

Guidance on rapid antibody kits for COVID-19

Not recommended for diagnosis of COVID-19 infection

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

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

- **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.**

S.No.	Kit Detail	*Lot no./Batch no.
1.	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
2.	COVID-19 IgM IgG Rapid Test: BioMedomics (CE-IVD)	20200226
3.	COVID-19 IgM/IgG Antibody Rapid Test: ZHUHAI LIVZON DIAGNOSTICS (CE-IVD)	CK2003010410
4.	New Coronavirus (COVID-19) IgG/IgM Rapid Test: Voxtur Bio Ltd, India	PCCV200301S
5.	COVID-19 IgM/IgG Antibody Detection Card Test: VANGUARD Diagnostics, India	RCOVID200301T
6.	Makesure COVID-19 Rapid test: HLL Lifecare Limited, India	CVCT030420 CVCT0204203 CVCT0104202
7.	YHLO iFlash-SARS-CoV-2 IgM and IgG detection kit (additional equipment required): CPC Diagnostics	20200206
8.	ACCUCARE IgM/IgG Lateral Flow Assay kit: LAB-CARE Diagnostics (India Pvt. Ltd)	CVC 200401
9.	Abchek COVID-19 IgM/IgG Antibody Rapid Test: NuLifecare	NUL/COV-19/R&D/001
10.	One Step Corona Virus (COVID-19) IgM/IgG Antibody Test: ALPINE BIOMEDICALS	A10420 A20420
11.	COVID 19 IgM/IgG Rapid Test Kit; Medsource Ozone Biomedicals (ver 2.0)	COV-002
12.	Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies: Immuno Science India Pvt. Ltd	E142001
13.	Standard Q Covid -19 IgM/IgG Duo test – One Step Rapid Antibody test: SD Biosensors	E054002 E054004

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14.	COVID-19 IgG/IgM Rapid Test Kit Rafael Diagnostic: BMT Diagnostics	COV20030059 COV20030059-1
15.	One Step COVID-19 IgM/IgG Antibody: SIDAK Life Care Pvt. Ltd.	COVID19S004A COVID19S004B COVID19S004C

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.