



Date: 22.10.2020

## Guidance on Rapid Antigen Test Kits for COVID-19

### Please Note:

- Below listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency does not lie 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, 37 ANTIGEN BASED RAPID TESTS KITS HAVE BEEN VALIDATED, 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)	COVID-19 Antigen Lateral Test Device	CVG200601 CVG200602 CVG200603	Oropharyngeal and Nasopharyngeal swabs
3.	Triviron 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	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	Sure status COVID-19 Ag Test	9710120S 9710220S 9710320S	Nasopharyngeal swab



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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. 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

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

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

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](mailto:drneetu.vijay@icmr.gov.in)



## Annexure I

### 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 extracted sample should be shaken and 2-3 drops to be added to the well of the lateral flow strip.



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<b>the kit.</b>	
<b>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.</b>	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.
<b>Control line may not appear in a positive test.</b>	Control line must appear for the test to be valid.
<b>Storage temperature: 4-30°C</b>	Storage temperature: 2-30°C



**Annexure II**

**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.	SD Biosensor	COVID FIA Antigen Test	South Korea / India	SD Biosensor
3.	POCT Services Pvt Ltd.	Q-Line Rapid COVID-19 Rapid Antigen Test <b>(Revalidated)</b>	India	POCT Services Pvt Ltd
4.	HLL Lifecare Ltd	Makesure Covid-19 Antigen Rapid Card <b>(Revalidated)</b>	India	HLL Lifecare Ltd
5.	Agappe Diagnostics, Kochi	AAG Q COVID-19 N-Antigen rapid test <b>(Revalidated)</b>	India	Agappe Diagnostics, Kochi
6.	Formosa Biomedical Technology Corp.	Formosa One Sure SARS-COV-2 Ag rapid Test Kit	Taiwan	Intai Lifesciences LLP, India
7.	Rapigen Inc	Biocredit COVID-19 Ag	South Korea	Imperial Life Sciences, Gurgaon
8.	Camtech Diagnostics	Camtech COVID-19 rapid Antigen Test	Singapore	Althea Pharma Pvt. Ltd, Mumbai
9.	Meril Diagnostics Pvt. Ltd	Meriscreen COVID-19 Antigen detection test	India	Meril Diagnostics Pvt. Ltd
10.	M/s Medsource Ozone Biomedicals Pvt Ltd.	COVID-19 Antigen Rapid Test	India	M/s Medsource Ozone Biomedicals Pvt Ltd.
11.	Aspen Laboratories Ltd.	ASPEN COVID antigen rapid test	India	Aspen Laboratories Ltd., Delhi
12.	Genuine Biosystem Private Limited	GB QUIK Covid-19 Rapid Antigen test Kit	India	Genuine Biosystem Private Limited
13.	GenBody Inc.	GenBody COVID-19 Ag rapid Test kit (VTM)	South Korea	Vishat Diagnostics Pvt. Ltd, Mumbai
14.	ScheBo BioTech Netanyastr.2	ScheBo SARS-CoV-2 Antigen ELISA	Germany	GastroLab India Pvt. Ltd.
15.	Oscar Medicare Pvt. Ltd.	COVID-19 rapid Antigen Test kit	India	Oscar Medicare Pvt. Ltd.
16.	ManKind Pharma	Rapid Point of Care COVID-19 Ag detection kit	India	ManKind Pharma



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S. No	Name of Company	Name of Kit	India/ Other countries	Name of the supplier
17.	Ubio Biotechnology Systems Pvt Ltd, Kochin	Antigen Detection rapid test for COVID 19	India	Ubio Biotechnology Systems Pvt Ltd, Kochin
18.	Abbott Rapid Diagnostics Division	Panbio Covid Antigen Rapid Test	Chicago	Alere Medical Pvt Ltd Gurgaon
19.	Athenese DX Pvt. Ltd., Chennai	TRUSTline COVID-19 Rapid Test Kit	India	Athenese DX Pvt. Ltd., Chennai
20.	Seloi Healthcare Pvt. Ltd.	Insta COVID-19 Ag one step SARS-CoV2 rapid test	India	Seloi Healthcare Pvt. Ltd.
21.	Real Time Analyzers Inc.	COVID-19 AG Saliva Test Kit	USA	Lisaline Lifesciences Technologies Pvt. Ltd.
22.	Genes2Me	VIRALSCREEN COVID-19 Rapid Antigen Test Kit	India	Genes2Me
23.	ImmunoScience India Pvt. Ltd.	Immuno Quick COVID-19 Ag Test Kit	India	ImmunoScience India Pvt. Ltd.
24.	Bhat Bio-Tech India (P) Ltd.	COVID-19 Antigen Rapid Card Test (ORAL SALIVA)	India	Invex Health, Mumbai India