



Date: 19/06/2020

Guidance on rapid antibody kits for COVID-19

Till date, 56 antibody based rapid tests have been validated, and the following were found to be satisfactory. 11 of these kits are manufactured in India.

S.No.	Name of Company	Name of Kit	Lot no./Batch no.
1.	BioMedomics (CE-IVD), China	Biomedomics COVID-19 IgM IgG Rapid Test	20200226
2.	Voxtur Bio Ltd, Surat (Gujarat), India	Coronavirus (COVID-19) IgG/IgM Rapid Test	PCCV200301S
3.	VANGUARD Diagnostics, Delhi, India	COVID-19 IgM/IgG Antibody Detection Card Test	RCOVID200301T
4.	HLL Lifecare Limited, Gurugram (Haryana) India	Makesure COVID-19 Rapid test	CVCT030420 CVCT0204203 CVCT0104202
5.	Lab Care Diagnostics India Pvt. Ltd, Mumbai (Maharashtra), India	ACCUCARE IgM/IgG Lateral Flow Assay kit	CVC 200401
6.	NuLifecare, Noida (Uttar Pradesh), India	Abchek COVID-19 IgM/IgG Antibody Rapid Test	NUL/COV-19/R&D/001
7.	Alpine Biomedicals, Ambala (Haryana), India	One Step Corona Virus (COVID-19) IgM/IgG Antibody Test	A10420 A20420
8.	Medsorce Ozone Biomedicals, Haryana, India	COVID 19 IgM/IgG Rapid Test Kit (ver 2.0)	COV-002
9.	Immuno Science India Pvt. Ltd, Pune (Maharashtra), India	Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies	E142001
10.	SD Biosensors, Healthcare Pvt. Ltd., Gugugram (Haryana), India	Standard Q Covid -19 IgM/IgG Duo test – One Step Rapid Antibody test	E054002 E054004
11.	BMT Diagnostics (Rafael Diagnostic), Israel	BMT COVID-19 IgG/IgM Rapid Test Kit	COV20030059 COV20030059-1
12.	SIDAK Life Care Pvt. Ltd., New Delhi, India	One Step COVID-19 IgM/IgG Antibody	COVID19S004A COVID19S004B COVID19S004C
13.	Diagnocure, Solan (Himachal Pradesh), India	Xamin COVID-19 Rapid Test Device	DI/COV19/R&D/001 DI/COV19/R&D/002

Rapid antibody tests are not recommended for diagnosis of COVID-19 infection

- Can be done on blood/serum/plasma samples
 - Test result is available within 30 minutes
 - Test may come positive after 7-10 days of infection
 - The test may remain positive for several weeks after infection
 - Positive test indicates exposure to SARS-CoV-2
 - Negative test does not rule out COVID-19 infection
- **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.**



Date: 19/06/2020

Guidance on rapid antibody kits for COVID-19

S. No.	Kit Detail	Lot no./Batch no.
14.	SARS-CoV-2 Antibody test (Lateral flow method): Guangzhou Wondfo Biotech Mylan Laboratories Limited (CE-IVD) M R Roofs Private Ltd Abbott Laboratories Zydus Cadilla	# W19500309 W19500302 W19500351 W19500338
15.	COVID-19 IgM/IgG Antibody Rapid Test: ZHUHAI LIVZON DIAGNOSTICS (CE-IVD)	# CK2003010410

The marketing licenses to the distributors of these 2 companies have been **cancelled** by the Central Drugs Standard Control Organization (CDSCO).

Antibody based rapid tests which are US-FDA approved can be used directly after due marketing approval from DCGI.