



**COVID-19 (nCorona) Virus Outbreak Control and Prevention State Cell
Health & Family Welfare Department
Government of Kerala**

**QUALITY ASSESSMENT AND QUALITY CONTROL OF
LABORATORIES PERFORMING RT-PCR FOR COVID-19.**

No-31/F2/2020/Health – 08th May 2020

Introduction:

Quality assessment (QA) is a critical aspect of good laboratory management. The assessment method helps to ascertain the level of functioning of the laboratory, their fidelity with the standard operating procedures and the best practices being adopted. The assessment also helps in "raising the bar" of the laboratories for excelling and ensures that there is no chance of an error except due to the reasons beyond our control.

The Department of Health and Family Welfare is introducing a quality assessment activity in laboratories performing RT-PCR for COVID-19.

Objective:

- To assess the quality of functioning of laboratories performing RT-PCR for COVID-19
- To reach to the best performing standards.

Quality Assessment team:

Sl.no	Name of Laboratory to be assessed	Name of Assessors	Designation
1.	Central University of Kerala, Periyar, Kasaragod LAB CODE: CUK	1. Dr. Aparna 2. Dr. Sameer V B	Asst. Surgeon, DH Kasaragod Asst Prof. Biochemistry, CUK.
2.	Malabar Cancer Center, Thalassery, Kannur	1. Dr. Leena 2. Dr. Junaid	Regional PH Lab, Kannur MO, THQH Pazhayangadi.

	LAB CODE: MCC		
3.	Govt. Medical College Kannur LAB CODE: GMCKNR	1.Dr Parthiban R 2.Dr.Leena	Associate Professor, Microbiology Division, MCC, Kannur Regional PH Lab,Kannur
4.	Govt. Medical College Kozhikode LAB CODE: GMCKZK	1.Dr.Sujatha 2. Dr. Kalpana George	Regional PH Lab, Kozhikode Associate Professor Microbiology, GMC Kozhikode
5.	Govt. Medical College Manjeri LAB CODE: GMCMJR	1.Dr. Abini 2. Dr. Pushpa	Regional PH Lab, Malappuram Associate Professor Microbiology, GMC Manjeri
6.	Govt. Medical College Thrissur LAB CODE: GMCTSR	1. Dr. Mary Alloysius 2. Dr. Soumya	Sr. Consultant, GH Thrissur MO, PHC Punnayur, Thrissur
7.	Govt. Medical College Ernakulam LAB CODE: GMCEKM	1.Dr. Shyla 2.Dr. Nikhilesh Menon R	Regional PH Lab, Ernakulam Asst. Nodal Officer Aardram, DMO(H), Ernakulam
8.	Govt. Medical College Kottayam LAB CODE: GMCKTM	1.Dr. Anupama 2.Dr. Aswathy Raj	Microbiologist, DH Kottayam. IUCBR & SSH, Kottayam.
9.	IUCBR & SSH, Kottayam LAB CODE: IUCBR	1.Dr. Shanimol 2. Dr. Anupama	Associate Professor Microbiology, Dept. Of Microbiology, GMC Kottayam Microbiologist DH Kottayam.
10.	Govt. Medical College Thiruvananthapuram LAB CODE: GMCTVM	1.Dr. Sunija Saikumar 2. Dr. Neetha Murthy	Director, State Public Health Lab, Tvpm Microbiologist IRL, Tvpm.
11.	SCTIMST, Thiruvananthapuram LAB CODE: SCTIMST	1.Dr.Sarada Devi 2.Dr. Neetha Murthy	Professor & Head Microbiology, GMC Tvpm Microbiologist, IRL, Tvpm
12.	RGCB, Thiruvananthapuram LAB CODE: RGCB	1.Dr. Saritha L 2.Dr. Heera Hassan	Associate Professor Microbiology, GMC Tvpm Asst. Professor, GMC Tvpm.
13.	State Public Health Laboratory, Trivandrum LAB CODE: SPHL	1.Dr. Jyothi R 2.Dr. Heera Hassan	Associate Professor Microbiology, GMC Tvpm Asst. Professor, GMC Tvpm

14.	DDRC SRL Diagnostics Pvt Ltd, Panampilly Nagar, Ernakulam. LAB CODE: DDRCPP	1.Dr.Arya Sivaprasad 2.Dr. Soumya	Microbiologist, GH Ernakulam. CMO, THQH Fort Kochi
15.	MIMS Lab Services, Govindapuram, Kozhikode. LAB CODE: MIMSKZK	1.Dr. Kalpana George 2. Dr. Aiswarya	Associate Professor Microbiology, GMC Kozhikode Asst. Professor, GMC Kozhikode
16.	Dane Diagnostics Pvt Ltd, 18/757 (1), RC Road, Palakkad LAB CODE: DANE	1. Dr. Jayanthi 2.Dr. Radhika	RCH Officer, DMO(H), Palakkad Blood Bank, DH Palakkad.
17.	Medivision Scan & Diagnostic Research Centre Pvt Ltd, Sreekandath Road, Kochi. LAB CODE: MEDVIS	1.Dr. Hanneth 2.Dr. Neethu John	MO, PHC Choornikkara Asst. Professor Microbiology, GMC Ernakulam
18.	Lab Services of Amrita Institute of Medical Sciences & Research Centre, AIMS-Ponekkara, Kochi. LAB CODE: AIMS	1.Dr.Joana Mary 2.Dr. Nikhilesh Menon R	Associate Professor Microbiology, GMC Ernakulam Asst. Nodal Officer Aardram, DMO(H), Ernakulam

Quality Assessment tool:

The tool for the quality assessment is a set of questionnaires designed for the purpose in MS Excel. The assessors shall conduct the activity using the tool and shall be emailed to them. The tool in MS Excel shall be provided and only that tool shall be used by the Assessors.

Quality Control (QC) Tool and Mechanism:

To ensure quality control of the lab, the assessors shall randomly select 3 positive and 3 negative aliquots (total of six only) tested previously in the last 2 weeks for QC from the list of samples tested. If no positives are present then negative samples may be taken.

The samples shall be collected and labelled as QC samples with name of lab and date in order to encode the samples. Anonymity with the lab shall be maintained regarding the coding of samples.

The samples shall be given codes as follows; LABCODEQC-1dd/mm/yyyy, LABCODEQC-2 dd/mm/yyyy, LABCODEQC-3 dd/mm/yyyy, LABCODEQC-4 dd/mm/yyyy, LABCODEQC-5 dd/mm/yyyy and LABCODEQC-6 dd/mm/yyyy for the six samples chosen. The LABCODEs are given in the table above.

The assessors shall keep a hard copy of the filled format (**annexure-1**) and shall not disclose the code and patient details with the lab being assessed.

The samples should be packed as per the existing guidelines and sent to NIV Alappuzha the same day. A covering letter should be sent along with the samples in the format given as **annexure-2**.

The laboratory being assessed shall ensure the transportation of the samples to NIV, Alappuzha.

Frequency of Quality Assessment Activity and Reporting:

The QA activity shall be performed twice a month (two weeks apart) and the soft copy(Excel sheet and scanned copy of annexure-1) of the report shall be sent to the email Id cov2eqa@gmail.com by **12 noon on or before 15th and 30th of every month.**

All information collected should be kept strictly confidential.

The lab in charge of NIV Alappuzha shall report the results of the encoded samples in the prescribed format (**annexure-3**) to cov2eqa@gmail.com once the results are ready.


Principal Secretary

Annexure-1

QUALITY CONTROL TOOL

NAME OF LABORATORY						
Name of Assessor-1						Date of QA assessment:
Name of Assessor-2						
Sample given assessors:	Code by	Name of patient	Age	Sex	Sample code given by lab	Result issued by the lab assessed.

Name and signature (with date) of assessor-1:.....

Name and signature (with date) of assessor-2:.....

Format for sending QC samples to NIV Alappuzha.

To,

**Lab in Charge
NIV, Alappuzha.**

Name of lab being assessed for Quality Control:.....

Date of assessment:.....

Total no of samples being sent:..... LABCODE:.....

Sl.no	SAMPLE CODE GIVEN BY ASSESSORS
1.	
2.	
3.	
4	
5.	
6.	

**Name and Designation of Assessor-1:
Assessor-2:**

Name and Designation of

.....

.....

.....

Sign with date:

Sign with date:

Name of Lab in charge:.....

Sign with Date:.....

REPORTING OF QC SAMPLES BY NIV ALAPPUZHA

LAB CODE:.....

DATE OF REPORTING:

SAMPLE CODE GIVEN BY ASSESSORS	RESULT	REMARKS

Name of lab in charge:.....

Signature of Lab in Charge with date:

Seal:
