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 basic/ applied research on acute diarrhoeal diseases of diverse aetiologies as well as on typhoid fever, infective hepatitis and HIV-1.

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 Dengue**
3. **Reagents/Kits for detection of Chikungunya**
4. **Reagents/Kits for detection of Influenza**
5. **Reagents/Kits for detection of Typhoid**

The companies are requested to follow the procedural instructions.

2. SCOPE

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

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

3. NUMBER OF TEST KITS TO BE SUBMITTED FOR VERIFICATION OF THE KIT ASSAY

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

4. CONTACT INFORMATION

Kit Evaluation Coordinator: **Dr. Ashis Debnath**
Email ID: **kitevaluation.niced@gmail.com**
Contact No.: 033 2370 5533, +91 8583814726

Kit evaluation requests may be sent to the above-mentioned email ID with a copy (cc) to **director-niced@icmr.gov.in**

5. KIT PERFORMANCE VERIFICATION PROCESSING CHARGES

The charges of the performance verification will be decided by the Kit Evaluation committee based on the mode pf operation.
The charges of performance verification need to be paid electronically in advance to ICMR-NICED Bank Account. The details of bank account will be provided once the kit has been accepted for verification.

Accepting/Rejecting assay kit for verification is the absolute decision of NICED.

6. PROCEDURE IN BRIEF

The Kit Evaluation Coordinator monitors the activities of kit performance verification at ICMR-NICED. The Coordinator receives requests for kit performance verification from the manufacturers, Government agencies, DCGI etc. and ensures efficient performance of 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 (refer Page 04). At the time of receiving the kits, stringent checks would be done to ensure that the proper storage conditions are strictly adhered to during transport and the kits are not expired or damaged.
2. Kit evaluation charges to be paid in advance to ICMR-NICED Bank Account when asked for.
3. An intimation mail regarding the payment and the date of sending the kits need to be sent before dispatching the kits.

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.

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Procedures to be Followed for In-Vitro Diagnostic Kit Performance Verification by ICMR-NICED

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.	Approval letter of the Kit Evaluation Coordinator, ICMR-NICED	□Yes□No
2.	Gross packaging and seal intact	□Yes□No
3.	Total number of tests supplied as mentioned	□Yes□No
4.	A production and quality control protocol has been attached along with certificate of analysis	□Yes□No
5.	Licensing certificate* provided by State/Central Licensing authority have been submitted	□Yes□No
6.	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	□Yes□No

*Certified and Authenticate copies of documents

Remark: If the reply is yes for all the columns (1-6) 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: