Rapid Antigen test for SARS COV2

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

Advisory on Use of Rapid Antigen Detection Test for COVID-19

Dated: 14th June 2020

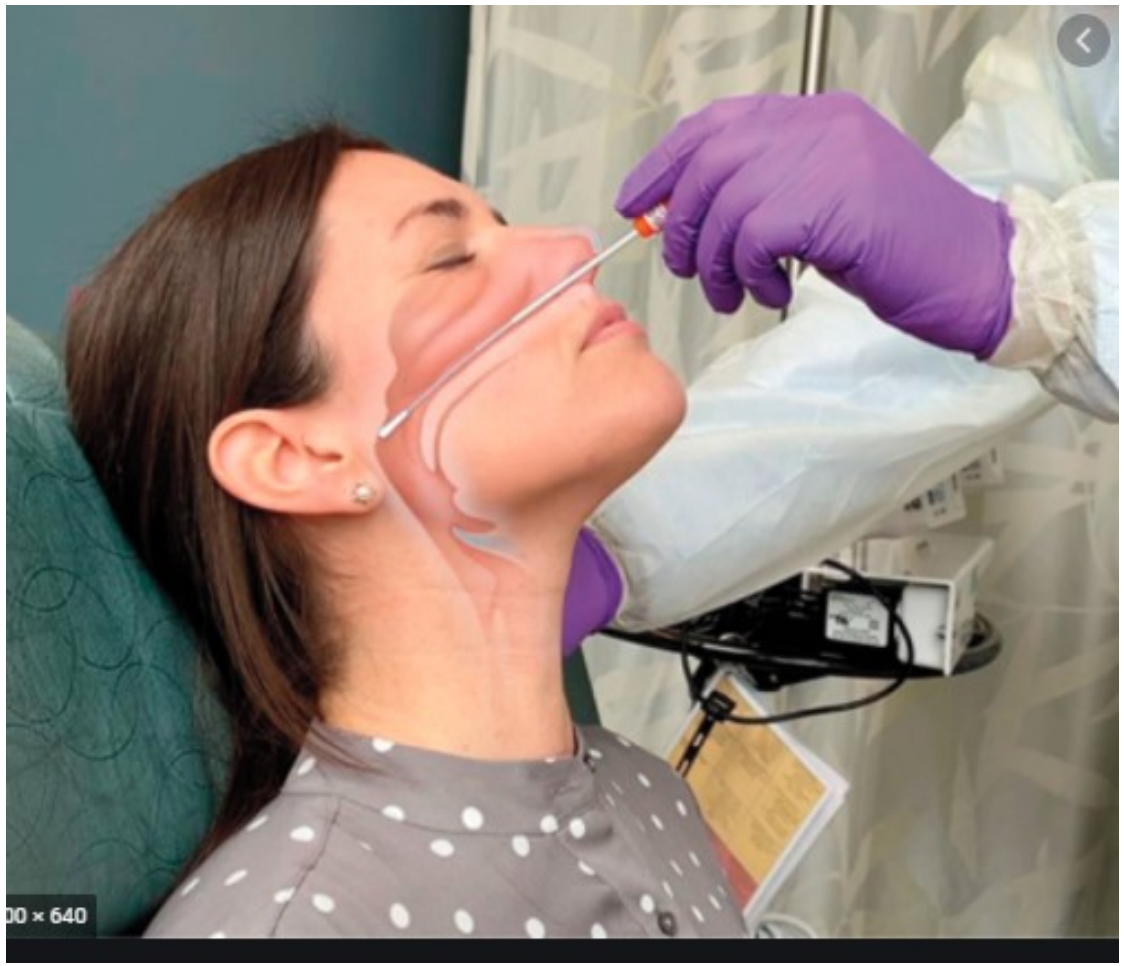
Background:

1. Real time RT-PCR is the gold standard frontline test for diagnosis of COVID19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for COVID19 diagnosis in India. All these platforms require specialized laboratory facilities in-terms of equipment, biosafety & biosecurity. Minimum time taken for the test varies between different systems with a minimum of 2-5 hours including the time taken for sample transportation. These specifications limit the widespread use of the RT-PCR test and also impedes quick augmentation of testing capacity in various containment zones and hospital settings.

2. In view of this, there is urgent need of a reliable point-of-care rapid antigen detection test with good sensitivity and specificity for early detection of the disease.

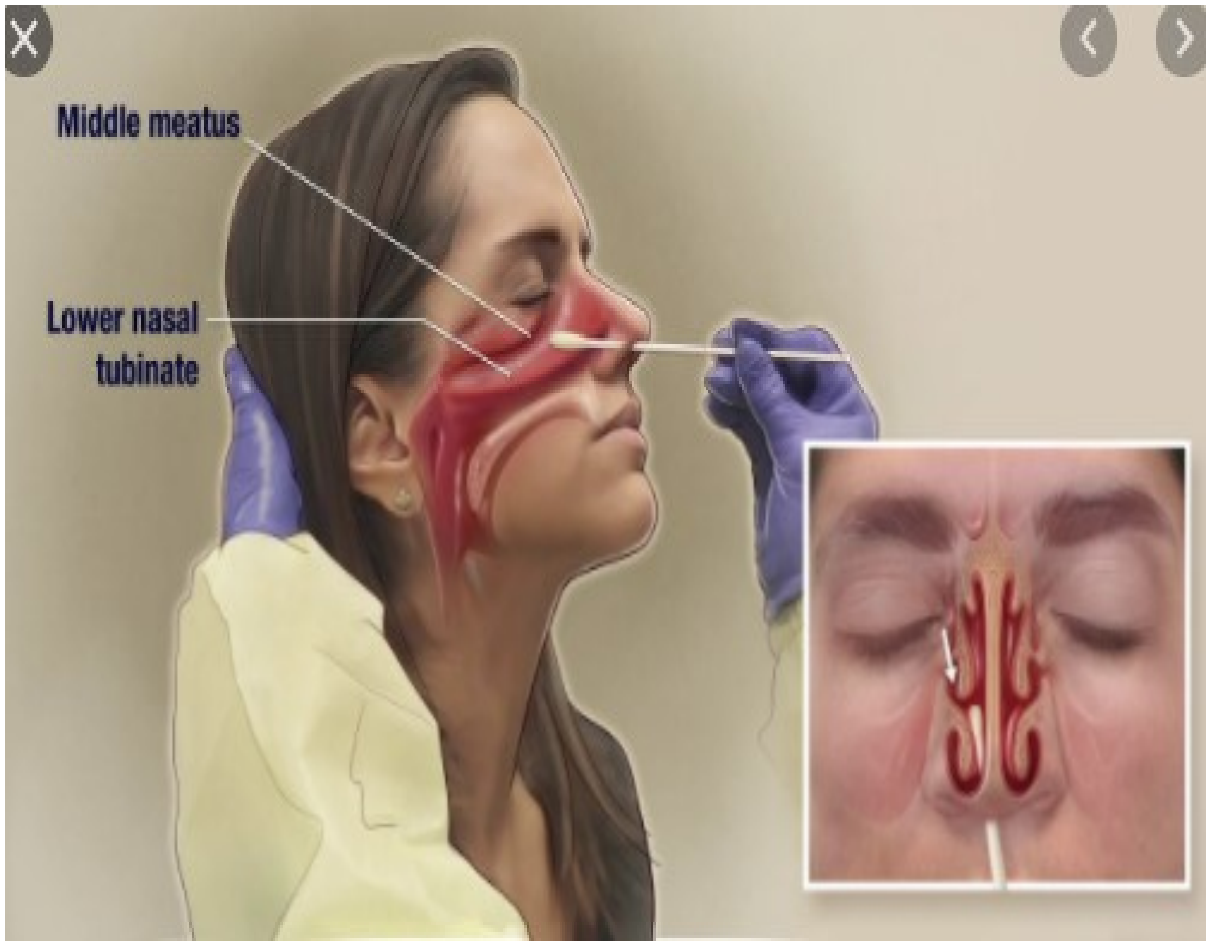
3. There are no reliable antigen detection tests available worldwide, which could be used as rapid point of care tests for quick detection of COVID-19 positive patients. Such tests would help in proper implementation of the Govt. strategy to test, track and treat. Such tests will also help in allaying the anxiety and fear of healthcare workers and aid in better clinical management of the patients. In view of this, an independent two site evaluation of the only available or stand-alone antigen detection assay available in India, **Standard Q COVID-19 Ag detection kit,** was conducted with an aim to evaluate its sensitivity, specificity and feasibility of use as a point-of-care test for early detection of SARS-CoV-2.

Sample Collection



Obtaining the Nasopharyngeal Swab Specimen.

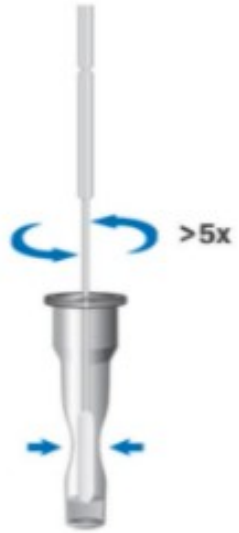
1. Insert the swab into the nostril, parallel to the palate.
2. If resistance is felt in the passage of the swab, reinsertion is advised at a different angle, closer to the floor of the nasal canal.
3. The swab should reach a depth equal to the distance from the nostrils to the outer opening of the ear.
4. The swab is left in place for several seconds to absorb secretions and then slowly removed while rotating it



1. Patient's head is tilted back at 70 degrees.
2. Swab is inserted and gently rotated, less than one inch (about 2 cm) into nostril parallel to the palate (not upwards) until resistance is met at turbinates.
3. The swab is rotated several times against nasal wall and this is repeated in other nostril using the same swab.

Obtaining the Nasal Swab Specimen.

SAMPLE PREPARATION



2a. Preparing a sample

Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.

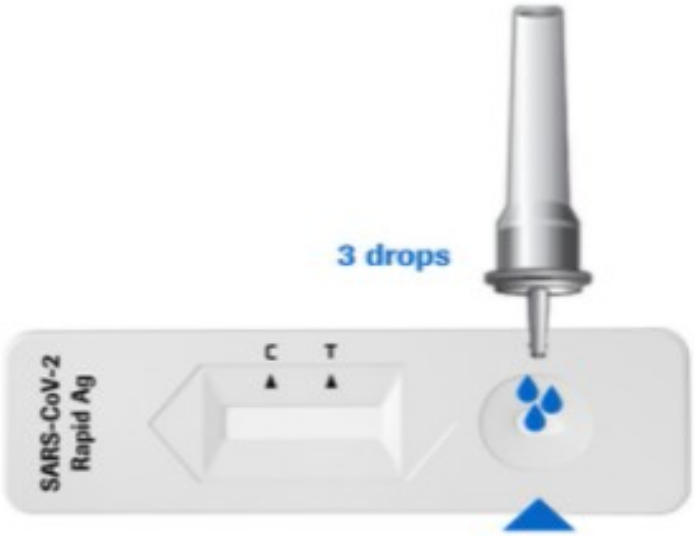
2b. Preparing a sample

Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

2c. Preparing a sample

Press the nozzle cap tightly onto the tube. Continue with 3a. Performing a test.

PERFORMING A TEST



3a. Performing a test

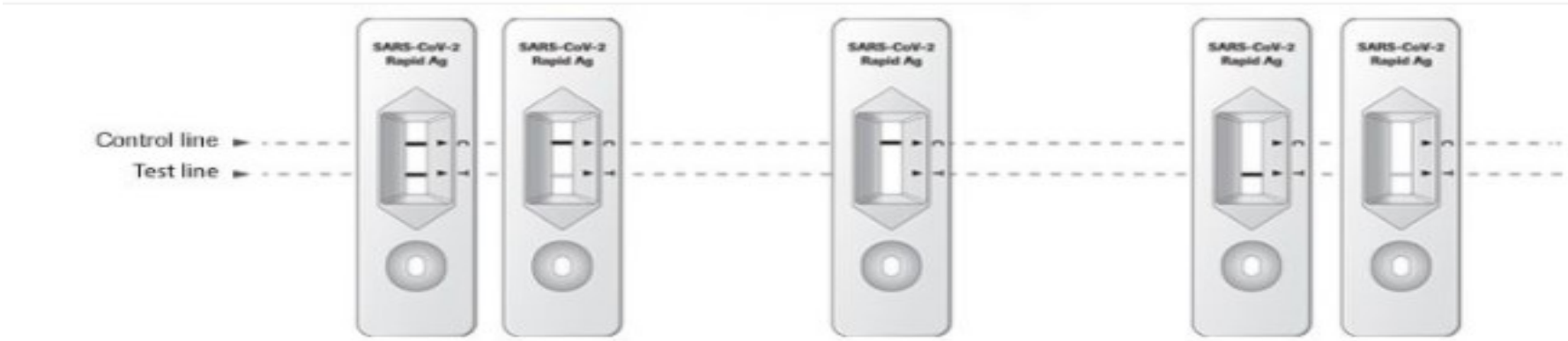
Apply 3 drops of extracted sample to the specimen well of the test device.

3b. Performing a test

Read the test result at 15 to 30 min.

Warning: Risk of incorrect results. Do not read the test result after 30 min.

RESULT INTERPRETATION

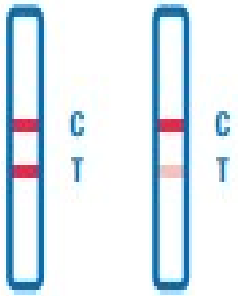


4. Interpreting results

A colored line appears in the top section of the result window to show that the test is working properly. This is the control line (C). Even if the control line is faint, the test should be considered to have been performed properly. If no control line is visible the test is invalid.

In case of a positive result, a colored line appears in the lower section of the result window. This is the test line (T). Even if the test line is very faint or not uniform, the test result should be interpreted as a positive result.

Positive

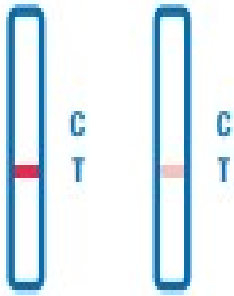


In case of a positive* result, a colored test line T appears in the lower section of the result window. Even if the test line is very faint or not uniform the test result should be interpreted as a positive result.

Negative

In case of a negative** result, only the control line C appears.

Invalid



If no control line C is visible, the test is always invalid.

* *Positive results should not be used as a sole basis for treatment or patient management decisions, and should be considered in the context of the patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.*

** *A negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or a molecular assay or ELISA, if necessary for patient management.*

All testing results using the standard q covid-19 ag detection assay must essentially be entered on the icmr covid-19 portal and also communicated to the state authorities and officials of the integrated disease surveillance programme (idsp) on a real-time basis

Annexure I

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^{O}C.

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

Date: 18.11.2020

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, 50 Antigen based Rapid Test Kits have been validated (including 10 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)	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	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
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

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

#Guidance for use is placed at **Annexure II**

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

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

क्रमांक प.7(92)(02)/.../ .../ .../ 20/ ...

जिला कलेक्टर (समस्त)
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विषयः– कोविड–19 की जॉच हेतु रेपिड ऐन्टीजन टेस्ट के उपयोग के संबंध में।

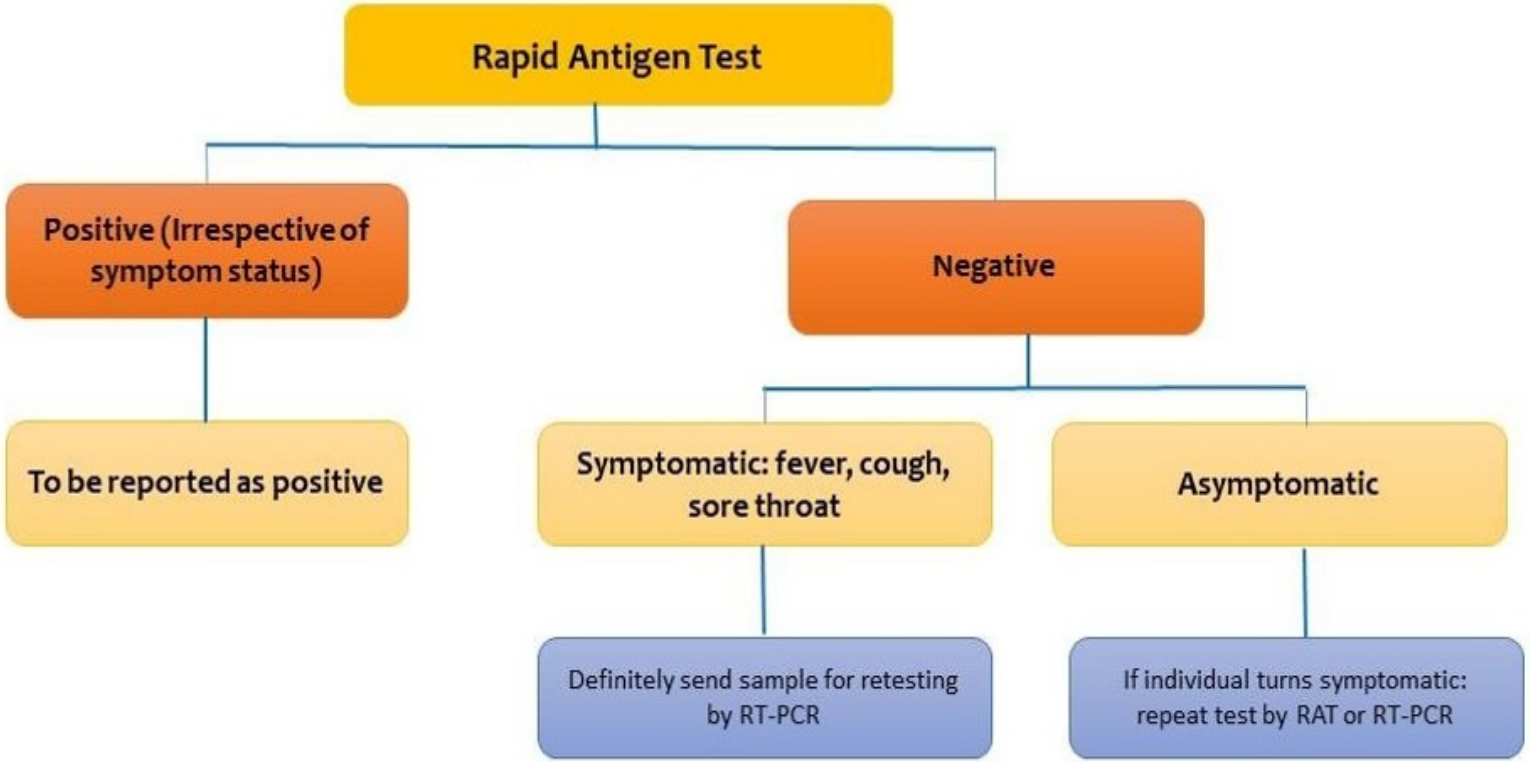
महोदय

राज्य में कोविड–19 की जॉच हेतु वर्तमान में RT-PCR Test का उपयोग किया जा रहा है। स्वास्थ्य एवं परिवार कल्याण मंत्रालय द्वारा समय–समय पर जॉच हेतु टेस्ट प्रोटोकॉल की अनुपालना में राज्य में विशेष परिस्थिति में रेपिड ऐन्टीजन टेस्ट की अनुमति प्रदान करने का निर्णय लिया गया है। राजकीय संस्थानों को रेपिड ऐन्टीजन टेस्ट हेतु आवश्यक उपकरण एवं कन्जूमेबल राज्य स्तर पर क्रय कर चिकित्सा संस्थानों को उपलब्ध करवाने हेतु चिकित्सा शिक्षा विभाग के अधीन एस.एम.एस. मेडिकल कॉलेज, जयपुर को अधिकृत किया गया है।

रेपिड ऐन्टीजन टेस्ट के उपयोग हेतु निम्नानुसार निर्देश जारी किये जाते है:–

1. कोविड–19 की जॉच हेतु वरीयता में RT-PCR Test की प्राथमिकता रहेगी। रेपिड ऐन्टीजन टेस्ट का उपयोग ILI लक्षण वाले मरीज में जॉच हेतु उपयोग में लिया जावे।
2. रेपिड ऐन्टीजन टेस्ट का उपयोग सामुदायिक स्वास्थ्य केन्द्र एवं इससे उच्च स्तर के राजकीय चिकित्सालयों एवं निजी अस्पतालों में अनुमत होगा।
3. चिकित्सालयों में ILI लक्षण वाले मरीज के उपस्थित होने पर उसकी कोविड–19 की जॉच हेतु रेपिड ऐन्टीजन टेस्ट का उपयोग किया जावे। रेपिड ऐन्टीजन टेस्ट का परिणाम आधा घन्टे में आ जाता है।
4. रेपिड ऐन्टीजन टेस्ट में जो व्यक्ति कोविड पोजिटिव आ जाता है उसे कोविड पोजिटिव माना जाकर तुरन्त आईसोलेट किया जावे। तद्उपरांत जारी प्रोटॉकाल अनुसार उपचार किया जावे।
5. परन्तु ILI लक्षण वाले व्यक्ति का टेस्ट कोविड नेगेटिव पाया जाता है तो उसका सैम्पल लिया जाकर RTPCR Test हेतु संबंधित माईक्रोबॉयलोजी लैब में भिजवाया जावे।
6. रेपिड ऐन्टीजन टेस्ट के डॉटा की एन्ट्री आईसीएमआर पोर्टल एवं राज्य हेल्थ पोर्टल पर करायी जावे। इस हेतु संबंधित चिकित्सा संस्थानों पर उपलब्ध कम्प्यूटर ऑपरेटर की सेवाओं का उपयोग किया जावे।

Algorithm for COVID-19 test interpretation using rapid antigen point-of-care test



- All positive and negative result should be entered into the ICMR portal on a real time basis after performing the antigen test
- Result of samples subjected to RT-PCR should be entered after the RT-PCR results are available

THANK YOU !