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: 05/04/2021

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.

Till date, 83 Antigen based Rapid Test Kits have been validated (including 14 revalidated Kits), and the following are found to be satisfactory

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., Valsad (Gujarat), India (Supplied by MyLab Discovery Solutions)	Accucare COVID-19 Antigen Lateral Test Device	CVG200601 CVG200602 CVG200603	Oropharyngeal and Nasopharyngeal swabs
3.	Trivitron Healthcare Pvt. Ltd., Chennai (TN), India	BIOCARD Pro COVID-19 Rapid Ag test kit	COVPGL-001 COVPGL-002 COVPGL-003	Nasopharyngeal swab
4.	Coris Bioconcept, Belgium	#COVID-19 Ag Respi Strip (VTM)	43242F2003 43512G2030 43464G2016	#Oropharyngeal swab in VTM
5.	Panion & BF Biotech., Taiwan	VSTRIP COVID-19 Antigen Rapid Test	IG10020S-R2004 IG10020S-R2005 IG10020S-R2006	Nasopharyngeal swab
6.	PCL Inc, South Korea	PCL COVID-19 Rapid FIA	2005K104 2005K105 2005K106	Nasopharyngeal swab
7.	Premier Medical Corporation, Valsad (Gujarat), India (Supplied by Cipla ltd.)	Sure status COVID-19 Ag Test (CIPtest COVID-19 Antigen Card Test)	9710120S 9710220S 9710320S	Nasopharyngeal swab

S. No	Name of company	Name of the kit	Lot no. / Batch No.	Sample used for validation
8.	Angstrom Biotech Pvt. Ltd., Alwar (Rajasthan), India	Angcard COVID-19 rapid Antigen Test kit	BCOVA03 BCOVA04 BCOVA05 BCOVA06	Nasopharyngeal and Oropharyngeal swabs
9.	GenBody Inc., South Korea	GenBody COVID-19 Ag rapid Test kit (POCT)	FMFC20201 FMFC16201 FMFC02201	Nasopharyngeal swab
10.	Ubio Biotechnology Systems Pvt. Ltd., Kochin (Kerala), India	SENSIT Rapid COVID-19 Ag kit	SO64012010 SO64012011 SO64012012	Nasopharyngeal swab
11.	Meril Diagnostics, Vapi (Gujarat), India	COVID-19 Antigen Detection Test	MRD131 MRD132 MRD133	Nasopharyngeal swab
12.	Alpine Biomedicals Pvt. Ltd., Ambala (Haryana), India	Alpine COVID-19 Antigen Rapid Test kit	LCOVG-010820 LCOVG-020820 LCOVG-030820	Nasopharyngeal swab
13.	SD Biosensor, South Korea	*Standard F COVID-19 Ag FIA Test Analyser: STANDARD F2400	FCO302010128 FCO302010129 FCO302009259	Nasopharyngeal swab
14.	Oscar Medicare Pvt. Ltd., Delhi, India	Oscar CORONA Rapid Ag Test kit	D004 D005 D006	Nasopharyngeal swab
15.	ImmunoScience India Pvt. Ltd., Pune (Maharshtra), India	ImmunoQuick COVID-19 Antigen Rapid Card test kit	E146001 E146002 E146003	Nasopharyngeal swab
16.	STRUmed Solutions Pvt. Ltd., Chennai (TamilNadu), India	iNSTAXPLOR™ COVID-19 Ag – Rapid Antigen Test	001 002 003	Nasopharyngeal swab
17.	Abbott Rapid Diagnostics Division, Chicago	Panbio Covid Antigen Rapid Test	41ADF039A 41ADF036A 41ADF037A	Nasopharyngeal swab
18.	ADVY Chemical Pvt. Ltd., Thane (Maharashtra), India	EzDx COVID-19 Rapid Ag Test	01/1220 02/1220 03/1220	Nasopharyngeal swab
19.	Ortho Clinical Diagnostics, Mumbai (Maharashtra), India	$Vitros SARS-CoV-2 Ag Test CLIA Kit Vitros 3600	0050 0051 0052	Nasopharyngeal swab in VTM

S. No	Name of company	Name of the kit	Lot no. / Batch No.	Sample used for validation
20.	Sri Sathya Sai Institute of Higher Learning, Anantpur (Andhra Pradesh), India	SAIC-19 Ag Kit	LORCAG1120A LORCAG1120B LORCAG1120C	Nasopharyngeal swab
21.	Medzome Lifesciences Pvt. Ltd., Solan (Himachal Pradesh), India	FutureCare COVID-19 Ag detection Test kit	MZCDA00120 MZCDA00220 MZCDA00320B	Nasopharyngeal swab
22.	Pathkits Healthcare Pvt. Ltd., Gurugram (Haryana), India	Pathkits SIMPLE COVID-19 Ag Rapid Test	RK/CO/AG/11/20/01 RK/CO/AG/11/20/02 RK/CO/AG/11/20/03	Nasopharyngeal swab
23.	Biofootprints Healthcare Pvt. Ltd.	MyTest COVID-19 Ag Test	MT057001 MT057002 MT057003	Nasopharyngeal swab
24.	Zephyr Biomedicals (Tulip Diagnostics) Goa, India	CoviRAT COVID-19 Rapid Antigen Test kit	ZRD/20/K-64 ZRD/20/K-65 ZRD/20/K-66	Nasopharyngeal swab
25.	Meril Diagnostics Pvt. Ltd., Vapi (Gujrat), India	Covid-19 Antigen Detection Test (FIA) Immunofluorescence Analyzer CHF200	MRD151 MRD152 MRD153	Nasopharyngeal swab
26.	Sidak Lifecare Pvt. Ltd., Jhajjar (Hayana), India	One Step novel corona virus (COVID-19) Antigen Test Kit	SLC_COAG_21/20 SLC_COAG_22/20 SLC_COAG_23/20	Nasopharyngeal swab

$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**
Individual validation reports of the above listed kits can be shared with the State Governments on request. Request may be sent at drneetu.vijay@icmr.gov.in

Annexure I

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

1. 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.

Record and interpret the results as follows:

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

Result = $\frac{Signal\ of\ test\ sample}{Signal\ of\ Cutoff\ (Cutoff\ Value)}$

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 ≤-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.

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.

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^{O}C.

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 of strip into tube containing sample and dilution buffer. The strip should be discarded after 15 minutes.	For STANDARD Q COVID-19 Ag: Results should be read between 15-30 mins. For COVID-19 Antigen Lateral test device: results should 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

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.	Agappe Diagnostics, Kochi	AAG Q COVID-19 N-Antigen rapid test	India	Agappe Diagnostics, Kochi
5.	Formosa Biomedical Technology Corp.	Formosa One Sure SARS-COV-2 Ag rapid Test Kit	Taiwan	Intai Lifesciences LLP, India
6.	Rapigen Inc	Biocredit COVID-19 Ag	South Korea	Imperial Life Sciences, Gurgaon
7.	Camtech Diagnostics	Camtech COVID-19 rapid Antigen Test	Singapore	Althea Pharma Pvt. Ltd, Mumbai
8.	M/s Medsource Ozone Biomedicals Pvt Ltd.	COVID-19 Antigen Rapid Test	India	M/s Medsource Ozone Biomedicals Pvt Ltd.
9.	Aspen Laboratories Ltd.	ASPEN COVID antigen rapid test	India	Aspen Laboratories Ltd., Delhi
10.	Genuine Biosystem Private Limited	GB QUIK Covid-19 Rapid Antigen test Kit	India	Genuine Biosystem Private Limited
11.	GenBody Inc.	GenBody COVID-19 Ag rapid Test kit (VTM)	South Korea	Vishat Diagnostics Pvt. Ltd, Mumbai
12.	ScheBo BioTech Netanyastr.2	ScheBo SARS-CoV-2 Antigen ELISA	Germany	GastroLab India Pvt. Ltd.
13.	ManKind Pharma	Rapid Point of Care COVID-19 Ag detection kit	India	ManKind Pharma
14.	Athenese DX Pvt. Ltd., Chennai	TRUSTline COVID-19 Rapid Test Kit	India	Athenese DX Pvt. Ltd., Chennai
15.	Seloi Healthcare Pvt. Ltd.	Insta COVID-19 Ag one step SARS-CoV2 rapid test	India	Seloi Healthcare Pvt. Ltd.
16.	Genes2Me	VIRALSCREEN COVID-19 Rapid Antigen Test Kit	India	Genes2Me
17.	ImmunoScience India Pvt. Ltd.	Immuno Quick COVID-19 Ag Test Kit (Dipstick)	India	ImmunoScience India Pvt. Ltd.
18.	J. Mitra & Co. Pvt. Ltd., Bangalore	COVID-19 Antigen Dot Test	India	J. Mitra & Co. Pvt. Ltd., Bangalore

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

S. No	Name of Company	Name of Kit	India/ Other countries	Name of the supplier
33.	Oscar Medicare Pvt. Ltd., Haridwar (Uttarakhand), India (Manufacturing Unit 2)	Oscar CORONA Rapid Ag Test kit-V.1	India	Oscar Medicare Pvt. Ltd., India
34.	Karwa Enterprises Pvt. Ltd., India	COVID-19 Antigen Rapid Test Cassette	India	Karwa Enterprises Pvt. Ltd.
35.	J. Mitra & Co. Pvt. Ltd., Bangalore	COVID-19 Ag Card Test	India	J. Mitra & Co. Pvt. Ltd., Bangalore
36.	M/S Biocan Diagnostics Inc., Canada	Tell Me FAST COVID-19 Ag Test	Canada	M/S Biocan Diagnostics Inc., Canada
37.	MyLab Discovery Solutions	MyLab PathoCatch SARS-CoV-2 Ag FIA test kit	India	MyLab Discovery Solutions
38.	Mediclone Biotech Pvt. Ltd, Chennai	@sight COVID-19 Antigen Test kit	India	Mediclone Biotech Pvt. Ltd, Chennai
39.	Capital Health Services India Private Limited, Hyderabad	Capital IHF COVIDAG 2019-nCOV RBD	India	Capital Health Services India Private Limited, Hyderabad
40.	Dynamed Equipments, Chennai	C19 Antigen Test Kit	India	Dynamed Equipments, Chennai
41.	Pentavalent BioSciences Pvt. Ltd., Bengaluru, Karnataka	Pentascan COVID-19 Ag Rapid Test kit	India	Pentavalent BioSciences Pvt. Ltd., Bengaluru, Karnataka
42.	Oscar Medicare Pvt. Ltd., Delhi, India	Oskit Corona Antigen FIA-R Test	India	Oscar Medicare Pvt. Ltd., Delhi, India
43.	Avecon Heathcare Pvt. Ltd.	MAXLINE COVID-19 Antigen Test	India	Avecon Heathcare Pvt. Ltd.