

कल्याण मंत्रालय, भारत सरकार

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

Date: 28.06.2021

Rapid Antigen Test Kits for COVID-19 (Oropharyngeal / Nasopharyngeal swabs)

Please Note:

- Below listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency does not lies with ICMR.
- Minimum acceptance criteria of sensitivity and specificity of Rapid Ag Test Kits:
 - Validated as a Point of Care Test (POCT) without transport to a laboratory setup-Sensitivity: 50% and above; Specificity: 95% and above
 - Validated in a laboratory setup with samples collected in Viral Transport Medium (VTM)-Sensitivity: 70% and above; Specificity: 99% and above
- Antigen based rapid tests which are US-FDA approved can be used directly after due marketing approval from DCGI.

<u>Till date, 118 Antigen based Rapid Test Kits have been validated (including 26 revalidated</u> Kits), and the following are found to be satisfactory

Individual validation reports of the below listed kits can be shared with the State Governments on request. Request may be sent at <u>drneetu.vijay@icmr.gov.in</u>

S. No	Name of company	Name of the kit	Lot no. / Batch No.	Sample used for validation
1.	SD Biosensor, South Korea / India	STANDARD Q COVID-19 Ag	E055003	Nasopharyngeal swab
2.	LabCare Diagnostics Ltd.,	Accucare COVID-19 Antigen	CVG200601	Oropharyngeal and
	Valsad (Gujarat), India	Lateral Test Device	CVG200602	Nasopharyngeal
	(Supplied by MyLab Discovery Solutions)		CVG200603	swabs
3.	Trivitron Healthcare Pvt.	BIOCARD Pro COVID-19	COVPGL-001	Nasopharyngeal
	Ltd., Chennai (TN), India	Rapid Ag test kit	COVPGL-002	swab
			COVPGL-003	
4.	Coris Bioconcept, Belgium	[#] COVID-19 Ag Respi Strip	43242F2003	#Oropharyngeal
		(VTM)	43512G2030	swab in VTM
			43464G2016	
5.	Panion & BF Biotech.,	VSTRIP COVID-19 Antigen	IG10020S-R2004	Nasopharyngeal
	Taiwan	Rapid Test	IG10020S-R2005	swab
	(Supplied by Tricell Biologics, Chennai)		IG10020S-R2006	
6.	PCL Inc, South Korea	PCL COVID-19 Rapid FIA	2005K104	Nasopharyngeal
	,	•	2005K105	swab
			2005K106	
7.	Premier Medical	Sure status COVID-19 Ag	9710120S	Nasopharyngeal
	Corporation, Valsad	Test (CIPtest COVID-19	9710220S	swab
	(Gujarat), India (Supplied by Cipla Itd.)	Antigen Card Test)	97103205	

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S. No	Name of company	Name of the kit	Lot no. / Batch No.	Sample used for validation
8.	Angstrom Biotech Pvt.	Angcard COVID-19 rapid	BCOVA03	Nasopharyngeal
	Ltd., Alwar (Rajasthan),	Antigen Test kit	BCOVA04	and
	India	•		Oropharyngeal
			BCOVA06	swabs
9.	GenBody Inc.,		FMFC20201	Nasopharyngeal
	South Korea	GenBody COVID-19 Ag	FMFC16201	swab
		rapid Test kit (POCT)	FMFC02201	
10.	Ubio Biotechnology		SO64012010	Nasopharyngeal
	Systems Pvt. Ltd., Kochin	SENSIT Rapid COVID-19	SO64012011	swab
	(Kerala), India	Ag kit	SO64012012	
11.	Meril Diagnostics, Vapi		MRD131	Nasopharyngeal
	(Gujarat), India	COVID-19 Antigen	MRD132	swab
		Detection Test	MRD133	
12.	Alpine Biomedicals Pvt.		LCOVG-010820	Nasopharyngeal
	Ltd., Ambala (Haryana),	Alpine COVID-19 Antigen	LCOVG-020820	swab
	India	Rapid Test kit	LCOVG-030820	
13.	SD Biosensor, South	*Standard F COVID-19 Ag	FCO302010128	Nasopharyngeal
	Korea	FIA Test	FCO302010129	swab
		Analyser: STANDARD	FCO302009259	
		F2400		
14.	Oscar Medicare Pvt. Ltd.,		D004	Nasopharyngeal
	Delhi, India	Oscar CORONA Rapid Ag	D005	swab
		Test kit	D006	
15.	ImmunoScience India	ImmunoQuick COVID-19	E146001	Nasopharyngeal
	Pvt. Ltd., Pune	Antigen Rapid Card test	E146002	swab
	(Maharshtra), India	kit	E146003	
16.	STRUmed Solutions Pvt.		001	Nasopharyngeal
	Ltd., Chennai	iNSTAXPLOR™ COVID-19	002	swab
	(TamilNadu), India	Ag – Rapid Antigen Test	003	
17.	Abbott Rapid Diagnostics		41ADF039A	Nasopharyngeal
	Division, Chicago		41ADF036A	swab
	, 0	Panbio Covid Antigen	41ADF037A	
		Rapid Test		
18.	ADVY Chemical Pvt. Ltd.,		01/1220	Nasopharyngeal
	Thane (Maharashtra),		02/1220	swab
	India	EzDx COVID-19 Rapid Ag	03/1220	
		Test		
19.	Ortho Clinical	^{\$} Vitros SARS-CoV-2 Ag	0050	Nasopharyngeal
	Diagnostics, Mumbai	Test CLIA Kit	0051	swab in VTM
	(Maharashtra), India	Vitros 3600	0052	

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S. No	Name of company	Name of the kit	Lot no. / Batch No.	Sample used for
				validation
20.	Sri Sathya Sai Institute of	SAIC-19 Ag Kit	LORCAG1120A	Nasopharyngeal
	Higher Learning,	LORCAG1120B		swab
	Anantpur (Andhra		LORCAG1120C	
	Pradesh), India			
21.	Medzome Lifesciences	FutureCare COVID-19 Ag	MZCDA00120	Nasopharyngeal
	Pvt. Ltd., Solan	detection Test kit	MZCDA00220	swab
	(Himachal Pradesh),		MZCDA00320B	
	India			
22.	Pathkits Healthcare Pvt.	Pathkits SIMPLE COVID-19	RK/CO/AG/11/20/01	Nasopharyngeal
	Ltd., Gurugram	Ag Rapid Test	RK/CO/AG/11/20/02	swab
	(Haryana), India		RK/CO/AG/11/20/03	
23.	Biofootprints Healthcare	MyTest COVID-19 Ag Test	MT057001	Nasopharyngeal
	Pvt. Ltd.		MT057002	swab
			MT057003	
24.	Zephyr Biomedicals		ZRD/20/K-64	Nasopharyngeal
	(Tulip Diagnostics) Goa,	CoviRAT COVID-19 Rapid	ZRD/20/K-65	swab
	India	Antigen Test kit	ZRD/20/K-66	
25.	Meril Diagnostics Pvt.	Covid-19 Antigen	MRD151	Nasopharyngeal
	Ltd., Vapi (Gujrat), India	Detection Test (FIA)	MRD152	swab
		Immunofluorescence	MRD153	
		Analyzer CHF200		
26.	Sidak Lifecare Pvt. Ltd.,	One Step novel corona	SLC_COAG_21/20	Nasopharyngeal
	Jhajjar (Hayana), India	virus (COVID-19) Antigen	SLC_COAG_22/20	swab
		Test Kit	SLC_COAG_23/20	
27.	Diagnocure (INDIA),	Xamin Covid-19 Ag Rapid	XCVG501	Nasopharyngeal
	Solan, HP	Test Device	XCVG502	swab
	,		XCVG503	
28.	Dia Sure	DSI COVID-19 Ag RAPID	CAG-E-001	Nasopharyngeal
	Immunodiagnostics LLP,	Test Kit	CAG-E-002	swab
	Delhi, India		CAG-E-003	
29.	Biolab Diagnostics India	Rapid Covid 19 Ag kit	9127T	Nasopharyngeal
	Pvt. Ltd., Mumbai		9120T	swab
	(Maharashtra), India		9133T	
30.	NextGen In Vitro	COVSCAN SARS-Co V-2	CVRA T022 1-01	Nasopharyngeal
	Diagnostics (P.) Limited.,	Antigen Detection kit	CVRA T022 1-02	swab
	Faridabad (Haryana),	, and gen Detection kit	CVRA T022 1-03	5000
	India			
31.	Oscar Medicare Pvt. Ltd.,	COVID-19 Antigen Card	CAG-H0004	Nasopharyngeal
51.	Haridwar (Uttarakhand),	Test	CAG-H0005	swab
	India	i CSC	CAG-H0005	5000
	india			
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32.	Agappe Diagnostic Pvt.	AG-Q COVID-19 N	R003001	Nasopharyngeal
	Ltd., Kerala	Antigen Rapid Diagnostic	R003002	swab
		Kit	R003003	
33.	Abbott Rapid Diagnostics	PanBio COVID-19 Antigen	41ADF315A	Nasal Swab
	Division, Chicago	Rapid Test Device	41ADF315A 41ADF317A	
	(Alere Medical Pvt. Ltd.)	(Home Test kit)		
34.	<mark>Athenese</mark> -Dx Private	TRUSTline COVID-19 Ag	RD1690C	Nasopharyngeal
	Limited, Chennai	Rapid Test	RD1691C	swab
			RD1692C	
35.	TaiDoc Technology	FORA [®] COVID-19 Antigen	20J005-0000	Nasopharyngeal
	Corporation, Taiwan	Rapid Test	20J122-0000 swab	
			20J129-0000	
36.	YuvRaj Biobiz Incubator	YBIO Rapid Test COVID-	L20CV01	Nasopharyngeal
	India Pvt. Ltd.	19 Ag Test kit	L20CV02	swab
			L20CV03	
		-TM		
37.	Mylab Discovery	CoviSelf [™]	AG00003-A-0421001E	Nasal swab
	Solutions Ltd., Pune	(PathoCatch) COVID-19	AG00003-A-0421002E	
	(Maharashtra), India	OTC Antigen LF device	AG00003-A-0421003E	
		(Home Test kit)		
38.	Patanjali Pharma Pvt.		CPAG1400	Nasopharyngeal
	Ltd., (IIT Mumbai), India	One step COVID-19	CPAG1401	swab
	Antigen detection		CPAG1402	
		(Cov-Ant)		
39.	SD Biosensor, Korea	SARS-CoV-2 Rapid Ag Test	QC03810411	Nasal Swab
	(Supplied by Roche	(Nasal)	QC03810471	
	Diagnostics)		QC03810521	
40.	Diagnostic Enterprises	COVID-19 Antigen Card	AGC-122001	Nasopharyngeal
	Parwanoo (Himachal		AGC-122022	swab
	Pradesh), India		AGC- 122003	
41.	NuLifecare, Noida (Uttar	Nulife COVID-19 Ag Rapid	COV/AG/RND01	Nasopharyngeal
	Pradesh), India	Test Device	COV/AG/RND02	swab
			COV/AG/RND03	
			E010/0000	
42.	J. Mitra Co. Ltd.,	ELISA based COVID-19 MICROLISA SARS-	ECA010820	Nasopharyngeal
	Bengaluru (Karnataka), India	CoV-2 detection kit	ECA020820	swab in VTM
	maia	Cov-2 detection kit	ECA030820	



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S. No	Name of company	Name of the kit	Lot no. / Batch No.	Sample used for
				validation
43.	Cadila Healthcare Pvt.	COVID-19 Antigen Rapid	RCNAG25-001	Nasopharyngeal
	Ltd., Ahmedabad	Test	RCNAG25-002	swab
	(Gujarat), India		RCNAG25-003	
44.	Seloi Healthcare Pvt.	INSTA COVID-19 Ag One	COR21001	Nasopharyngeal
	Ltd, Mumbai	Step SARS-CoV-2 Antigen	COR21002	swab
	(Maharashtra), India	Rapid Test	COR21003	

^{\$}Guidance for use is placed at **Annexure I**

*Guidance for use is placed at Annexure II

[#]Guidance for use is placed at Annexure III

List of Rapid Ag Test kits validated and not approved is placed at Annexure IV



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Annexure I

Guidance for use of VITROS[®] SARS CoV2 Antigen CLIA based Test from Ortho Clinical Diagnostics

- The VITROS[®] SARS CoV2 Antigen assay is a chemiluminescent immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal (NP) specimens from individuals who are suspected of COVID-19 within one to five days of the onset of symptoms, or mid-turbinate specimens collected from asymptomatic individuals.
- 2. The assay should be performed in VITROS[®] 3600 Immunodiagnostics system or VITROS[®] 5600 / VITROS[®] XT 7600 Integrated system from Ortho.

VITROS SARS CoV2 antigen assay - Procedural Steps: -

Stage 1: Nasopharyngeal swab specimen collection:

- 1. Collect a nasopharyngeal swab specimen by inserting the sterile swab into the nostril.
- 2. Push the sterile swab until resistance is met at the level of the turbinate.
- 3. Rotate the sterile swab several times against the nasopharyngeal wall & leave in the place for 10 seconds to saturate the swab tip.
- 4. Remove the swab from the nostril carefully.
- 5. Place the swab specimen into the viral transport medium buffer tube and close the tube tightly.
- 6. Transport the swab sample in VTM to the laboratory in cold chain.
- 7. The sample can be stored in the Room temperature (Below 30°C) up to 24 hrs from the time of sample collection or at 2 8°C for up to 48 hrs from the time of sample collection.

Stage 2: Sample preparation for testing:

- 1. Sample preparation needs to be performed in BSL-2 level cabinet in the Laboratory.
- 2. Mix the swab specimen in VTM tube well (vortex approximately 3-5 seconds).
- 3. Transfer 100 µL VITROS[®] SARS-CoV-2 Antigen Extraction Buffer into a labelled new sample tube.
- 4. Add 400 μL viral sample to the above tube (to maintain 1:4 ratio of extraction buffer: sample)
- 5. Mix well (Cap/Plug the sample tube and vortex approximately 3-5 seconds)

Stage 3: Sample processing in VITROS[®] systems:

- 1. Place/load the prepared/extracted sample tube in stage 2, after de-capping on to the VITROS[®] instrument V3600/V5600/XT7600; An amount of 80 μL of extracted sample is used for each determination.
- 2. Program VITROS 3600 / VITROS 5600 / VITROS XT 7600 system to process the samples for CV2Ag. The system can used to program test either in a STAT/Random/Batch mode.
- 3. System processes the samples automatically using disposable VersaTips for both sample as well as reagents to prevent any cross-contamination. The results will be delivered in 48 minutes after sample aspiration, in the form of S/Co value.



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Record and interpret the results as follows:

Results are automatically calculated by the VITROS Immunodiagnostic and VITROS Integrated Systems.

Result = <u>
Signal of Cutoff (Cutoff Value)</u>

Interpretation of Results: Sample results will be displayed with a numerical signal to cutoff (S/C) value and a "Non-reactive" (negative) or "Reactive" (positive) label.

Results (S/C)	< 1.00	≥ 1.00
Result Text	Non-reactive (negative)	Reactive (positive)

Signal to cutoff numerical values will increase as the amount of SARS-CoV-2 antigen present in the sample increases.

General Guidance:

- It is recommended that the test should be performed as per latest ICMR guidelines for COVID-19 testing and manufacturer's IFU (instructions for use)
- Samples may be stored at \leq -20 °C and may be subjected to 5 freeze-thaw cycles.
- VITROS[®] SARS CoV2 antigen assay is to be used for the qualitative detection of SARS-CoV-2 antigens from nasopharyngeal or mid-turbinate swab specimens only. The nasal and saliva samples are not yet validated.
- Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The test can detect both viable and non-viable SARS CoV2 antigenic material.
- A false negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore a negative test result does not eliminate the possibility of SARS CoV2 infection. Individuals with CT values greater than or equal to 34 are unlikely to have replication competent virus.
- Negative results from patients with symptom onset outside of one to five days of symptom onset should be treated as presumptive.
- The sensitivity/antigen detection ability of the VITROS[®] SARS CoV2 antigen assay may vary depending upon the quality of the VTM buffer used for sample collection. The five validated VTM are 1. CDC formulation based VTM, 2. COPAN (BD) UTM, 3. NewProv VTM, 4. Hardy VTM, & 5. Remel M4RT VTM. Labs using other VTM/UTM are directed to validate the compatibility internally with the VITROS[®] CLIA antigen assay, before delivering patient results.



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Annexure II

Guidance for use of Standard F covid-19 Ag FIA Test (SD Biosensor)

Brief SOP for the Standard F COVID-19 Ag Test:

- 1. STANDARD F COVID-19 Ag FIA is a Europium based fluorescent immunoassay for the qualitative detection of the specific nucleocapsid protein antigen from SARS- CoV-2 in nasopharyngeal swab specimen. STANDARD F COVID-19 Ag FIA should be used with Standard F analysers (F100, F200, F2400) manufactured by SD Biosensor.
- 2. The Kit Contents are the Test Device, Specimen Extraction Buffer Tube, Sterile Swab for sample collection, Nozzle Cap & Instructions for Use

Standard F COVID-19 Ag FIA Procedural Steps: -Stage 1: preparing the specimen

- 1. To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril
- 2. Using the gentle rotation, push the sterile swab until resistance is met at the level of the turbinate
- 3. Rotate the sterile swab several times against the nasopharyngeal wall & leave in the place for 10 seconds to saturate the swab tip
- 4. Remove the swab from the nostril carefully
- 5. Repeat the above procedure in the other nostril
- 6. Place the swab specimen into the buffer tube. While squeezing the buffer tube, stir the swab more than 10 times. This buffer inactivates the virus thereby reducing the biosafety & biosecurity requirements.
- 7. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab
- 8. Press the nozzle cap tightly onto the buffer tube

Stage 2.1: Performing the Test (READ ONLY MODE)

- 1. Prepare the test devices depending on the workload
- 2. Prepare Extracted Specimens in the buffer tubes
- 3. Mark the Test Cartridges as per specimen application plan (from 1, 2, 3 ... and patient ID)
- 4. Apply 4 drops of extracted specimen to the specimen well of the test device as per above sequence at about 20 seconds intervals
- 5. Leave the test device for 15 minutes on a flat surface for incubation
- 6. Prepare F100 or F200 analyser & select the READ ONLY MODE as per user manual
- 7. Insert the test device into the analyser which has completed incubation duration
- 8. Select the specimen type
- 9. The analyser will automatically scan & display the results in 1 minute after specimen type selection.



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Stage 2.2: Performing the Test (STANDARD MODE)

- 1. Choose Standard Test Mode & Insert the Test Device when prompted
- 2. Apply 4 drops of extracted specimen to the Specimen well of the test deice
- 3. After applying the specimen, immediately press 'TEST START' button
- 4. The analyser will automatically display the result after 15 minutes

General guidance:

- Specimen may be stored at room temperature for up to 30 minutes 1 hour in the buffer tube
- Result Time for COVID-19 Ag FIA on Standard F analyzer system under READ ONLY MODE is 1 minute only after completing an incubation for 15 minutes
- Sample should be collected from both the nostrils
- Print out can be taken within 10 seconds after getting the result on the analyzer screen
- Patient ID can be written on the test cartridges for record keeping
- Print Results could be used further for reporting to ICMR or State Governments as per their statutory requirement
- Memory 5,000 results in F2400, 3,000 results in F200 & 1,000 results in F100 could be stored for later reference & analysis
- Data Transfer The data stored in the analyzers could be transferred over LIS & HIS interfaces in F2400 & F200 analyzers and could be made available easily for clinical decision making
- It is recommended that the test should be performed onsite under strict medical supervision, following proper COVID-19 testing guidelines & maintaining the kit temperature between 2^o to 30^oC.



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Annexure III

Guidance for use of COVID-19 Ag Respi-Strip (CorisBioConcept)

*COVID-19 Ag Respi-Strip (Coris BioConcept) involves a different methodology of testing as compared to the other two antigen testing kits approved by ICMR till now. This test cannot be performed bedside and requires a BSL-2 set-up for running the test.

Brief methodology of use of COVID-19 Ag Respi-Strip (CorisBioConcept):

- 1. The Nasopharyngeal and/or Oropharyngeal swab will be collected from COVID-19 suspect patient in Viral Transport Medium (VTM).
- 2. The collected swab in VTM will be brought to the laboratory in appropriate cold chain conditions.
- 3. Once the sample is brought to the laboratory, it will need to be handled in a BSL-2 level cabinet for aliquoting, putting in lysis buffer and loading the test strip.
 - Steps 1 & 2 will be performed as per the standard practice followed for collection and transport of samples for COVID-19 RT-PCR test.
 - Step 3 will need to be performed as per manufacturers' instructions given with the test kit.

Differences between COVID-19 Ag Respi-Strip (CorisBioConcept) and other antigen test kits approved by ICMR are as follows:

COVID-19 Ag Respi-Strip (Coris BioConcept)	Other approved Ag Assays
Cannot be employed as a point of care test	Can be employed as a point of care test
Test kit does not have a sample collection swab	Test kit has a sample collection swab
Nasopharyngeal and/or Oropharyngeal swab in VTM should be used.	STANDARD Q COVID-19 Ag kit and BIOCARD Pro COVID- 19: Only nasopharyngeal swab should be used. For COVID-19 Antigen Lateral test device: Throat/nasal/nasopharyngeal swab can be used.
Sample has to be collected using the standard swab provided with VTM. Once collected, the sample needs to be put into the VTM tube.	Sample needs to be collected using the swab provided with the kit. Once collected the swab needs to be directly put into the extraction buffer (in tube) provided in the kit which inactivates the virus. The swab needs to be stirred and squeezed (about 5 times) to extract the sample.
The collected sample needs to be transported into a BSL-2 lab in cold chain conditions	No transport to a BSL-2 lab is required as this is a point of care test.
100 μl of the VTM sample needs to be added to the dilution buffer in a test tube provided with the kit.	The extracted sample should be shaken and 2-3 drops to be added to the well of the lateral flow strip.



Read results in 15 mins or earlier after insertion	For STANDARD Q COVID-19 Ag: Results should be read
of strip into tube containing sample and dilution	between 15-30 mins.
buffer. The strip should be discarded after 15	For COVID-19 Antigen Lateral test device: results should
minutes.	be read within 15-20 minutes.
Control line may not appear in a positive test.	Control line must appear for the test to be valid.
Storage temperature: 4-30°C	Storage temperature: 2-30°C



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Annexure IV

List of Rapid Ag Test kits validated, and Not Approved

S. No	Name of Company	Name of Kit	India/ Other countries	Name of the supplier
1.	Bhat Bio-Tech India, Bangalore	COVID-19 Antigen Rapid Card Test	India	Invex Health, Mumbai India
2.	POCT Services Pvt Ltd.	Q-Line Rapid COVID-19 Rapid Antigen Test	India	POCT Services Pvt Ltd
3.	HLL Lifecare Ltd	Makesure Covid-19 Antigen Rapid Card	India	HLL Lifecare Ltd
4.	Formosa Biomedical Technology Corp.	Formosa One Sure SARS-COV-2 Ag rapid Test Kit	Taiwan	Intai Lifesciences LLP, India
5.	Rapigen Inc	Biocredit COVID-19 Ag	South Korea	Imperial Life Sciences, Gurgaon
6.	Camtech Diagnostics	Camtech COVID-19 rapid Antigen Test	Singapore	Althea Pharma Pvt. Ltd, Mumbai
7.	M/s Medsource Ozone Biomedicals Pvt Ltd.	COVID-19 Antigen Rapid Test	India	M/s Medsource Ozone Biomedicals Pvt Ltd.
8.	Aspen Laboratories Ltd.	ASPEN COVID antigen rapid test	India	Aspen Laboratories Ltd., Delhi
9.	Genuine Biosystem Private Limited	GB QUIK Covid-19 Rapid Antigen test Kit	India	Genuine Biosystem Private Limited
10.	GenBody Inc.	GenBody COVID-19 Ag rapid Test kit (VTM)	South Korea	Vishat Diagnostics Pvt. Ltd, Mumbai
11.	ScheBo BioTech Netanyastr.2	ScheBo SARS-CoV-2 Antigen ELISA	Germany	GastroLab India Pvt. Ltd.
12.	ManKind Pharma	Rapid Point of Care COVID-19 Ag detection kit	India	ManKind Pharma
13.	Genes2Me	VIRALSCREEN COVID- 19 Rapid Antigen Test Kit	India	Genes2Me
14.	ImmunoScience India Pvt. Ltd.	Immuno Quick COVID- 19 Ag Test Kit (Dipstick)	India	ImmunoScience India Pvt. Ltd.
15.	J. Mitra & Co. Pvt. Ltd., Bangalore	COVID-19 Antigen Dot Test	India	J. Mitra & Co. Pvt. Ltd., Bangalore
16.	Shanghai Liangrun Biomedical Technology Co. Ltd, China	LionRun SARS-CoV 2 Ag	China	Shanghai Liangrun Biomedical Technology Co. Ltd, China

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S. No	Name of Company	Name of Kit	India/ Other countries	Name of the supplier
17.	Voxtur Bio Ltd., India	VOXPRESS COVID-19	India	Voxtur Bio Ltd., India
17.		Ag rapid test	mula	
18.	Genomic Diagnostics, USA	COVID-19 viral Ag Test kit	USA	Genomic Diagnostics, USA
19.	Salofa Oy	SARS-CoV-2 Antigen quantitative assay kit (Enzyme-linked immunoassay)	Finland	MODILIFE Kesha Sales Private Limited, India
20.	TaiDoc Tech Coorporation, Taiwan	V TRUST Covid-19 Antigen Rapid Test	Taiwan	UR DISTREE PVT LTD., India
21.	M/s Metadesign Solutions Pvt. Ltd., Gurugram (Haryana), India	PK COVID-19 Ag Rapid Detection kit	India	M/s Metadesign Solutions Pvt. Ltd., Gurugram (Haryana), India
22.	Mediforce Healthcare Pvt. Ltd., Merrut (Uttar Pradesh), India	MediCheck COVID-19 Antigen Test	India	Mediforce Healthcare Pvt. Ltd., Merrut (Uttar Pradesh), India
23.	VanGuard Diagnostics Pvt. Ltd., Delhi, India	VDx COVID-19 Rapid Antigen Test	India	VanGuard Diagnostics Pvt. Ltd., Delhi, India
24.	Corios Bioconcept, Belgium	COVID-19 Ag Respi- Striip (POCT)	Belgium	Vishat Diagnostics Pvt. Ltd, Mumbai
25.	NDFOS Co. Ltd., Seoul, Korea	ND COVID-19 Ag Test Strip	Korea	Life Technologies (India) Pvt. Ltd.
26.	Bioline Diagnostics LLP, Delhi, India	SARS-CoV2 Antigen Lateral Flow Assay	India	Bioline Diagnostics LLP, Delhi, India
27.	Kilpest India Ltd., Bhopal (Madhya Pradesh), India	TRURAPID COVID-19 Ag Test	India	Kilpest India Ltd., Bhopal (Madhya Pradesh), India
28.	Calth Inc., Republic of Korea	LabGun COVID-19 Rapid Ag kit	Republic of Korea	Siemens Healthcare Pvt. Ltd., India
29.	Humasis Co. Ltd., South Korea	Humasis COVID-19 Ag Test	S Korea	MT Promedt Consulting, Germany
30.	Karwa Enterprises Pvt. Ltd., India	COVID-19 Antigen Rapid Test Cassette	India	Karwa Enterprises Pvt. Ltd.
31.	J. Mitra & Co. Pvt. Ltd.,	COVID-19 Ag Card Test	India	J. Mitra & Co. Pvt. Ltd., Bangalore



S. No	Name of Company	Name of Kit	India/ Other countries	Name of the supplier
	Bangalore			
32.	M/S Biocan Diagnostics Inc., Canada	Tell Me FAST COVID-19 Ag Test	Canada	M/S Biocan Diagnostics Inc., Canada
33.	MyLab Discovery Solutions	MyLab PathoCatch SARS-CoV-2 Ag FIA test kit	India	MyLab Discovery Solutions
34.	Mediclone Biotech Pvt. Ltd, Chennai	@sight COVID-19 Antigen Test kit	India	<mark>Mediclone</mark> Biotech Pvt. Ltd, Chennai
35.	Capital Health Services India Private Limited, Hyderabad	Capital IHF COVIDAG 2019-nCOV RBD	India	<mark>Capital</mark> Health Services India Private Limited, Hyderabad
36.	Dynamed Equipments, Chennai	C19 Antigen Test Kit	India	<mark>Dynamed Equipments, Chennai</mark>
37.	Pentavalent BioSciences Pvt. Ltd., Bengaluru, Karnataka	Pentascan COVID-19 Ag Rapid Test kit	India	Pentavalent BioSciences Pvt. Ltd., Bengaluru, Karnataka
38.	Oscar Medicare Pvt. Ltd., Delhi, India	Oskit Corona Antigen FIA-R Test	India	Oscar Medicare Pvt. Ltd., Delhi, India
39.	Avecon Healthcare Pvt. Ltd.	MAXLINE COVID-19 Antigen Test	India	Avecon Heathcare Pvt. Ltd.
40.	Edge Pharma Pvt. Ltd.	EdgeXpress COVID-19 Antigen Detection Test	India	Edge Pharma Pvt. Ltd.
41.	Karwa Enterprises Pvt. Ltd., India	SARS-COV 2 Rapid Antigen Test (N protein)	India	Karwa Enterprises Pvt. Ltd., India
42.	Bioline Diagnostics LLP, New Delhi	FIRSTVIEW COVID-19 Ag FIA Test Device	India	Bioline Diagnostics LLP, New Delhi
43.	<mark>Sensiva Health LLP.,</mark> USA	Sensiva Health Rapid Ag Test kit	USA	<mark>Sensiva Health LLP., USA</mark>
44.	Astam Diagnostics Pvt. Ltd.	One Step COVID-19 Ag Test	India	Astam Diagnostics Pvt. Ltd.
45.	M/s Prantae Solutions Pvt. Ltd	ELISA based EyeRa SARS-CoV-2 Ag Detection kit-on beads Ag detection	India	M/s Prantae Solutions Pvt. Ltd
46.	Achira Labs Pvt Ltd, Benguluru	Achira COVID-19 Rapid Ag Test Kit	India	Achira Labs Pvt Ltd, Benguluru
47.	Promea Therapeutics Pvt. Ltd.	Proflow Covid 19 antigen test kit	India	Promea Therapeutics Pvt. Ltd.



S. No	Name of Company	Name of Kit	India/ Other countries	Name of the supplier
48.	M/s <mark>Standard</mark> Analytic		India	M/s <mark>Standard Analytical</mark> Laborato
	al			ry (ND) Pvt. Ltd
	Laboratory (ND) Pvt.	Novel corona virus		
	Ltd.	(Ncovid-19) Certiquick		