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

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TILL DATE, 24 ANTIGEN BASED RAPID TESTS KITS HAVE BEEN VALIDATED, AND THE FOLLOWING ARE FOUND TO BE SATISFACTORY

S. No	Name of the kit	Name of company	Lot no. / Batch No.
1.	STANDARD Q COVID-19 Ag	SD Biosensor, South Korea / India	**E055003**
2.	COVID-19 Antigen Lateral Test Device	LabCare Diagnostics Ltd., India	**CVG200601** **CVG200602** **CVG200603**
3.	BIOCARD Pro COVID-19 Rapid Ag test kit	Trivitron Healthcare Pvt. Ltd., India	**COVPGL-001** **COVPGL-002** **COVPGL-003**
4.	***COVID-19 Ag Respi Strip**	Coris Bioconcept, Belgium	**43242F2003** **43512G2030** **43464G2016**

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

Please Note:

- **Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.**
- **Antigen based rapid tests which are US-FDA approved can be used directly after due marketing approval from DCGI.**

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.

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