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

PROCEDURES TO BE FOLLOWED FOR IN-VITRO DIAGNOSTIC KIT PERFORMANCE VERIFICATION BY 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 etiologies as well as on typhoid fever, infective hepatitis and HIV related epidemiological research and screening.

ICMR-NICED being a member of the Consortium of NRLs for Kit Quality Testing provides kit evaluation services, since 2010, to ensure quality diagnostics for HIV, HBV and HCV for national programs sponsored by National AIDS Control Organization (NACO). As per revised notification dated 13/09/2019 from Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services, Ministry of Health & Family Welfare (Diagnostic Division), ICMR-NICED has been included for conducting performance evaluation of the following In-vitro Diagnostics on request:

1. Reagents/Kits for detection of Cholera
2. Reagents/Kits for detection of Typhoid
3. Reagents/Kits for detection of Dengue
4. Reagents/Kits for detection of Chikungunya
5. Reagents/Kits for detection of Influenza

The companies are requested to follow the procedural instructions.

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2. SCOPE

Performance verification of following In-vitro Diagnostic kits at ICMR-NICED :-

- Cholera: Immuno Diagnostic Test
- Typhoid: Immuno Diagnostic Test
- Influenza: Molecular Test
- Dengue: Immuno Diagnostic Test
- Chikungunya: Immuno Diagnostic Test

3. NUMBER OF TESTS TO BE SUBMITTED FOR VERIFICATION OF THE KIT:

- Cholera – 200 tests
- Typhoid – 200 tests
- Influenza – 200 tests
- Dengue – 200 tests
- Chikungunya – 200 tests

4. CONTACT INFORMATION:

Nodal person :- Dr. Nibedita Debnath

Contact No. :- 8638700093

Email ID :- drnibedita21@gmail.com

Kit evaluation request may be sent to the above mentioned email ID with a copy (cc): to shanta.niced@icmr.gov.in (Director ICMR-NICED)

5. KIT PERFORMANCE VERIFICATION PROCESSING CHARGES:

Currently the charges of evaluation are as follows:

- Immuno-diagnostic kits: Rs. 1,00,000/- per batch
- Molecular-diagnostic kits: Rs. 2,50,000/- per batch

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

6. PROCEDURE IN BRIEF:

The designated nodal person coordinates the activities of kit performance verification at ICMR-NICED. The Nodal person receives requests for kit performance verification from the manufacturers, Government agencies, DCGI etc. 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 to the requester:

1. Supply of designated number of kits following the check list. At the time of receiving the kits, stringent check needs to be done to ensure that the storage conditions are adhered to during transport and the kits are not damaged.
2. Kit evaluation charges to be paid in advance to ICMR-NICED Bank Account.

7. TURN AROUND TIME (TAT):

The turnaround time for kit performance verification report is maximum 4 weeks. The scanned copy of report will be sent to the requester by email and the hard copy of the report will be sent by speed post.

Checklist to be filled before sending the kits for performance verification

Details of the kit:

Name of the assay:

Principle of the assay:

Manufacturer:

Lot/ Batch No.:

Number of kits sent:

Date of Manufacture:

Date of Expiry:

Check the following things before sending the kit for performance verification

1.	Gross packaging and seal intact	Yes	No
2.	Total number of tests supplied as mentioned	Yes	No
3.	A production and Quality control protocol has been attached along with certificate of analysis.	Yes	No
4.	Licensing certificate* provided by State/ Central Licensing authority have been submitted	Yes	No
5.	A kit insert in English language comprising of details of the product, steps for performance of the test, calculation & interpretation of the result has been provided *Certified and Authenticate copies of documents	Yes	No

Remark: If the reply is yes for all the columns (1-5) above, kit may be accepted for testing. Kits with incomplete documents 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 kit will be rejected.

Name, Designation and Signature of the authorized staff:

Date:

Time: