

## List of Rapid Antigen Test Kits approved for testing of Covid-19

**Date: 31.03.2022**

<b>S. No.</b>	<b>Name of the Firm</b>	<b>Type of Kit</b>	<b>Country</b>	<b>Remarks</b>
1.	M/s. S D Biosensor Healthcare Pvt Ltd, Haryana	Standard Q COVID-19Ag	Indigenous	Sample drawn
2.	M/s. Lab Care Diag. India Pvt Ltd	COVID-19 Antigen Lateral Flow Test Device	Indigenous	Sample drawn
3.	M/s. Vishat Diag. Pvt Ltd	COVID-19 Ag Respi-Strip	M/S CorisBioconcept, Belgium	Sample drawn
4.	M/s. Tulip Diag. Pvt Ltd	Double Antigen Screening Test	Indigenous	
5.	M/s Triviron Healthcare	Biocard Pro Covid-19 Antigen test	Indigenous	Sample drawn
6.	M/s Vishat Diagnostic Pvt Ltd, Pune	GenBody COVID-19 Ag	M/s GenBody Inc, South Korea.	Sample drawn
7.	M/s Fitcare Private Limited, Assam.	COVID-19 Antigen Rapid Test	M/s Genbody Inc, South Korea	
8.	M/s Angstrom Biotech Pvt. Ltd, Haryana	COVID 19 ANTIGEN KIT	Indigenous	Sample drawn
9.	M/s. Premier Medical Corporation Private Limited, Gujarat.	COVID-19 Antigen Card Test	Indigenous	
10.	M/s Meril Diagnostics Private Limited, Gujarat	COVID-19 Antigen Detection Test Kit (MERISCREEN)	Indigenous	
11.	M/s Ubio Biotechnology Systems Private Limited, Kerala.	COVID-19 Ag Test	Indigenous	
12.	M/s Oscar Medicare Private Limited, Delhi	Corona Antigen test	Indigenous	
13.	M/s Alpine Biomedicals Private Limited, Haryana	Alpine One Step Novel Coronavirus (COVID-19) Antigen Rapid Test Kit	Indigenous	
14.	M/s Alere Medical Private Limited, Haryana	Panbio™ COVID-19 Ag Rapid Test Device (Nasopharyngeal)	M/s Abbott Diagnostics Korea Inc, South Korea	
15.	M/s. ZEPHYR BIOMEDICALS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED, Goa	Rapid test for detection of SARS-CoV-2 Antigen in human nasal swab (NS) and nasopharyngeal (NP) swab specimens ( PerkinElmer COVID-19 Antigen Test (NS, NP))	Indigenous	
16.	M/s Strumed Solutions Private Limited,	iNSTAXPLOR COVID 19 RAPID ANTIGEN	Indigenous	

	Chennai	TEST		
17.	M/s. Tricell Biologics Private Limited, Chennai	COVID-19 Antigen Rapid Test Kit	M/s Panion& BF Biotech Inc., Taiwan	
18.	M/s. Immunoscience India Private Limited, Pune	ImmunoQuickRapid Test for Detection of COVID-19 Antigen-Device	Indigenous	
19.	M/s. Ortho Clinical Diagnostics India Private Limited, Thane, Maharashtra	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	M/s Ortho Clinical Diagnostics Inc, USA	
20.	M/s ZEPHYR BIOMEDICALS A DIVISION OF TULIP DIAGNOSTICS PRIVATE LIMITED, Goa	COVIRAT - Rapid test for detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimens (Device)	Indigenous	
21.	M/s Advy Chemical Pvt Ltd, Mumbai	EzDx Covid-19 Rapid Antigen test for the Qualitative detection of SARS-CoV-2 antigen from nasopharyngeal swab Specimen	Indigenous	
22.	M/s. Ortho Clinical Diagnostics India Private Limited, Mumbai	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	M/s Ortho Clinical Diagnostics, UK	
23.	M/s Roche Diagnostics India Pvt. Ltd., Mumbai	SARS-CoV-2 Rapid Antigen Test	M/s SD Biosensor, South Korea	
24.	M/s Sidak Life Care Pvt Ltd, New Delhi	Antigen Test Kit (COVID 19)	Indigenous	
25.	M/s PREMIER MEDICAL CORPORATION, PRIVATE LIMITED, Gujarat	COVID-19 Antigen Card Test (NC/PC) - Sure Status	Indigenous	
26.		COVID-19 Antigen Card Test (Home Test) - Sure Status	Indigenous	
27.	M/s Meril Diagnostics Private Limited, Gujarat	COVID-19 Antigen Detection Test( <b>EVO</b> ) <b>(Additional brand)</b>	Indigenous	
28.		COVID-19 Antigen Detection Test <b>(MERISCREEN PLUS)</b>	Indigenous	
29.	M/s Biofootprints Healthcare Pvt Ltd, New Delhi	Mytest COVID-19 Ag Test Kit	Indigenous	
30.	M/s Diagnocure India, Baddi, Solan	XAMIN COVID-19 Ag Rapid Test Device	Indigenous	
31.	M/s Oscar Medicare Private Limited, Haridwar, Uttarakhand (India)	OSCAR Corona Antigen Test	Indigenous	
32.	M/s. Meril Diagnostics Private Limited,	Meril COVID-19 antigen detection test (FIA)	Indigenous	

	Gujarat			
33.	M/s Medzome Life Sciencez Private Limited, New Delhi	FutureCare COVID-19 Antigen Detection Kit	Indigenous	
34.	M/s Roche Diagnostics India Pvt. Ltd, Mumbai	SARS-CoV-2 Rapid Antigen Test Nasal	M/s SD Biosensor, South Korea.	
35.	M/s Roche Diagnostics India Pvt. Ltd, Mumbai	Elecsys SARS-CoV-2 Antigen (ECLIA)	M/s Roche Diagnostics GmbH, Germany	
36.	M/s Alere Medical Private Limited, Rewari, Haryana	Panbio™ COVID-19 Ag Rapid Test Device (Nasal)	M/s Abbott Diagnostics Korea Inc, South Korea	
37.	M/s M/s Athenese -Dx Private Limited, Chennai	TRUSTline COVID-19 Ag Rapid Test	Indigenous	
38.	M/s Becton Dickinson India Private Limited, Chennai	BD Veritor System For Rapid Detection of SARS-CoV-2 Antigen (chromatographic digital immunoassay)	M/s BD Rapid Diagnostics (Suzhou) Co. Ltd., China	
39.	M/s Becton Dickinson India Private Limited, Chennai	BD Veritor System For Rapid Detection of SARS-CoV-2 (Model no. 256082)	M/s BD Rapid Diagnostics (Suzhou) Co. Ltd, China	
40.	M/s. Peerless Biotech Pvt. Ltd. Chennai	Flowflex SARS-CoV-2 Antigen Rapid Test	M/s Acon Biotech (Hangzhou) Co. Ltd., China.	
41.	M/s QIAGEN India Pvt. Ltd, Delhi	mo-screen Corona Antigen Test	M/s Zhejiang Orient Gene Biotech Co., Ltd, China	
42.	M/s SNIBE DIAGNOSTIC (India) Private Limited, Gurgaon	MAGLUMI SARS-CoV-2 Ag (CLIA)	M/s Shenzhen New Industries Biomedical Engineering Co., Ltd., China	
43.	M/s Imperial Life Sciences Pvt. Ltd, Gurgaon, Haryana	BIOCREDIT COVID-19 Ag	M/s RapiGEN INC., South Korea	
44.	M/s Becton Dickinson India Private Limited, Chennai	BD Kit for Rapid Detection of SARS-CoV-2 Antigen	M/s BD Rapid Diagnostics (Suzhou) Co. Ltd., China	
45.	M/s Biolab Diagnostics India Pvt. Ltd, Mumbai	Rapid diagnostics kit for Covid 19 Antigen	Indigenous	
46.	M/s Weldon Biotech India Pvt. Ltd, Delhi	Ichroma COVID-19 Ag	M/s Boditech Med Inc., South Korea	
47.	M/s Nulife, Noida	AbChek Covid-19 Antigen Rapid test kit	Indigenous	
48.	M/s Agappe Diagnostics Ltd. Kerala	AG-Q COVID-19 N Antigen Rapid Diagnostic Test Kit	Indigenous	
49.	M/s Biotime Healthcare Pvt Ltd, Ahmedabad, Gujarat	Vazyme Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV-2) Antigen	M/s Nanjing Vazyme Medical Technology Co., Ltd, China	
50.	M/s YUVRAJ BIOBIZ INCUBATOR INDIA	YBIO COVID19 AG TEST	Indigenous	

	PRIVATE LIMITED, Chennai			
51.	M/s TCM Limited, Kerala	fluorecare SARS-CoV-2 Spike Protein Test Kit (Colloidal Gold Chromatographic Immunoassay)	M/s Shenzhen Microprofit Biotech Co. Ltd., China	
52.	M/s Diagnostic Enterprises, HP	COVID 19 ANTIGEN CARD	Indigenous	
53.	M/s Dia Sure Immunodiagnostic LLP, Delhi	DSI Rapid Antigen Test for Novel Corona Virus (nCOVID-19)	Indigenous	
54.	M/s. Ortho Clinical Diagnostics India Private Limited, Mumbai	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack	M/s Ortho Clinical Diagnostics, UK	
55.	M/s Matrix Labs, Chennai	Finecare™ 2019-nCoV Antigen Test	M/s GUANGZHOU WONDFO BIOTECH CO. LTD, China	
56.	M/s BIODX HEALTHCARE, New Delhi	SARS-CoV-2 Antigen Assay Kit (Colloidal Gold Method)	M/s Zybio Inc, China	
57.	M/s INVEX HEALTH PRIVATE LIMITED, MP	Wondfo2019- nCoV Antigen Test	M/s Guangzhou Wondfo Biotech Co, Ltd., China	
58.	M/s POCT Services Private Limited, New Delhi	FlowflexSars-COV-2 Antigen Rapid Test	M/s Acon Biotech (Hangzhou) Co. Ltd. China	
59.	M/s DEEP MEDITECH PVT. LTD, New Delhi	Flowflex Sars-COV-2 Antigen Rapid Test	M/s Acon Biotech (Hangzhou) Co., Ltd., China	
60.	M/s Regulatory1, Bengaluru	SARS-CoV-2 Antigen Test Kit (LFIA)	M/s Jiangsu Medomics Medical Technology Co. Ltd, China	
61.	M/s Viola Diagnostic Systems - A Division Of Tulip Diagnostics Private Limited,, PANTNAGAR, Uttarakhand	Rapid test for detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimens (Device)	Indigenous	
62.	M/s Vishat Diagnostic Pvt Ltd, Mumbai	All TestCOVID-19 Antigen Rapid Test	M/s Hangzhou AllTest Biotech Co., Ltd., China	
63.	M/s Viola Diagnostic Systems - A Division Of Tulip Diagnostics Private Limited,, PANTNAGAR, Uttarakhand	Rapid test for detection of SARS-CoV-2 Antigen in human nasopharyngeal swab specimens (Device)	Indigenous	
64.	M/s Vishat Diagnostic Pvt Ltd, Mumbai	All Test COVID-19 Antigen Rapid Test	M/s Hangzhou AllTest Biotech Co., Ltd., China	
65.	M/s Excel Global Health, Karnataka	V-Strip COVID-19 Rapid Antigen Test Kit	M/s Panion & BF Biotech Inc., Taiwan	

66.	M/s PATHKITS HEALTHCARE PRIVATE LIMITED, Haryana	COVID-19 Ag Rapid Test	Indigenous	
67.	M/s Cadila Healthcare Limited, Gujarat	SARS CoV-2 Antigen Rapid Test	Indigenous	
68.	M/s GENES 2ME PVT. LTD, Delhi	RapiCov Rapid Antigen Test Kit for COVID-19	Indigenous	
69.	M/s Becton Dickinson India Private Limited, Chennai	BD Veritor System For Rapid Detection of SARS-CoV-2 (Model no. 256089)	M/s BD Rapid Diagnostics (Suzhou) Co. Ltd, China	
70.	M/s Meril Diagnostics Private Limited, Gujarat	CoviFind Covid-19 Antigen Test	Indigenous	
71.	M/s Parekh Integrated Services Pvt. Ltd, Rewari, Haryana	QuickVue® SARS Antigen Test	M/s QUIDEL CORPORATION, California, USA.	
72.	M/s Parekh Integrated Services Pvt. Ltd, Rewari, Haryana	LumiraDx SARS-CoV-2 Ag Test Strip Kit	M/s LumiraDx UK Ltd., UK	
73.	M/s Oscar Medicare Private Limited, Delhi	identi SARS-CoV-2 Rapid Antigen Test	Indigenous	
74.	M/s Selo HealthCare Pvt Ltd, Mumbai	INSTA COVID Antigen Rapid Test	Indigenous	
75.	M/s SD Biosensor Healthcare Pvt. Ltd, Gurgaon, Haryana	ULTRA COVID-19 Ag One Step COVID-19 Antigen Test (Additional Brand)	Indigenous	
76.	M/s Transasia Bio-Medicals Ltd, Mumbai	EbraQik COVID-19 Antigen Test Card	Indigenous	
77.	M/s PATANJALI PHARMA PRIVATE LIMITED, Mumbai	Cov Ant One Step Covid-19 Antigen Test	Indigenous	
78.	M/s. NeoDx Biotech Labs Pvt Ltd, Bengaluru	Cassette - SARS-CoV-2 Antigen Test	M/s. ACON Biotech (Hangzhou) Co., Ltd., China	
79.	M/s. POLY MEDICURE LIMITED, Faridabad, Haryana (India).	One step COVID-19 Antigen detection test device	Indigenous	
80.	M/s KOSH BIO PRIVATE LIMITED, Delhi (India) - 110065	SARS-CoV-2: Rapid Antigen Test	Indigenous	
81.	M/s LORVEN BIOLOGICS PRIVATE LIMITED, Hyderabad	Lorven Antigen Rapid Detection Test Kit	Indigenous	
82.	M/s J. MITRA & CO. PVT. LTD., A - 180 / 181, Delhi (India) - 110020	COVID 19 Ag Card	Indigenous	
83.	M/S Boditech Med India Private Limited, Mumbai	AFIAS COVID-19 Ag (FIA)	M/s Boditech Med Inc, South korea	

84.	M/s Mylab Discovery SOLUTIONS Pvt. Ltd, Pune	PathoCatch™, Gazelle™ COVID-19 FIA Ag Test Kit	Indigenous	
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**Covid 19 Antigen Home Test / Self-Test Kits**

S. No.	Name of the Firm	Type of Kit	Country	Remarks
1.	M/s MYLAB DISCOVERY SOLUTION PVT. LTD, Pune	COVID-19 ANTIGEN LATERAL FLOW TEST DEVICE OTC HOME TEST	Indigenous	2 sites approved
2.	M/s Meril Diagnostics Private Limited, Gujarat	Covid-19 Antigen Self Test	Indigenous	
3.	M/s Alere Medical Private Limited, Haryana	Panbio COVID-19 Antigen Self Test	M/s Abbott Diagnostics Korea Inc, South Korea	
4.	M/s Nulife, Uttar Pradesh (India) - 201301	Home Test -Covid-19 Antigen Rapid kit	Indigenous	
5.	M/s SD Biosensor Healthcare Pvt.Ltd, Haryana	ULTRA Covi-Catch , One Step COVID-19 Antigen Test (Self Test)	Indigenous	
6.	M/s Angstrom Biotech Pvt. Ltd., Alwar, Rajasthan (India) - 301019	ANG CARD COVID - 19 Antigen - <b>Saliva</b> (Self Test Kit)	Indigenous	
7.	M/s SD Biosensor Healthcare Pvt. Ltd, Haryana (India)	COVID-19 At-Home Test <b>(Additional brand)</b>	Indigenous	
8.	M/s Siemens Healthcare Private Limited, Gurgaon.	CLINITEST® Rapid COVID- 19 Antigen Self-Test	M/s Healgen Scientific Limited Liability Company, USA @ : M/s Zhejiang Orient Gene Biotech Co.,Ltd, China	
9.	M/s Roche Diagnostics India Private Limited @ M/s SD Biosensor Healthcare Pvt. Ltd, Gurgaon, Haryana	COVID-19 At Home Test	Indigenous	
10.	M/s Tata Medical And Diagnostics Limited at NuLife, UP	TATA MD CHECK COVID-19 Antigen Self-Test Kit	Indigenous	
11.	M/s. Zephyr Biomedicals A Division Of Tulip Diagnostics Private Limited, Goa	COVIRAT Rapid test for detection of SARS-CoV-2 Antigen in Human Nasal Swab Specimen at Home	Indigenous	

		(Device)		
12.	M/s Genes2Me Private Limited, Haryana (India) - 122001	CoviEasy COVID-19 Rapid Antigen Self Test	Indigenous	
13.	M/s Premier Medical Corporation Private Limited, Gujarat.	Sure Status® COVID-19 Antigen Card Test (Home Test)	Indigenous	

Based on the ICMR validation reports and documents as per Medical Device Rules 2017, the number of diagnostic kits meant for Covid-19 approved as under as on **31.03.2022**.

<b>Rapid/ Elisa / CLIA (Serology based)</b>	<b>RT-PCR (Molecular based )</b>	<b>Antigen Test</b>	<b>Antigen Home Test / Self Test</b>
155	260	84	13
Import - 96	Import - 160	Import - 37	Import-02
Indigenous -59	Indigenous -100	Indigenous – 47	Indigenous - 11



