



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 12.02.2021

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.
- Below 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, 196 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



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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.	PCL, Inc., Seoul, Republic of Korea (Hemogenomics Pvt. Ltd.)	PCL COVID-19 IgG/IgM Rapid Gold	COV03 – 200421 COV03 – 200325 COV03 - 200318
14.	Oscar Medicare Pvt. Ltd., (Delhi) India	Rapid test - Corona Antibody (IgM/IgG)	COV-D005 COV-D006 COV-D007
15.	Edinburgh Genetics, UK	Edinburgh Genetics COVID-19 Colloidal Gold Immunoassay Testing kit IgG / IgM combined	2000705A 2000652A 2000555A
16.	BioPanda Reagents, UK (Inbios (Delhi), India)	COVID-19 Rapid Test	NCP20042902 NCP20052204 NCP20051603
17.	Athenese-Dx Private Limited, Chennai (TamilNadu), India	TRUSTline COVID-19 Ab Rapid Test	F1708202 F1708203 F1708204
18.	Beijing Zhangjian Antai Diagnostic Technology, China (Aura Medical Devices Pvt. Ltd.)	Corona virus (COVID-19) Rapid Test	20200401 20200303
19.	Zephyr Biomedicals (A Division of Tulip Diagnostics Pvt. Ltd.)	Rapid Test for detection of IgM and IgG antibodies	ZRD/20/K-26 ZRD/20/K-25
20.	Oscar Medicare Pvt Ltd., (Delhi) India	Corona IgG Ab detection Test (OSCOVID-IgG)	CIG-D001 CIG-D002 CIG-D003
21.	Zephyr Biomedicals (A Division of Tulip Diagnostics Pvt. Ltd.)	IgG Covimmuno Device	ZRD/20/K-50 ZRD/20/K-51
22.	Edge Pharma Pvt. Ltd., Mumbai (Maharashtra), India	EdgeXpress Covid-19 Ab detection Test Kit (IgG/IgM)	ELRDCO0004 ELRDCO0005 ELRDCO0006
23.	Advy Chemicals Pvt. Ltd.	EzDx™ Covid-19 IgG/IgM Rapid Antibody Test	RD-COV 01/0920 RD-COV 02/0920 RD-COV 03/0920
24.	Oscar Medicare Pvt. Ltd.	Optra Shield COVID-19 (IgG) Rapid Test Kit	OSC-G001 OSC-G002 OSC-G003



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25.	Premier Medical Corporation Private Ltd., Valsad (Gujarat), India	Sure Status COVID-19 IgG/IgM Card Test	96I0420S 96I0520S 96I0620S
26.	Diagnocure, Solan (HP), India	Xamin COVID-19 Rapid Test Device	DI/COVG/401 DI/COVG/402 DI/COVG/403
#27.	Guangzhou Wondfo Biotech M R Roofs Private Ltd Abbott Laboratories Zydus Cadilla	SARS-CoV-2 Antibody test (Lateral flow method)	W19500309 W19500302 W19500351 W19500338
#28.	Zhuhai Livzon Diagnostics (CE- IVD)	COVID-19 IgM/IgG Antibody Rapid Test	CK2003010410
##29.	BioMedomics (CE-IVD), China	Biomedomics COVID-19 IgM IgG Rapid Test	20200226
##30.	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 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.