

Guidance on rapid antibody kits for COVID-19

Till date, 42 antibody based rapid tests have been validated, and the following were found to be satisfactory. 10 of these kits are manufactured in India.

S.No.	Kit Detail	Lot no./Batch no.
1.	COVID-19 IgM IgG Rapid Test: BioMedomics (CE-IVD)	20200226
2.	New Coronavirus (COVID-19) IgG/IgM Rapid Test: Voxtur Bio Ltd, India	PCCV200301S
3.	COVID-19 IgM/IgG Antibody Detection Card Test: VANGUARD Diagnostics, India	RCOVID200301T
4.	Makesure COVID-19 Rapid test: HLL Lifecare Limited, India	CVCT030420 CVCT0204203 CVCT0104202
5.	YHLO iFlash-SARS-CoV-2 IgM and IgG detection kit (additional equipment required): CPC Diagnostics	20200206
6.	ACCUCARE IgM/IgG Lateral Flow Assay kit: LAB-CARE Diagnostics (India Pvt. Ltd)	CVC 200401
7.	Abchek COVID-19 IgM/IgG Antibody Rapid Test: NuLifecare	NUL/COV-19/R&D/001
8.	One Step Corona Virus (COVID-19) IgM/IgG Antibody Test: ALPINE BIOMEDICALS	A10420 A20420
9.	COVID 19 IgM/IgG Rapid Test Kit; Medsource Ozone Biomedicals (ver 2.0)	COV-002
10.	Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies: Immuno Science India Pvt. Ltd	E142001
11.	Standard Q Covid -19 IgM/IgG Duo test – One Step Rapid Antibody test: SD Biosensors	E054002 E054004
12.	COVID-19 IgG/IgM Rapid Test Kit Rafael Diagnostic: BMT Diagnostics	COV20030059 COV20030059-1
13.	One Step COVID-19 IgM/IgG Antibody: SIDAK Life Care Pvt. Ltd.	COVID19S004A COVID19S004B COVID19S004C

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.

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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 CE-IVD approved

The complete list of CE-marked rapid SARS-CoV-2 antibody tests is available at (<https://www.finddx.org/covid-19/pipeline/>). CE-IVD approved kits can be used directly after due marketing approval from DCGI.