



# ICMR-DCGI

# GUIDELINES FOR VALIDATION AND BATCH TESTING OF COVID-19 DIAGNOSTIC KITS

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# GUIDELINES FOR VALIDATION AND BATCH TESTING OF COVID-19 DIAGNOSTIC KITS

*(This is recommendatory and dynamic document without prejudice to statutory provisions)*

## 1. VALIDATION

### 1.1 RT-PCR Kits

1.1.1 US-FDA approved kits will not require validation.

1.1.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: First batch of kits will require validation from any of ICMR identified validation centres (Annexure I) prior to DCGI approval; thereafter for post marketing; additional two batches should be tested as per medical device rule in four months time.

### 1.2 RNA Extraction and VTM Kits

1.2.1 US-FDA approved kits will not require validation.

1.2.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: One batch of kits will require validation from any of ICMR identified validation centres prior to DCGI approval.

### 1.3 Rapid Antibody Test; ELISA and CLIA Kits

1.3.1 US-FDA approved kits will not require validation.

1.3.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: The testing of three batches of kits will be required for validation from any of ICMR identified validation centres prior to DCGI approval.

## 2. BATCH TESTING FOR RT-PCR, RNA EXTRACTION KITS, VTM, RAPID ANTIBODY TEST, ELISA AND CLIA KITS

2.1 The firm will be required to provide batch testing certificate while delivering the consignment.

2.2 ICMR identified validation centre will undertake random samples testing of batches of kits for quality assurance

## 3. PROCEDURE FOR VALIDATION

3.1 The requests for validation of kits for RT-PCR; RNA Extraction, VTM, Rapid Antibody Test, ELISA and CLIA will be sent by the manufacturer/supplier through e-mail **(gstoteja@gmail.com) to Dr. G. S. Toteja, Additional Director General, ICMR and National Nodal Officer for validation**. The request from the manufacturer/supplier should mandatorily be accompanied with information as per Annexure II

3.2 The request after receipt and scrutiny will be :

3.2.1 Forwarded to any one of the ICMR identified validation centres depending upon the work load and other logistics issue if it is **first time validation**.

3.2.2 If the kit is for second time validation or subsequent validation or in case of any other issue; the manufacturer has to provide justification which will be reviewed at ICMR, New Delhi and decision will be communicated to manufacturer/supplier within a week. The request for re-validation will only be considered if there is any significant change in the composition or type of reagents in the kit.

3.3 Once the kit is delivered to the validation centre with adequate number of test reactions required, reagents, methodology etc; validation report will be sent to the manufacturer/supplier within 15 days.

**ANNEXURE I**

# Centres for Validation and Batch Testing of COVID-19 Diagnostic Kits

| S.No | Name of the Institute |
|---|---|
| | **ICMR INSTITUTES** |
| 1. | ICMR – National Institute of Virology (NIV), Pune |
| 2. | ICMR- Regional Medical Research Centre (RMRC), Bhubaneswar |
| 3. | ICMR- National Institute for Research in Reproductive Health (NIRRH) , Mumbai |
| 4. | ICMR- Rajendra Memorial Research Institute of Medical Science (RMRIMS), Patna |
| 5. | ICMR- National Institute of Virology (NIV) field unit, Alappuzha |
| 6. | ICMR- National AIDS Research Institute (NARI), Pune |
| 7. | ICMR- National Institute of Pathology (NIP), New Delhi |
| 8. | ICMR - National Institute of Cholera and Enteric Diseases (NICED), Kolkata |
| 9. | ICMR- National Institute for Implementation Research on Non-Communicable Diseases (NIIRNCD), Jodhpur |
| | **DBT INSTITUTES** |
| 10. | DBT- Translational Health Science and Technology Institute (THSTI), Faridabad |
| 11. | DBT- International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi |
| 12. | DBT- Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram |
| 13. | DBT- Institute of Life Sciences (ILS), Bhubaneswar |
| 14. | DBT- Institute for Stem Cell Science and Regenerative Medicine (InSTEM), Bengaluru |
| | **CSIR INSTITUTES** |
| 15. | CSIR- Institute of Genomics and Integrative Biology (IGIB), New Delhi |
| 16. | CSIR- Institute of Microbial Technology (IMTECH), Chandigarh |
| 17. | CSIR- Centre for Cellular & Molecular Biology (CCMB), Hyderabad |
| | **OTHERS** |
| 18. | Kasturba Hospital for Infectious Diseases, Mumbai |
| 19. | Institute of Liver and Biliary Sciences, New Delhi |
| 20. | Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh |
| 21. | King George's Medical University (KGMU), Lucknow |
| 22. | National Institute of Biologicals (NIB), Noida |
| 23. | The King Institute of Preventive Medicine and Research, Chennai |
| 24. | Sawai Man Singh Medical College, Jaipur |

**ANNEXURE II**

## FORMAT FOR INFORMATION FOR VALIDATION OF RT-PCR/RNA EXTRACTION KITS/VTM AND RAPID ANTIBODY TEST, ELISA AND CLIA

## A. RT-PCR KITS

| Name of the Company (manufacturer) | Name of the supplier | Name of the Kit & Batch No. | Multiplex or *Singleplex with no. of genes | First Time Validation by ICMR (Yes/No) | If it is not first time validation | |
|---|---|---|---|---|---|---|
| | | | | | Details of last validation along with validation report | Difference in Kit composition as compared to first validation |
| | | | | | | |

* Only kit with minimum two gene targets will be considered

## B. RNA EXTRACTION KITS

| Name of the Company (manufacturer) | Name of the supplier | Name of the Kit & Batch No. | Magnetic or Column Based | First Time Validation by ICMR (Yes/No) | If it is not first time validation | |
|---|---|---|---|---|---|---|
| | | | | | Details of last validation along with validation report | Difference in Kit composition as compared to first validation |
| | | | | | | |

## C. VTM, RAPID ANTIBODY TEST, ELISA AND CLIA

| Name of the Company (manufacturer) | Name of the supplier | Name of the KIT & Batch No. | First Time Validation by ICMR (Yes/No) | If it is not first time validation | |
|---|---|---|---|---|---|
| | | | | Details of last validation along with validation report | Difference in product as compared to first validation |
| | | | | | |

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