



ICMR-DCGI

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

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DEPARTMENT OF HEALTH RESEARCH
MINISTRY OF HEALTH AND FAMILY WELFARE,
GOVERNMENT OF INDIA



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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