



Date: 04.09.2020

## 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.
- 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, 142 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.	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.	Guangzhou Wondfo Biotech M R Roofs Private Ltd Abbott Laboratories Zydus Cadilla	SARS-CoV-2 Antibody test (Lateral flow method)	W19500309 W19500302 W19500351 W19500338
#21.	Zhuhai Livzon Diagnostics (CE-IVD)	COVID-19 IgM/IgG Antibody Rapid Test	CK2003010410
##22.	BioMedomics (CE-IVD), China	Biomedomics COVID-19 IgM IgG Rapid Test	20200226
##23.	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.