Standard Operating Procedure for Rapid Antigen Detection Test Kit for COVID-19

1. **Rapid Point-of-Care (PoC) Antigen Detection Test (for diagnosis along with RT-PCR):** Since the focus of the Entire Health System is to Test, Track and Treat COVID-19 patients, it is imperative to explore the existing antigen-based assays as point-of-care (PoC) tests for early detection of SARS-CoV-2. Such tests, if reliable are very valuable at field level for early detection of infection and quick containment. Most of such tests have relatively moderate Sensitivity but high Specificity. Presently Rapid Antigen Detection Kit has been provided to State by ICMR approved manufacturer i.e. SD-Biosensor. Any other supplier/ Manufacturer for rapid antigen detection kit has to be approved by ICMR.

2. It is now recommended to use Standard Q COVID-19 Ag detection test as a point of care diagnostic assay for testing in the containment zones as well as hospitals in combination with the Gold Standard RT-PCR test. ICMR has issued an advisory dated 14th June 2020 in this regard, which may be accessed at:

   https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test_14062020.pdf.

3. **ICMR recommends deployment of the rapid antigen PoC test in the following settings:**
   - i) All containment zones identified by the State Governments,
   - ii) All Central & State Government Medical Colleges and Government hospitals
   - iii) All private hospitals approved by National Accreditation Board for Hospitals & Healthcare (NABH).
   - iv) All private labs accredited by National Accreditation Board for Laboratories (NABL) and approved by ICMR as COVID-19 testing labs.

4. **Rapid antigen PoC test is recommended for use subject to the following conditions:**
   - i) All hospitals, labs (NABH, NABL Accredited), State Govts intending to perform the PoC antigen test need to register with ICMR to obtain the login credentials for data entry.
   - ii) All data of testing needs to be entered into the ICMR portal on a real time basis. The ICMR portal has been modified to include a component on antigen testing. Detailed video is available on ICMR website at http://www.icmr.gov.in/video/Data_Entry_Antigen_v4.mp4.
   - iii) All labs/hospitals initiating testing through the rapid antigen PoC test need to ensure that all symptomatic negative patients should be essentially referred to a real-time RT-PCR test for COVID-19. This is particularly essential as the rapid antigen PoC test has a moderate sensitivity.
   - iv) All the entities using antigen PoC test are expected to tie up with the nearest RT-PCR COVID-19 testing lab to ensure that all symptomatic who are negative by the rapid antigen test get tested at the nearest facility.
   - v) The date of individuals tested by RT-PCR will need to be entered through the lab performing the RT- PCR test. All qualified medical practitioners including private practitioners, Ayush Practitioners to prescribe COVID test to any individual fulfilling the criteria for testing as per ICMR guidelines. In fact, ICMR strongly recommends that laboratories (NABH, NABL Accredited) should be free to test any individual in accordance to the ICMR guidelines as early testing will help in containing the virus and saving lives. Report for Rapid antigen Detection Test should be generated and conveyed to District Surveillance Officer within 12 hours. Charges to perform Rapid Antigen Detection test by Private hospitals/Private labs has to be according to Govt. guidelines.

5. **Use of Standard Q COVID-19 Ag a point of care diagnostic assay is recommended in the following settings in combination with the Gold Standard RT-PCR test:**

A. Containment zones or hotspots (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):

i) All symptomatic Influenza Like Illness (ILI).

ii) Asymptomatic direct and high-risk contacts with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

B. **Healthcare settings** (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):

i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.

ii) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high- risk groups:

- Patients undergoing chemotherapy
- Immunosuppressed patients including those who are HIV+;
- Patients diagnosed with malignant disease;
- Transplant patients;
- Elderly patients (>65 yrs. of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)

iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:

- Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures etc.
- Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis etc.

C. **Sampling of Dead body in case of suspected COIVD-19 Deaths (State Initiative).**

6. **Use of the rapid antigen test is recommended in A, B & C categories above subject to the following conditions:**

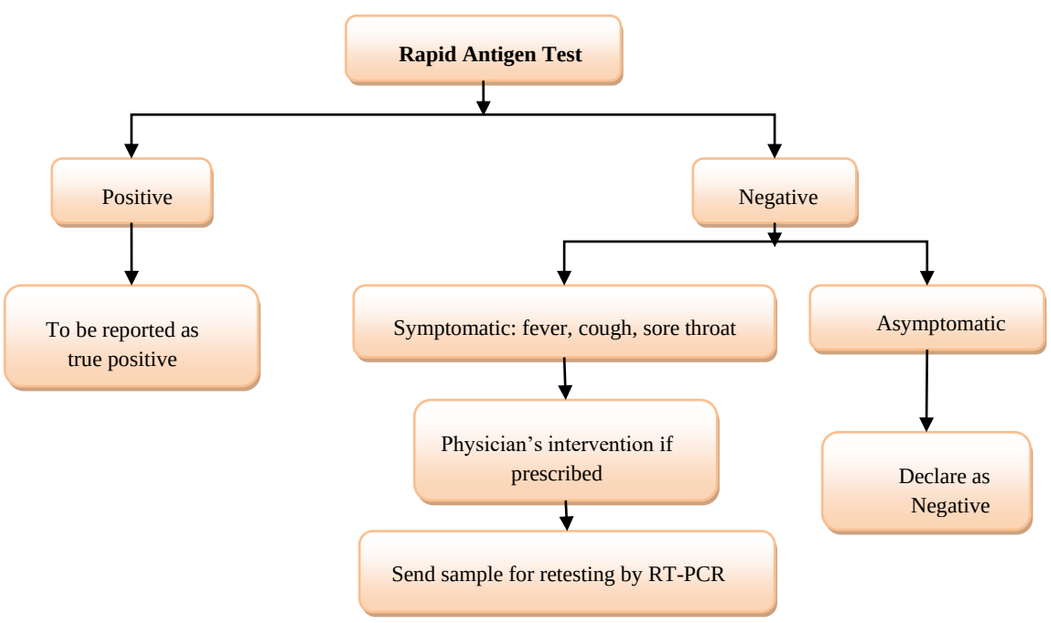
i) Should be interpreted between 15 to 30 minutes with a naked eye. No interpretation should be made before 15 minutes of after 30 minutes.

ii) Symptomatic individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.

iii) Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.

iv) The test should be conducted onsite under strict medical supervision and within one hour of sample collection in extraction buffer.

Algorithm for COVID-19 Testing using Rapid Antigen point-of-care test.



7. All the testing protocols as laid down by ICMR and the Government of India from time to time shall be followed by the Private Laboratories.
8. At the time of sampling, the identification, address and verified mobile number of the person, who is being tested, must be noted for record, as per specimen referring form (SRF). The data should be uploaded on the ICMR portal at the time of taking the sample. The test report should be communicated to the patient immediately after the testing is complete.
9. A positive test report should be immediately communicated to the Civil Surgeon of the concerned district through e-mail within 12 hours.
10. All the private NABL & ICMR approved laboratories to ensure that information of the patient is maintained with utmost confidentiality. All the private COVID-19 testing laboratories must preserve generated data for future verification by the State Government.
11. The laboratories need to ensure that rates are displayed in visible manner.
12. The management of approved private laboratories should appoint a Nodal Officer from their side and submit their details to the concerned Civil Surgeon/Deputy Commissioners.
13. All the Deputy Commissioners and Civil Surgeons in the State shall closely monitor the concerned labs to enforce the rates strictly by through wide publicity.
14. All the laboratory staff involved in COVID-I9 testing should be appropriately trained in Good Laboratory Practices.
15. All the biomedical waste should be disposed-off in accordance with National guidelines (https://dhr.gov.in/sites/default/files/Bio-medical_Waste_Management_Rules_2016.pdf).
16. The access to specified data and analysis to stakeholders like State Health Department and MoHFW will be provided for timely initiation of contact tracing and appropriate control measures.