REGULATION OF IN-VITRO DIAGNOSTIC REAGENTS/KITS IN INDIA

Central Drugs Standard Control Organization (CDSCO)

Directorate General of Health Services,
Ministry of Health & Family Welfare,
Government of India

Website Link:
https://cdsco.gov.in/opencms/opencms/en/Home/

February 2021

Medical Devices Rules, 2017

- MoH&FW, Government of India has notified the Medical Devices Rules, 2017 vide G.S.R. 78(E) dated 31.01.2017 under the provisions of the Drugs and Cosmetics Act, 1940. These rule are effective from 01.01.2018 to regulate the Clinical Investigation, Manufacture, Import, Sale and Distribution of the Medical Devices in the country.

  (Link: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzE4MA==)

- In-vitro Diagnostic reagents and kits are regulated under sub-clause (i) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) under the provision of Medical Devices Rules, 2017.

Regulatory Authorities

IVD MD Risk based Classification Activity	Class A	Class B	Class C	Class D
Import	CLA	CLA	CLA	CLA
Manufacture	SLA	SLA	CLA	CLA
Permission to conduct CI /CPE	Permission from CLA			
Sale	SLA			
QMS Verification	Notified Body	Notified Body	CLA	CLA
FSC	SLA	SLA	CLA	CLA
MSC / NCC	SLA	SLA	CLA	CLA
Neutral/Special code	CLA	CLA	CLA	CLA

* ***CLA:*** *Central Licensing Authority,* ***SLA:*** *State Licensing Authority,* ***CPE****: Clinical Performance Evaluation,* ***NCC****: Non Conviction Certificate,* ***MSC****: Market Standing Certificate,* ***FSC****: Free Sale Certificate*

Update on Regulation of COVID-19 IVD Regents/Kits

IVD type	COVID-19 IVD PCR/ RAPID/ ELISA/ CLIA	Viral transport kit (VTM)	RNA/DNA Extraction kit	Molecular transport medium (MTM)
Device Class	Class C	Class A	Class C	Class C
Import	CLA	CLA	CLA	CLA
Manufacture	CLA	SLA	CLA	CLA
Requirements of MD-25	Abbreviate, defer, or waive On national emergency	NIL	NIL	NIL
Requirements of MD-29	As post license condition On national emergency	NIL	NIL	NIL
PER Requirements for USFDA-Approved	NIL (Prior approval)	NIL	NIL	NIL
PER Requirements for Non-USFDA Indigenous	PCR kit 1 lot Prior approval and 2 lot post marketing Rapid/ELISA/CLIA 3 lot Prior approval	1 lot Prior approval	1 lot Prior approval	1 lot Prior approval

Regulatory pathway for Domestic manufacturing of COVID-19 Reagents/kits

Obtain Test licence in Form MD-13 by applying in Form MD-12 along with fee for each IVD INR 500 and documents as per the checklist available on the MD Online portal

(Website link: https://cdscomdonline.gov.in/NewMedDev/Homepage)

Obtain manufacturing license in Form MD-9 or MD-10 (loan license) by applying in Form MD-7 or MD-8 (loan license) along with fee for one site INR 50000 and per product INR 1000 and documents as per checklist available on the MD Online portal.

Firm shall obtain Permission to manufacture new In vitro diagnostic medical device in Form MD-29 by applying in Form MD-28 along with a fee of INR 25000 and documents as per checklist available on the MD Online portal

•Above mentioned Applications ie (MD-12, MD-7/8, & MD-28) may be submitted simultaneously and processed parallelly.

•Application received , reviewed, audited (where applicable) and recommended to LA by concerned CDSCO zonal/sub zonal office in coordination with CDSCO(HQ)

Regulatory pathway for Import of COVID-19 Reagents/kits

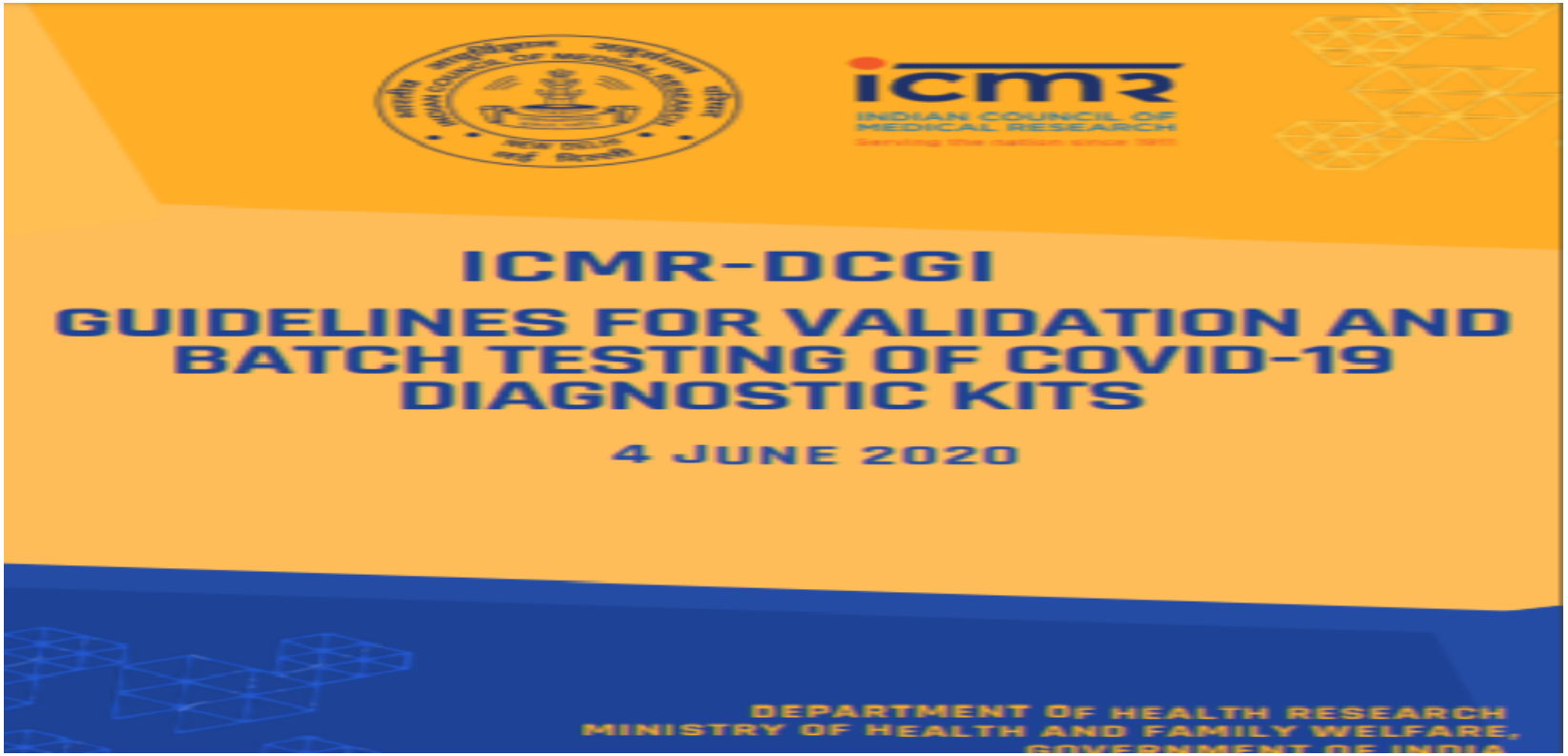
Obtain Import Test licence in Form MD-17 by applying in Form MD-16 along with fee for each IVD $100 and documents as per the checklist available on the MD Online portal

Obtain Import license in Form MD-15 by applying in Form MD-14 along with fee for one site $3000 and per product $500 and documents as per checklist available on the MD Online portal.

Firm shall obtain Permission to import new In vitro diagnostic medical device in Form MD-29 by applying in Form MD-28 along with a fee of INR 25000 and documents as per checklist available on the MD Online portal

•Above mentioned Applications ie (MD-16, MD-14, & MD-28) may be submitted simultaneously and processed parallelly.
•Application received, reviewed and recommended to LA by CDSCO(HQ)

Efforts taken by CDSCO during COVID-19 Pandemic



Identified Centres for Validation and Batch Testing of COVID-19 Diagnostic Kits in India:

- ✓09 ICMR Institutes
- ✓03 CSIR Institutes
- ✓05 DBT Institutes
- ✓07 other laboratories

Acceptance Criteria for SARS-CoV-2 Diagnostic Kits

Type of Kit	Acceptance Criteria
RT-PCR Kit	Sensitivity: 95% and above Specificity: 99% and above
RNA Extraction Kit	At least 95% concordance among positive At least 90% concordance among negative samples > 95 % samples showing amplification in internal control
VTM	100% concordance among spiked samples 100% samples showing amplification in internal control
Antibody Rapid Kit	Sensitivity: 90% and above Specificity: 99% and above
ELISA / CLIA Kit	IgM: Sensitivity- 90% and above Specificity- 99% and above IgG: Sensitivity- 90% and above Specificity- 95% and above
Rapid Ag Test Kits	• Validated as a Point of Care Test (POCT) without transport to a laboratory setup: Sensitivity: 50% and above; Specificity: 95% and above • Validated in a laboratory setup with samples collected in Viral Transport Medium (VTM): Sensitivity: 70% and above; Specificity: 99% and above

ICMR website updates

icmr भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

COVID-19

150 YEARS OF CELEBRATING THE MAHATMA

Home | About Us | COVID-19 | Tenders | Media | Contact Us | Visit Main Website

Kits Validation & Batch Testing

Show 10 entries Search:

SNo	Date	Information	Download
1	01/02/2021	List of Rapid Antigen Test Kits for COVID-19, validated by ICMR	
2	25/01/2021	Performance evaluation of commercial kits for real time PCR for COVID-19 by ICMR identified validation centres	
3	06/01/2021	List of companies / vendors of Saliva Based Rapid Antigen test kits for COVID-19 validated / being validated by ICMR	
4	29/12/2020	List of antibody (IgM, IgG) based rapid tests	
5	29/12/2020	Invitation for Expression of Interest for Validation of Rapid Antigen Detection Assays for COVID-19	
6	03/11/2020	List of IgG ELISA/CLIA kits for COVID-19 validated by ICMR identified validation centres	
7	10/09/2020	Validation of SARS-COV2 Diagnostic Commodities: Acceptance Criteria	
8	04/06/2020	ICMR-DCGI Guidelines for Validation and Batch Testing of COVID-19 Diagnostic Kits & Validation centres	

Showing 1 to 8 of 8 entries Previous 1 Next

Website Link: https://www.icmr.gov.in/ckitevaluation.html

CDSCO

Fast track Approval for COVID-19 IVD Kits/Reagents

Time line comparisons:

Application Type	Time line under MDR 2017	For COVID 19 IVDMD
Manufacturing Test license - MD12	30 days	Within 7 days (DCGI issued public notice dated 19-03-2020)
Import Test license – MD16	30 days	Within 7 days (DCGI issued public notice dated 19-03-2020)
Application for conduct clinical performance evaluation of new IVD MD – MD24	90 days	Abbreviate, defer, or waive Under MDR2017 (DCGI issued public notice dated 19-03-2020)
Application for permission to Import / manufacture New IVD MD – MD28	120 days	Abbreviate, defer, or waive Under MDR2017 (DCGI issued public notice dated 19-03-2020)
Application for manufacturing license for sale of IVD MD Form MD-7 or MD-8 (loan license) Class C/D	i. Scrutiny within 45 days ii. Site inspection within 60 days iii. License issued within 45 days of Inspection report	Expedited review and accelerated approval (DCGI issued public notice dated 19-03-2020)
Application for Import for sale of IVD MD Form MD-14	270 days	Expedited review and accelerated approval (DCGI issued public notice dated 19-03-2020)

Achievements

- For addressing various questions on regulatory practices in IVD, Frequently Asked Questions (FAQ) on In vitro diagnostic medical devices is uploaded on CDSCO website. Also regular interactions are taking place with all the stakeholders to resolve their regulatory issues.

- CDSCO has also started Public relations office (PRO) to assist any start-up/ innovator/ industry person in facilitating regulatory clearances. Function from 10:00 am to 5.30 pm in all working days.

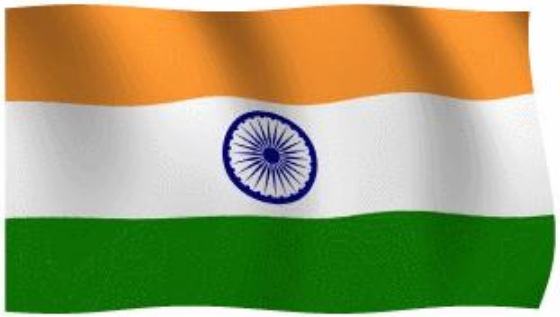
- All licenses Import/ manufacturing, Permission of clinical performance evaluation, Permission for new IVD MD, Registrations of Private IVD MD testing Labs, Post approval changes processed in online portal.

- Organized stakeholders training and awareness programs on NEW MDR 2017 and online portal.

- Fast track clearances of COVID-19 IVD MD applications from March 2020 to till date same appreciated by various stakeholders.

- Latest list of approved COVID-19 kits are being uploaded in CDSCO website. As on 01.02.2021, 177 PCR kits and 128 Rapid/ CLIA/ ELISA kits for the detection of COVID-19 infection have been approved by this office.

“Without diagnostics, treatment is blind”



Thank you