Family Welfare, Bengaluru
- 7) Director of Medical Education, Bengaluru
- 8) All District Health Officers / All Dist. Surgeons.

Annexure 1

Mandatory Details to be provided by participating labs to the referral lab.

1. Name of the Participating Lab :
2. Name of Laboratory-In-Charge:
3. E mail address of participating lab:
4. Date and time of despatch of sample to Referral lab:

Sl No.	Sample ID	Name of RT PCR kit used	Date tested	Ct Values of target genes						CoVid 19 Result (Pos/Neg)
				E	ORF1	RdRp	N	S	Others	
1										
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Date :

(Signature)