



Date: 14.08.2020

GUIDANCE ON RAPID ANTIBODY TEST KITS FOR COVID-19

RAPID ANTIBODY tests are not recommended for

- Clinical diagnosis of COVID-19 infection
- Enrollment of human subjects for any clinical trial
- Determining the immune status of an individual to declare him/her as recovered

Please Note:

- These rapid antibody test kits have been validated in the laboratory. However, the performance of the kits may be subject to variation under field conditions.
- Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.
- Antibody based rapid tests which are US-FDA approved can be used directly after due marketing approval from DCGI.

Till date, 104 antibody based rapid tests have been validated, and the following were found to be satisfactory

S.No.	Name of Company	Name of Kit	Lot no./Batch no.
1.	Voxtur Bio Ltd, Surat (Gujarat), India	Coronavirus (COVID-19) IgG/IgM Rapid Test	PCCV200301S
2.	VANGUARD Diagnostics, Delhi, India	COVID-19 IgM/IgG Antibody Detection Card Test	RCOVID200301T
3.	HLL Lifecare Limited, Gurugram (India) India	Makesure COVID-19 Rapid test	CVCT030420 CVCT0204203 CVCT0104202
4.	Lab Care Diagnostics India Pvt. Ltd, Mumbai (Maharashtra), India	ACCUCARE IgM/IgG Lateral Flow Assay kit	CVC 200401
5.	NuLifecare, Noida (UP), India	Abchek COVID-19 IgM/IgG Antibody Rapid Test	NUL/COV-19/R&D/001
6.	Alpine Biomedicals, Ambala (Haryana), India	One Step Corona Virus (COVID-19) IgM/IgG Antibody Test	A10420 A20420
7.	Medsorce Ozone Biomedicals, Haryana, India	COVID 19 IgM/IgG Rapid Test Kit (ver 2.0)	COV-002
8.	Immuno Science India Pvt. Ltd, Pune, India	Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies	E142001
9.	BMT Diagnostics (Rafael Diagnostic), Israel	BMT COVID-19 IgG/IgM Rapid Test Kit	COV20030059 COV20030059-1



S.No.	Name of Company	Name of Kit	Lot no./Batch no.
10.	SIDAK Life Care Pvt. Ltd., New Delhi, India	One Step COVID-19 IgM/IgG Antibody	COVID19S004A COVID19S004B COVID19S004C
11.	Diagnocure, Solan (HP), India	Xamin COVID-19 Rapid Test Device	DI/COV19/R&D/001 DI/COV19/R&D/002
12.	ImmunoScience India Pvt. Ltd.	ImmunoQuick COVID-19 IgG Rapid Test Device	E143001 E143002 E143003
#13.	Guangzhou Wondfo Biotech M R Roofs Private Ltd Abbott Laboratories Zydus Cadilla	SARS-CoV-2 Antibody test (Lateral flow method)	W19500309 W19500302 W19500351 W19500338
#14.	Zhuhai Livzon Diagnostics (CE- IVD)	COVID-19 IgM/IgG Antibody Rapid Test:	CK2003010410
##15.	BioMedomics (CE-IVD), China	Biomedomics COVID-19 IgM IgG Rapid Test	20200226
##16.	M/s S.D. Biosensor, Inc South Korea	Standard Q Covid -19 IgM/IgG Duo test	E054002 E054004

The marketing licenses to the distributors of companies at s.no. 13 & 14 have been **cancelled** by the Central Drugs Standard Control Organization (CDSCO).

Rapid Antibody kit of Biomedomics COVID-19 IgM IgG Rapid Test manufactured by BioMedomics (CE-IVD), China and Standard Q Covid -19 IgM/IgG Duo test manufactured by M/s S.D. Biosensor, Inc South Korea of the specified batches were evaluated by ICMR earlier. However, the marketing licenses of the distributors of the above two companies have been **suspended** by the Central Drugs Standard Control Organization (CDSCO) after removal of the COVID-19 serology test kits from the notification list by USFDA.