



icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH

NICED
NATIONAL INSTITUTE OF
CHOLERA AND ENTERIC DISEASES

आई. सी. एम. आर. – राष्ट्रीय कॉलरा और आंत्र रोग संस्थान
ICMR - NATIONAL INSTITUTE OF CHOLERA AND ENTERIC DISEASES
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार
Department of Health Research, Ministry of Health and Family Welfare, Govt. of India

WHO COLLABORATING CENTRE FOR RESEARCH AND TRAINING ON DIARRHOEAL DISEASES

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PROCEDURES TO BE FOLLOWED FOR INTER-LABORATORY QUALITY CONTROL FROM ICMR-NICED

1. INTRODUCTION

ICMR-National Institute of Cholera and Enteric Diseases (ICMR-NICED), a premier public health institute under Indian Council of Medical Research (ICMR), has been conducting research on acute diarrhoeal diseases of diverse aetiologies as well as on typhoid fever, infective hepatitis, viral infections like Dengue, Chikungunya, Influenza, and other Respiratory Viruses, Zika and HIV related epidemiological research and screening.

ICMR-NICED is a designated referral lab performing Inter-Laboratory Quality Control (ILQC) program for SARS-CoV-2 conducted by ICMR. The HIV laboratory, bacteriology laboratory and the Regional Virus Research and Diagnostic Laboratory (VRDL) at ICMR-NICED are NABL accredited. Regular ILQC is performed with apex referral labs for Dengue NS1, Dengue IgM, Chikungunya IgM, Influenza panel, other respiratory viral panel, Hepatitis panel, Scrub Typhus, Leptospira, etc. In addition, IVD kits are evaluated at ICMR-NICED on directive of ICMR, CDSCO and as a member of Consortium of NRLs for Kit Quality Testing.

The diagnostic centres are requested to follow the procedural instructions.

2. SCOPE

Inter Lab Quality Control (ILQC) of following diagnostic tests at ICMR-NICED:

A. Serological Assays:

1. Dengue NS1
2. Dengue IgM
3. Chikungunya IgM
4. Hepatitis A IgM
5. Hepatitis E IgM

Procedures to be Followed for ILQC from ICMR-NICED

6. Hepatitis B Surface Antigen (HBsAg)
7. Anti Hepatitis C Antibody
8. Scrub Typhus IgM
9. Leptospira IgM

B. Molecular Assays:

1. Influenza panel PCR (Inf A and subtypes H1N1, H3N2; Inf B and subtypes Yamagata, Victoria)
2. Other respiratory virus panel PCR (RSV A,B; hMPV; PIV 1,2,3,4; Adenovirus, Rhinovirus)

3. NUMBER AND VOLUME OF SAMPLES TO BE SUBMITTED FOR ILQC

- Negative samples: 06 and Positive samples: 06; 500-1000µl each

4. CONTACT INFORMATION

ILQC Coordinator: **Dr. Ashis Debnath**

Email ID: **ilqc.niced@gmail.com**

Contact No.: 033 2370 5533, +91 8902830788

ILQC requests may be sent to the above-mentioned email ID with a copy (cc) to **shanta.niced@icmr.gov.in** (Director ICMR-NICED)

5. ILQC PROCESSING CHARGES

Currently the charges of evaluation are as follows:

- Serological Assays: Rs. 10,000/- per panel
- Molecular Assays: Rs. 25,000/- per panel

The charges of ILQC have to be paid electronically in advance to ICMR-NICED Bank Account. The details of bank account will be provided on request.

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6. PROCEDURE IN BRIEF

The ILQC Coordinator monitors the activities of ILQC at ICMR-NICED. The Coordinator receives requests for ILQC from the Hospitals or Diagnostic centres and ensures efficient functioning at ICMR-NICED Lab following Standard Operating Procedures (SOPs).

The Institute accepts the requests provided the following terms and conditions are acceptable:

1. ILQC charges to be paid in advance to ICMR-NICED Bank Account when asked for.
2. An intimation mail regarding the payment (mentioning transaction details) and the date of sending the samples need to be sent before dispatching the samples.
3. Provide designated number of positive and negative samples following the check list (refer Page 04). At the time of receiving the QC samples, stringent checks would be done to ensure that the proper packaging, sample vial labelling and proper transportation temperature conditions (cold chain) are strictly adhered to during transport and the samples are not leaked/damaged during transportation.

The scanned copy of the report will be sent by email and the hard copy will be sent by speed post.

7. TURN AROUND TIME (TAT)

The turnaround time for ILQC report is maximum 4 weeks from date of receiving the samples.

8. VALIDITY OF THE REPORT

The ILQC certificate will remain valid for 6 months from the date of issue.

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Procedures to be Followed for ILQC from ICMR-NICED

**CHECKLIST TO BE FILLED BEFORE SENDING THE ILQC
SAMPLES FOR EVALUATION**

Details of test to be evaluated:

Name of the test:

Type of test:

Procedure of test used in testing lab:

Number of samples sent:

Proper Labelling of individual samples:

Date of sample collection:

Storage conditions:

Check the following things before sending the ILQC samples for evaluation

1.	Approval letter of the ILQC Coordinator, ICMR-NICED	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Proper labelling of individual samples	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Triple layer packaging	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Proper transportation temperature maintained	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	Total number of samples supplied as mentioned	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Line list of samples attached	<input type="checkbox"/> Yes <input type="checkbox"/> No

*Certified and Authenticate copies of documents

Remark: If the reply is yes for all the columns (1-6) above, ILQC samples may be accepted for evaluation. Samples not transported in triple layer package or proper transportation temperature (cold chain) not maintained will not be accepted. In rare instance of deficiencies on any of the above points the details will have to be submitted within 10 working days, failing which the ILQC samples will be rejected.

Name, Designation and Signature of the authorized staff:

Date:

Time: