



Date: 26/08/2020

LIST OF COMPANIES / VENDORS OF ANTIGEN BASED TEST KITS FOR COVID-19 VALIDATED / BEING VALIDATED BY ICMR

S. No	Name of the kit	Name of company	India/ Other countries	Name of the supplier	Current status at validation centre
1.	STANDARD Q COVID-19 Ag	SD Biosensor	South Korea / India	SD Biosensor	Validated, Approved
2.	COVID-19 Antigen Lateral Test Device	LabCare Diagnostics Ltd.	India	MyLab Discovery Solutions	Validated, Approved
3.	*COVID-19 Ag Respi Strip	Coris Bioconcept	Belgium	Vishat Diagnostics Pvt. Ltd, Mumbai	Validated, Approved
4.	COVID-19 Antigen Rapid Card Test	Bhat Bio-Tech India, Bangalore	India	Invex Health, India	Validated, Not Approved
5.	COVID FIA Antigen Test	SD Biosensor	South Korea / India	SD Biosensor	Validated, Not Approved
6.	Q-Line Rapid COVID-19 Rapid Antigen Test	POCT Services Pvt Ltd.	India	POCT Services Pvt Ltd	Validated, Not Approved
7.	Makesure Covid-19 Antigen Rapid Card	HLL Lifecare Ltd	India	HLL Lifecare Ltd	Validated, Not Approved
8.	AAG Q COVID-19 N-Antigen rapid test	Agappe Diagnostics, Kochi	India	Agappe Diagnostics, Kochi	Validated, Not Approved
9.	Formosa One Sure SARS-COV-2 Ag rapid Test Kit	Formosa Biomedical Technology Corp.	Taiwan	Intai Lifesciences LLP, India	Validated, Not Approved
10.	Biocredit COVID-19 Ag	Rapigen Inc	South Korea	Imperial Life Sciences, Gurgaon	Validated, Not Approved
11.	Camtech COVID-19 rapid Antigen Test	Camtech Diagnostics	Singapore	Althea Pharma Pvt. Ltd, Mumbai	Validated, Not Approved
12.	Meriscreen COVID-19 Antigen detection test	Meril Diagnostics Pvt. Ltd	India	Meril Diagnostics Pvt. Ltd	Validated, Not Approved
13.	COVID-19 rapid Antigen Test kit	Angstrom Biotech Pvt. Ltd.	India	Angstrom Biotech Pvt. Ltd.	Validated, Not Approved
14.	COVID-19 Antigen	M/s Medsource Ozone	India	M/s Medsource	Validated,



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	Rapid Test	Biomedicals Pvt Ltd.		Ozone Biomedicals Pvt Ltd.	Not Approved
15.	ASPEN COVID antigen rapid test	Aspen Laboratories Ltd.	India	Aspen Laboratories Ltd., Delhi	Validated, Not Approved
16.	GB QUIK Covid-19 Rapid Antigen test Kit	Genuine Biosystem Private Limited	India	Genuine Biosystem Private Limited	Validated, Not Approved
17.	GenBody COVID-19 Ag rapid Test kit	GenBody Inc.	South Korea	Vishat Diagnostics Pvt. Ltd, Mumbai	Validated, Not Approved
18.	ScheBo SARS-CoV-2 Antigen ELISA	ScheBo BioTech Netanyastr.2	Germany	GastroLab India Pvt. Ltd.	Validated, Not Approved
19.	COVID-19 rapid Antigen Test kit	Oscar Medicare Pvt. Ltd.	India	Oscar Medicare Pvt. Ltd.	Validated, Not Approved
20.	V Strip COVID-19 Antigen rapid Test	Panion & BF Biotech, Taiwan	Taiwan	Tricell Biologics, Chennai	Under Validation
21.	CoviSaliva Antigen Test kit	Real-Time Analyzers Inc.,USA	USA	Lisaline Lifescience Technologies Pvt. Ltd., Thane	Under Validation
22.	TRUSTline COVID-19 Ag Rapid Test	Athenese-Dx Pvt. Ltd., Chennai	India	Athenese-Dx Pvt. Ltd., Chennai	Under Validation
23.	Antigen Detection rapid test for COVID 19	Ubio Biotechnology Systems Pvt Ltd, Kochin	India	Ubio Biotechnology Systems Pvt Ltd, Kochin	Under Validation

***Guidance for use is placed at Annexure I**



Annexure 1

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

ICMR has recently validated 13 COVID-19 antigen test kits. Of these, 3 kits have been approved for use till now:

1. STANDARD Q COVID-19 Ag of SD Biosensor
2. COVID-19 Antigen Lateral Test Device of Lab Care Diagnostics Ltd.
3. *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)	STANDARD Q COVID-19 Ag (SD Biosensor) & COVID-19 Antigen Lateral test Device (Lab Care Diagnostics Ltd)
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: Only nasopharyngeal swab should be used. For COVID-19 Antigen Lateral test device: Throat/nasal/nasopharyngeal swab can be used.



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Department of Health Research, Ministry of Health
and Family Welfare, Government of India

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