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

ADVISORY

Newer Additional Strategies for COVID-19 Testing

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Existing strategies for COVID-19 testing:

1. **Real Time RT-PCR** is the gold standard test for detecting cases of COVID-19. The test requires specialized laboratory setup with specific biosafety and biosecurity precautions to be followed. Average time taken is around 4-5 hours from receipt of sample to getting the result. The advantage of this platform lies in its accuracy of detection as well as ability to run upto 90 samples in a single run. In view of the specialized laboratory requirements, this test cannot be performed at every district level lab which do not have molecular virology facilities. However, wherever available, it is advised to use real time RT-PCR as the frontline test for diagnosis of SARS-CoV-2.

2. **The TrueNat and CBNAAT** systems have also been deployed for diagnosis of COVID-19 in view of availability of customized cartridges. These platforms have widespread availability even at district and primary health center level as these platforms are widely used for diagnosis of Tuberculosis and other infectious diseases. These platforms have a quick turnaround time (30 -60 minutes) but only 1-4 samples can be tested in one run, limiting the maximum numbers that can be tested to 24-48 samples / day only. The viral lysis buffer that comes with the COVID-19 cartridges inactivates the virus and poses minimum biosafety hazard. Safety is further augmented by the closed nature of these platforms and minimum sample handling. These features have facilitated use of these platforms at grass root level thereby increasing access to testing.

3. All COVID-19 tests conducted through RT-PCR, TrueNat and CBNAAT are reported on ICMR data entry portal which helps in drawing the National estimates on numbers of tests conducted, numbers of positives, tests conducted per million population etc. This data portal is the single National source of data entry which is accessed by all relevant Ministries / Departments for defining National strategies for COVID-19. ICMR urges all the laboratories to continue entering data into the ICMR portal https://cvstatus.icmr.gov.in/login.php to help in guiding the National strategies appropriately.

4. In an effort to ramp up testing capacity, ICMR has approved a total of 1000 COVID-19 testing labs in both public (730) and private sector (270). This includes RT-PCR labs (557); TrueNat Labs (363) and CBNAAT Labs (80). However, inspite of these developments, access to testing still remains a huge challenge in a large country like India. There is a definite need to increase the outreach of testing by introducing rapid point of care diagnostic tests. Also, there is value in conducting serosurveys with IgG based antibody tests in certain situations. In view of this, it is now suggested to include additional testing methods to improve the access and availability of testing in various parts of the country.

Newer additional strategies for COVID-19 Testing:

I. Rapid Point-of-Care (PoC) Antigen Detection Test (for diagnosis along with RT-PCR):

5. Since the entire public health machinery is focused to test, track and treat COVID-19 patients, it is imperative to explore the existing antigen-based assays as point-of-care tests for early detection of SARS-CoV-2. Such tests, if reliable would be valuable at field level for early detection of infection and quick containment. Availability of antigen-based detection tests is very limited all across the world. Most of such tests have relatively **moderate sensitivity but high specificity**. However, manufacturers of all antigen-based tests are encouraged to approach ICMR for validation and inclusion of their test in the wider testing approach of the country. A positive test should be considered as a true positive whereas all symptomatic individuals testing negative through the rapid antigen test should be confirmed with a real-time PCR test.

6. ICMR and AIIMS, Delhi independently evaluated the stand-alone rapid point of care antigen detection assay which **does not require a specialized machine** and can be interpreted with a naked eye. The test is a promising tool for quick diagnosis of SARS-CoV-2 in field settings. The assay is known as **Standard Q COVID-19 Ag kit** and has been developed by SD Biosensor with manufacturing unit at Manesar, Gurugram. On validation, the test has been found to have a very high specificity with moderate sensitivity. 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. The recommended use of the rapid antigen PoC as per the ICMR advisory is enclosed at **Annexure 1.**

7. **Standard Q COVID-19 Ag kit** is available with the local vendor of SD Biosensor.
   Contact details are as follows:
   Dr. CS Bedi.
   Mobile No: +919810426069; Email: drbedi@icloud.com

   For any technical assistance /clarifications regarding the performance of the test, details of the ICMR contact point are given below:
   Dr. Sidhartha Giri
   Email: sidhartha.g@icmr.gov.in

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.

Rapid antigen PoC test is recommended for use subject to the following conditions:

i) All hospitals, labs, State Govts intending to perform the **PoC antigen test need to register with ICMR to obtain the login credentials for data entry. Interested Institutions may send their request on the following email id's:**

ag-pvthosp-nabh@icmr.gov.in
ag-govthosp@icmr.gov.in

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 data of individuals tested by RT-PCR will need to be entered through the lab performing the RT-PCR test.

II. IgG Antibody test for COVID-19 (Only for surveillance and not diagnosis):

8. IgG antibodies generally start appearing after two weeks of onset of infection, once the individual has recovered after infection and last for several months. Therefore, the IgG test is not useful for detecting acute infection. However, detection of IgG antibodies for SARS-CoV-2 may be useful in the following situations:

   a. Serosurveys to understand the proportion of population exposed to infection with SARS-CoV-2 including asymptomatic individuals. Depending upon the level of seroprevalence of infection, appropriate public health interventions can be planned and implemented for prevention and control of the disease. Periodic serosurveys are useful to guide the policy makers.

   b. Survey in high risk or **vulnerable populations (health care workers, frontline workers, immunocompromised individuals, individuals in containment zones etc)** to know who has been infected in the past and has now recovered. The groups of individuals who should be prioritized for such serosurveys is enclosed at **Annexure 2.**

9. It is strictly advised to use IgG based ELISA and CLIA assays only for conduct of serosurveys. ICMR has validated and approved IgG ELISA kits for COVID-19. In addition, USFDA approved IgG ELISA and CLIA kits are also available and can be used. Guidance of ICMR on the list of available ELISA and CLIA kits can be accessed at https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_03062020.pdf. It is advised to enable all **Government and Private Hospitals, Offices, Public Sector Units etc. to perform the antibody-based testing.** This will help in allaying the fear and anxiety of health care workers, office employees etc. As the apex research organization of the country, ICMR is mandated to review and

conduct research on the evolving trends of the disease and accordingly advise the states / country on the public health policies. In view of this, it is advised to share the comprehensive report of antibody testing with ICMR at the email id given below: mmurhekar@gmail.com.

10. Since test, track and treat is the only way to prevent spread of infection and save lives, it is imperative that testing should be made widely available to **all symptomatic individuals in every part of the country and contact tracing mechanisms for containment of infection are further strengthened**. ICMR advises all concerned State Governments, Public and Private Institutions to take required steps to scale up testing for COVID-19 by deploying combination of various tests as advised above.

Annexure 1:

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.

ILI case is defined as one with acute respiratory infection with fever ≥ 38°C AND cough.

Use of the rapid antigen test is recommended in A & B 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.*

Annexure 2:

Possible groups/ community/ population based on specific requirement for sero-survey by using IgG ELISA test.

i.) **Immuno-compromised patients:** PLHIV, patients on immuno-suppressive treatment, TB, SARI, COPD, patients on dialysis to be considered for testing;

ii.) **Individuals in containment zones:** In identified containment zones and buffer zones where large number/ cluster of cases have been identified as demarcated geographical areas with residential, commercial structures;

iii.) **Health Care Workers:** Specifically, all doctors including specialists, nursing staff, support staff, sanitary and other staff including the staff at registration, pharmacists, client facing desk clerks etc. Those workers in health care settings who either faces patients (whether known COVID 19 +ve or not), involved in their care or are in environment of potentially shared spaces or handling fomites;

iv.) **Security personnel:** All security personnel facing the visitors, conducting their security screening, physical checking and thermal screening. This includes CISF personnel involved in security especially of offices;

v.) **Police and paramilitary personnel civil defense & volunteers:** police personnel and volunteers involved in duties facing large number of individuals or those coming in contact with potentially infected individuals, fomites or settings/ places;

vi.) **Press corps:** Press reporters covering field, interviews, press briefings, etc. and support staff;

vii.) **Rural, tribal population (after reverse migration):** Migrant workers who have travelled back from urban and peri-urban areas to rural, tribal, hard to reach areas in the country as well as natives after coming in contact with returned migrants.

viii.) **Industrial workers or labour force:** industry workers, daily wagers, migrant workers, temporary travel related workers, hospitality related works, service sector who are in large number or groups and has potential to spread transmission rapidly in workplace settings;

ix.) **Farmers, vendors visiting large markets:** Farmers, sellers, brokers, purchasing vendors, distributors and other persons including drivers and labor by virtue of visiting crowded places like main markets where large exchange of materials happen between farmers and vendors during purchase and sell of vegetables etc.;

x.) **Staff in municipal bodies:** Municipal staff working in areas like sanitation, water supply, electricity, etc. where interactions with citizens is expected; and

xi.) **Drivers:** Drivers of hospital ambulances, hearse, buses, auto, taxies, etc. who have been on work font faced large number of individual previously or going to face in future. Bus conductors, cleaners and helping staff also should be included;

xii.) **Banks, post, couriers, telecom offices:** public or private banks, small or large branches of banks and post, telecom offices as well as couriers;

xiii.) **Shops:** Vendors and/ or owners as well as staff working in shops for essential goods, groceries, vegetables, milk, bread, chemists working at pharmacies, eateries and take away restaurants, etc.;

xiv.) **Air travel related staff:** All ground staff, security staff, janitors, sanitation staff, flight captains and crew for domestic and international as well as cargo may be considered;

xv.) **International operations:** All members of overseas operations for evaluation;

xvi.) **Congregate settings:** People staying or working in slums with very high population density with poorly ventilated building, structures. Persons staying in institutional settings like old age homes, orphanage, asylums, shelters for homeless, hostels, etc. may also be considered;

xvii.) **Prisons:** All prisoners with or without symptoms whenever there is a batch transfer or reported symptomatic;