



Directorate of Health and Family Welfare Services

No. NHM/28/MDNHM/2020-2021

Date: 19.10.2020

Guidelines for Inter- Laboratory Quality Control (ILQC) for Molecular based testing Laboratories undertaking RT-PCR testing & State Guidelines for CBNAAT & TrueNAT testing for Covid-19 testing in Karnataka.

Back ground:

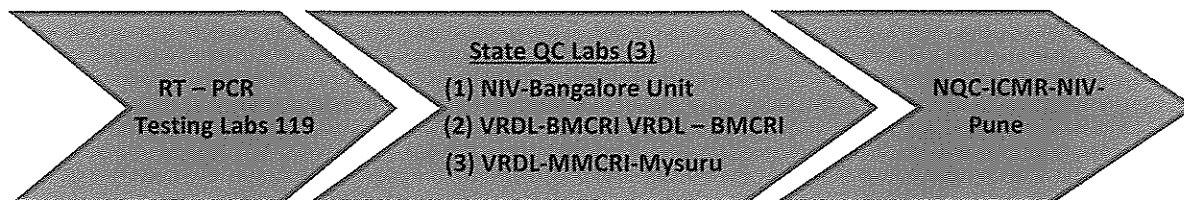
SARS-COV2 sample testing services commenced in Karnataka on Feb 2nd 2020 in two labs: National Institute of Virology (NIV)- Bangalore Unit and VRDL- Bangalore Medical College & Research Institute- (BMCRI) who tested about five samples.

Due to the high commitment and sincere efforts made by the Government of Karnataka, there has been an exponential rise in the number of RT-PCR labs established in the State with a total of 119 RT-PCR labs : Govt -43 and Private -76 (as on 07-10-2020)

During September 2020, ICMR has issued the Inter-Laboratory Quality Control (ILQC) Guidelines for adoption across all RT-PCR labs in the country. This is a 3 tiered structure. Tier-1 -National Quality Control lab (NIV-Pune), Tier-2:33 State Quality Control (SQC) labs identified by ICMR across the country and Tier-3 the State RT-PCR testing laboratories (119- as on 06-10-2020)

In Karnataka, three State Quality Control (SQC) Labs have been identified:

- 1) NIV-Bangalore Unit : State Level Virus Research & Diagnostic Laboratory, Inside Rajiv Gandhi Institute of Chest Diseases (RGICD) Premises, Dharmavaram College Post Bengaluru-560 029 Ph : 080 26654084 /26654074 ; e-mail: ashokmniv@gmail.com
- 2) VRDL-BMCRI : State level Virus Research & Diagnostic Laboratory, Department of Microbiology, K.R. Road, Fort, Bengaluru-560 002. Ph. 080 26705345; e-mail : vrdlbmcri@gmail.com
- 3) VRDL-MMCRI, Department of Microbiology, K R Hospital campus, Mysuru, Irwin Road, Mysuru-570001. e-mail : vrdlmmcricri@gmail.com, Mob: 9900571039



(Note: 119 labs as on 07.10.2020 has been put up here the list and roster would be updated on a monthly basis and shared with the testing labs. ICMR approved new labs will be added on to the QC roster by the end of every month and would be participating after 2 months in ILQC).

Operational mechanism:

- A) To facilitate the whole process, ICMR has launched an online portal for ILQC activity - URL for this portal is <https://covidqcqa.icmr.org.in>. Laboratories can login with their username password which is already being used for patient entry. (Video with demo of same shared in mail)
- B) Samples need to be sent by the testing laboratories to the assigned SQC by the 10th of the month as per the roster which has been annexed: (Annexures 1-3). Quarterly samples need to be sent to the SQC by all the testing laboratories mandatorily.
(For e.g. if a testing lab has sent samples for QC in October 2020, next they would be sending samples only in January 2021).

Details of the samples to be sent for QC are as follows:

- i) Five positive clinical samples (both Nasopharyngeal (NS) & Throat Swab (TS) randomly selected over one week.
- ii) Five negative clinical samples (both Nasopharyngeal (NS) & Throat swab (TS) samples randomly collected over one week.
- iii) Positive and negative samples are to be sent by the testing labs and after dispatching, the testing lab has to enter details of samples dispatched into the online portal as per the video attached with this email.
- iv) Testing labs should ensure that the samples for QC reach the assigned lab by the 10th of the month based on the roster.
- v) Once SQC lab receives the samples from the testing lab, they will enter the date of receipt of samples from the testing lab. The SQC will run the samples and results will be fed into the portal.
- vi) Results (as percent concordance) will be sent automatically to the concerned laboratory via portal.
- vii) Samples from testing laboratories located to local SQCS Bengaluru Urban, Rural District and Mysuru District will be sent directly to the assigned labs on their own. All other Government and Private testing laboratories from other districts will liaise with the respective District Surveillance Officer (DSO) and ensure that samples reach the assigned SQC by the 10th of the month.

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Please note: This month's samples for QC will be acceptable up to 31st October 2020.

- viii) NO RESULTS WILL BE SENT FROM SQC LABS TO TESTING LABS.
- ix) All ICMR approved RT-PCR labs who have been approved by ICMR also for CBNAAT and /or for TrueNAT testing will simultaneously send samples for RT-PCR, CBNAAT (SQC: VRDL-BMCRI) or TrueNAT (SQC: VRDL-MMCRI) to the identified SQC indicated in the roster.

Storage of samples for QC:

All testing labs will ensure proper storage of samples at -80C (or at least at -20C)

Labelling, Packing & Shipment of samples to assigned SQC:

All samples should have a label with the name of the testing lab and sample ID. It would be the responsibility of the individual Testing laboratory to ensure that the samples sent are in screw-capped vials, packed in three layers of packing material. Would also ensure that there are no spillages/leakages of infectious materials during transportation /shipment and cold-chain is maintained from the time of dispatch until the receipt by the SQC. All Bio-safety and Biosecurity precautions should be followed as per IATA. Any carelessly packed samples with leakages with no maintenance of cold-chain would outright be rejected by the receiving SQC lab and samples need to be re-sent during the following month. Kindly do not resend samples during the same month.

IMPORTANT: KINDLY DO NOT COURIER YOUR SAMPLES TO THE ASSIGNED SQC AS IT IS A RISK TO THE POSTAL DEPT. /COURIER SERVICES EMPLOYEES

Duration of storage of samples:

(Ref: ICMR Guidelines for storage of respiratory specimens collected for COVID-19 diagnosis by RT-PCR platforms in Government Laboratories /approved Private Laboratories doing COVID-19 testing by Real time RT- PCR /CBNAAT/True NAT methodologies dated 25-06-2020)

1. In the ongoing laboratory testing for COVID-19 diagnosis by molecular diagnostic methods, clinical specimens or a subset of the clinical specimens which may need to be retained for various purposes such as performing additional tests for quality control purposes or for use as control materials to assess newer diagnostic tests. In addition, a laboratory may need to store specimens for projects aimed at studying genomic epidemiology of the SARS CoV2 virus across regions and over time.
2. All samples being stored for long-term must be appropriately labelled indicating laboratory identifiers, date of sample collection and must be stored in properly

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functioning -80 degree C deep freezers. A proper inventory (preferably electronic) of stored samples should be essentially maintained.

3. With the surge in testing across the country, the total number of tested samples has gone up considerably. Keeping this in view, ICMR has advised the following:
 - a) Laboratories that are serving as validation centres for COVID-19 diagnostic kits are advised to preserve adequate numbers of positive and negative samples to prepare appropriate panels for validation etc.
 - b) At a minimum, all samples testing positive for SARS CoV2 must be retained for at least 30 days from the date of testing before being destroyed. Depending on the freezer space availability in a particular laboratory, one or more aliquots of the positive specimen may be retained for the period.
 - c) A Government laboratory may decide on the number of positive /negative samples to retain in the long term based on the availability of freezer space as well as perceived research agenda of the Laboratory for COVID-19 in the future.
 - d) If the number of samples tested positive at a laboratory is considerably large and the lab is unable to retain all positive samples beyond 30 days, a minimum of 10% of all positives detected at the laboratory in a month or 40-50 positives preferably with equal numbers of high, moderate and low viral load should be stored for a period of 1 year at least. A single aliquot of a positive sample may be retained taking into account freezer space availability at the laboratory.
 - e) Considering that the number of samples tested negative at each laboratory will vary depending on the sample load and testing capacity of the laboratory, a minimum of 50 samples or 1-2% of all negative tested samples over a month, whichever is smaller should be retained at the testing laboratory for a period of 1 year. A single aliquot of a negative sample may be retained taking into account the freezer space availability at the laboratory.
 - f) In case of any **discordance**, additional **five positive** and **three negative samples need to be sent during the following month**.
 - g) If QC results are concordant all the QC samples may be destroyed and labs will keep record of destruction.
 - h) Appropriate procedure to disinfect all samples prior to disposal must be followed.
 - i) If samples of any testing laboratory are rejected by the SQC for any of the valid reasons eg lack of maintenance of cold-chain; sample leakages due to improper packing; labeling issues etc. then the testing lab needs to re-send samples again during the following month and **NOT** during the same month.
 - j) An Abstract of the Reports of ILQC conducted for the testing laboratories -RT-PCR samples sent during the month will be shared routinely by the three SQCs

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-NIV Bangalore Unit, VRDL-BMCRI & VRDL-MMCRI to the MD NHM by the 10th of the following month both through hard and soft copies to the mail id (qcqakar@gmail.com)

- k) Samples of validity labs to be interchanged.
- l) Henceforth, all correspondence and communication with regards to Inter-Laboratory Quality Control (ILQC) for RT-PCR labs will be through the mail id :qcqakar@gmail.com

External Quality Control Services for CBNAAT and TrueNAT testing laboratories initiated by the Department of Health & Family Welfare, Government of Karnataka:

To ensure that the samples tested through CBNAAT and True NAT technologies by both the Government & Private Laboratories in the State conform to Quality Standards, an External Quality Control Services Programme has been initiated by the Department of Health & Family Welfare, Government of Karnataka on similar lines as the Inter- Laboratory Quality Control System for RT-PCR Labs by ICMR.

The identified SQC for CBNAAT is VRDL –BMCRI-Bengaluru & for TrueNAT Labs is VRDL-MMCRI- Mysuru.

It is mandatory for all the ICMR approved Government and Private CBNAAT and True NAT laboratories whether undertaking exclusively CBNAAT or TrueNAT testing or along with RT-PCR testing to participate in the External Quality Control Services of the Government and send samples according to the following guidelines.

- A) Samples need to be sent by the testing laboratories to the assigned SQC by the 10th of the month as per the roster which has been annexed: (Annexures 3-4). Quarterly samples need to be sent to the SQC by all the testing laboratories mandatorily.
(For eg, if a testing lab has sent samples for QC in October 2020, next they would be sending samples only in January 2021).

Details of the samples to be sent for QC are as follows:

- i) Five positive clinical samples (both Nasopharyngeal (NS) & Throat Swab (TS) randomly selected over one week. If possible those samples with Ct value between 25 – 35 to be selected.
- ii) Five negative clinical samples (both Nasopharyngeal (NS) & Throat swab (TS) samples randomly collected over one week.
- iii) Testing labs should ensure that the samples for QC reach the assigned lab by the 10th of the month based on the roster

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- iv) Results (as percent concordance) will be sent by the SQC to your official mail id.
- v) Samples from testing laboratories located in Bengaluru Urban, Rural District and Mysuru lab will be sent directly to the assigned labs on their own. All other Government and Private testing laboratories from other districts will liaise with the respective District Surveillance Officer (DSO) and ensure that samples reach the assigned SQC by the 10th of the month.
- vi) All ICMR approved RT-PCR labs who have been approved by ICMR for CBNAAT and /or TrueNAT testing in their laboratories will simultaneously send samples for RT-PCR, CBNAAT or TrueNAT testing as the case may be, to the identified SQC based on the quarterly roster.

Storage of samples for QC:

All testing labs will ensure proper storage of samples at -80C (or at least at -20C)

Labeling, Packing& Shipment of samples to assigned SQC:

All samples should have a label with the name of the testing lab and sample ID. It would be the responsibility of the individual Testing laboratory to ensure that the samples sent are appropriately packed in three layers of packing material to ensure that there would be no spillages/leakages of infectious materials during transportation /shipment and cold-chain is maintained from the time of dispatch until the receipt by the SQC. All Bio-safety and Biosecurity precautions should be followed as per IATA. Any carelessly packed samples with leakages, with no maintenance of cold-chain or labels would be rejected by the receiving SQC lab and samples would need to be re-sent during the following month. Kindly do not resend samples during the same month.

Such ICMR approved labs which have RT-PCR and CBNAAT/TrueNAT Lab facilities will send during the same month separate number of samples for RT-PCR and separate number of samples for CBNAAT or TrueNAT to the assigned SQC mentioned in the Guidelines.

However, when sending samples they will **NOT** be able to use the On-line Portal to submit details of samples dispatched as currently ICMR has designed the online Portal for ILQC for RT-PCR testing labs only and therefore kindly do not try to do online entries.

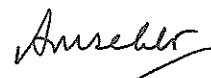
Hence, all samples sent from CBNAAT/TrueNAT labs should be accompanied with hard copies of details of samples along with an "Acknowledgement" Slip stating date and time of receipt of samples with signature and seal of the SQC, Head and name of Institution which will serve as a proof of receipt and acceptance of samples sent for QC by the testing lab to the SQC.

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It is being emphasized again that all Government and Private CBNAAT and True NAT Labs located in Bangalore Urban, Bangalore Rural District and Mysuru District will send samples directly themselves to the identified SQC by the 10th of every month. For samples outside Bangalore Urban/Rural District, Mysuru District will liaise with their respective District Surveillance Officer (DSO) between 1-7th of the month who will arrange for the pick-up and shipment of the samples to the assigned SQC by the 10th(Contact details of District Surveillance Officers of all Districts is put up as Annexure- 5). Samples of validity labs to be interchanged.

SQC VRDL- BMCRI laboratory which has been identified by the State for CBNAAT and VRDL- MMCRI for True NAT testing laboratories in the State, will send the QC Report to the respective laboratory upon completion of testing, preferably every month or at least before the next round of samples for the quarter are sent to them from the same testing laboratory.

Henceforth, all correspondence and communication with regards to External Quality Control Services for CBNAAT and TrueNAT Testing will be through the mail id: qcqakar@gmail.com



(Dr. Arundhathi Chandrasekhar)
Mission Director
National Health Mission

Copy for necessary action;

1. Deputy Commissioners of all districts
2. Chief Executive Officer, ZPs of all districts
3. District Health and Family Welfare Officers of all districts
4. District Surveillance Officers of all districts
5. Nodal Officers of all labs

Copy for kind information;

1. Additional Chief Secretary to Government, Department of Health and Family Welfare.
2. Additional Chief Secretary to Government, Department of Planning, Programme Monitoring and Statistics.
3. Commissioner, Health & Family Welfare Services.

