



National Health Mission
SDA Complex, Kasumpti, Shimla-9
Himachal Pradesh

Dated: Shimla-171009, 27 July 2020

MISSION DIRECTOR (NHM)

27 JUL 2020

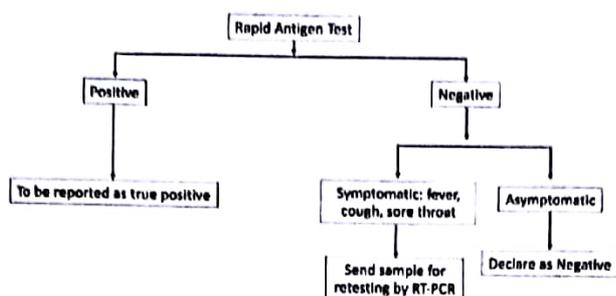
New Shimla-9 (H.P.)

CIRCULAR

Real time RT-PCR is the gold standard test for diagnosis of COVID-19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for COVID19 diagnosis in the State. 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 and the time taken for sample transportation. These issues limit the widespread use of the RT-PCR test and also impede quick augmentation of testing capacity in various settings.

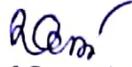
Requests have been received from Industry Associations for permissions for conducting Rapid Antigen tests keeping in view the challenges in terms of RT PCR result cycles as well as capacity of administration, which in turn is delaying the reopening of Industry in case any positive case is found in any industry. The request has been carefully considered keeping in view the advisories being issued from time to time by Ministry of Health and Family Welfare, Government of India and ICMR, New Delhi, the following guidelines are laid down for conducting the Rapid Antigen Tests by the Industrial units/factories/commercial establishments etc. for their employees/workers:

1. RT-PCR tests including CBNAAT and TrueNat remain the gold standard for diagnosis of COVID-19. The Antigen tests have high specificity and relatively low sensitivity.
2. The results of the Rapid Antigen Kits shall be interpreted as per the following algorithm:



3. For testing the symptomatic negatives, the samples shall be sent to the RT-PCR Lab which is conducting the COVID-19 Samples for the particular area in which Industrial unit/factory/commercial establishment is located.
4. Only those Antigen based assays shall be used which are validated and approved by ICMR. The Present list is annexed with this circular and the updated list can be seen at www.icmr.gov.in from time to time.
5. Sample collection, transportation and testing will be the sole responsibility of the Industrial unit/factory/commercial establishment. The Industrial unit/factory/commercial establishment shall enter into an agreement with a diagnostic lab/hospital having requisite strength of Medical and Paramedical Staff, at its own level, for the purpose.
6. It has to be ensured that the details of sample collected and results of samples be entered on the ICMR portal for which a formal letter of request shall be sent by the Industrial unit/factory/commercial establishment to the concerned Chief Medical Officer. The State Surveillance Officer shall issue login credentials for the Industrial units/factories/commercial establishments upon the recommendations of the concerned Chief Medical Officer.
7. The cost of testing and other expenses of the employees/workers shall be taken up by the Industrial units/factories/commercial establishments on their own and the costs shall not be passed on to the employees/workers in any case.
8. It is recommended that this test should be conducted on all the workers/employees who are working in that Industry/establishment. If any positive case is found, he/she should be isolated and all the workers/employees should be tested again on 6th-7th day and so on and so forth. If a worker/employee joins the industry due to in-station movement, before starting work, he/she should be tested and if negative, then only

allowed to work. If workers join the concerned Industry and intermingle before testing with the existing workers, the whole lot is recommended to be tested on 6th-7th day of exposure.


Additional Chief Secretary (Health) to the
Government of Himachal Pradesh

Endst no. As Above, Dated: Shimla-9, the 27/7/20

Copy for information and necessary action to:

1. Special Secretary (Health) to the Government of Himachal Pradesh
2. All Deputy Commissioners, Himachal Pradesh
3. Director Health Services, Himachal Pradesh
4. Director Medical Education, Himachal Pradesh
5. Director (Industries), Himachal Pradesh
6. All Chief Medical Officers, Himachal Pradesh
7. All Principals, Medical Colleges in Himachal Pradesh
8. All Senior Medical Superintendents in Himachal Pradesh
9. State Surveillance Officer, NHM, Himachal Pradesh
10. All Industrial Associations including BBN Industries Association in reference to their Letter no. BBNIA/Representation- Health/2020 dated 15th July 2020.




Additional Chief Secretary (Health) to the
Government of Himachal Pradesh

**INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH**

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 standalone antigen detection assay: **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.

4. Brief description of the Standard Q COVID-19 Ag detection:

- i) **Standard Q COVID-19 Ag detection kit** is a rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. has been developed by SD Biosensor, a South Korea based company, having its manufacturing unit in Manesar, Gurugram, India.
- ii) Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.
- iii) One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, bronchoalveolar lavage or sputum) should be used.
- iv) After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing

biosafety and biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

- v) Once the sample is collected in the extraction buffer, it is stable only for one hour. Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting. Transportation to the lab is not recommended.
- vi) Once the sample goes into the buffer and is mixed properly, the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are put into the well of the test strip.
- vii) The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. Maximum duration for interpreting a positive or negative test is 30 minutes. After that the test strip should be discarded.
- viii) The test kit should be stored between 2° to 30° C.
- ix) Detailed instructions for use can be accessed through the video link: <https://youtu.be/mBdaOHJWxl4>

5. Validation of the Test:

I. Sites:

Standard Q COVID-19 Ag detection assay by SD Biosensor was evaluated independently by the following agencies:

- i) Indian Council of Medical Research, Delhi; and
- ii) All India Institute of Medical Sciences, Delhi

II. Results:

- i) Standard Q COVID-19 Ag rapid antigen detection test has a very high specificity (i.e. ability to detect true negatives). Specificity ranged from 99.3 to 100% at the two sites.
- ii) Sensitivity of the test (i.e. ability to detect true positives) ranged from 50.6% to 84% in two independent evaluations, depending upon the viral load of the patient. Higher viral load correlated with higher sensitivity.

6. Conclusions and Recommendations:

- i) Standard Q COVID-19 Ag detection assay by SD Biosensor is the standalone antigen detection test which is available in India and has been validated.
- ii) ICMR encourages other manufacturers / developers who have antigen detection assays to come forward for validation.

iii) **In view of its high specificity while relatively low sensitivity, ICMR recommends the use of Standard Q COVID-19 Ag detection assay as a point of care diagnostic assay for testing 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;
 - Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

****ILI case is defined as one with acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ AND cough.***

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

- i) Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.
- ii) The test should be conducted **onsite** under strict medical supervision and within one hour of sample collection in extraction buffer.
- iii) Suspected 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.**



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कल्याण मंत्रालय, भारत सरकार

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

ADVISORY

Newer Additional Strategies for COVID-19 Testing

Dated: 23/06/2020

Existing strategies for COVID-19 testing:

- 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.
- 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.
- 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.
- 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:

1. 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](https://www.icmr.gov.in/pdf/covid/strategy/Advisory%20for%20rapid%20antigen%20test%2014062020.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



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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):
- All symptomatic Influenza Like Illness (ILI).
 - 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):
- All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
 - 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)
 - 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 $\geq 38^{\circ}\text{C}$ AND cough.***

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

- Should be interpreted between 15 to 30 minutes with a naked eye. No interpretation should be made before 15 minutes or after 30 minutes.
- 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.**
- Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.
- 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 front 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;

130382/2020/O/o-SSO

डॉ. जी. एस. टोटेजा
अपर महानिदेशक
Dr. G. S. Toteja
Additional Director General



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वी. रामलिंगस्वामी भवन, अंसारी नगर नई दिल्ली-110029

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare, Govt. of India
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi - 110029

D.O.No.ECD/COVID-19/Misc./2020
6th July, 2020

Dear Sir/Madam,

This is in continuation to the earlier communication of ICMR and MoH&FW dated 1st July 2020 regarding "empowering citizens for testing of SARS-CoV-2".

Please find attached a self-explanatory algorithm for interpreting the test results of the rapid antigen point-of-care test.

With regards

Yours sincerely

(Dr. G.S. Toteja)

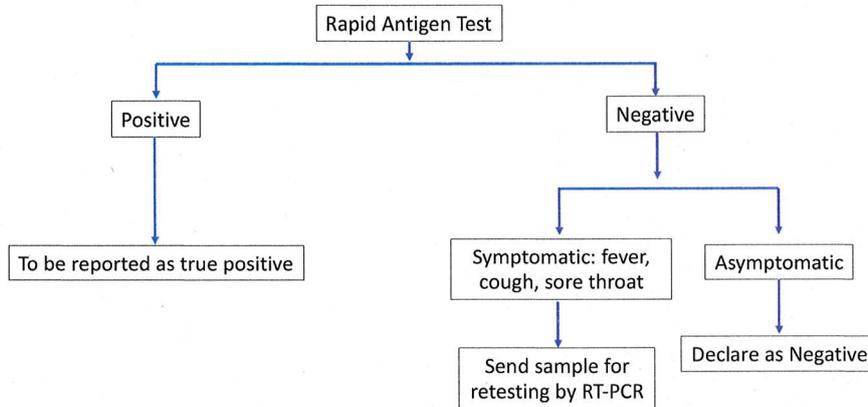
Enclosed: As above

All Chief Secretaries (States)/Addl.Chief Secretaries/Secretaries/Commissioners/Principal Secretaries (Health & Family Welfare)

CC:

1. Ms. Preeti Sudan, Secretary, Health & F.W., Nirman Bhawan, New Delhi.
2. Shri Rajesh Bhushan, OSD, Ministry of Health & F.W., Nirman Bhawan, New Delhi.

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



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



सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएस, एफएएससी, एफ.एन.ए., डी.एस.सी.

सचिव, भारत सरकार

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महानिदेशक, आई सी एम आर

Prof. (Dr.) Balram Bhargava, Padma Shri

MD, DM, FRCP (Glasg.), FRCP (Edin.),
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Secretary to the Government of India

Department of Health Research
Ministry of Health & Family Welfare &
Director-General, ICMR



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Indian Council of Medical Research

Department of Health Research
Ministry of Health & Family Welfare
Government of India
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029

DO No. ECD/COVID-19/Misc./2020

Dated July 16, 2020

Subject:- District-wise login credentials for rapid antigen testing for COVID-19

Dear colleagues

At the outset, I would like to convey my appreciation for State/ UT Government's efforts to scale up the COVID-19 testing to save precious lives and save livelihoods. As a nation, everyone has risen to meet this challenge and this combined effort has led to a situation wherein everyday more than 3.20 lakh tests are carried out in the country and in all more than one Crore tests have been done.

2. Key strategy to save lives and protect livelihoods remains 'tests, track, treat'. Our continuous endeavor is to increase testing capacity and provide more and more access to people for testing. ICMR recently approved a point-of-care rapid antigen test for diagnosis of COVID-19, in addition to the already existing molecular diagnostic tools. Antigen test is a promising tool for quick diagnosis of COVID-19.

3. ICMR has advised the use of this test for quick detection of COVID-19 patients in containment zones and hospitals. Please refer to the ICMR advisory dated 14th June 2020 and a subsequent advisory of 23rd June 2020 which can be accessed at:

https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062020.pdf

&

https://www.icmr.gov.in/pdf/covid/strategy/New_additional_Advisory_23062020_3.pdf.

4. In addition, ICMR has invited researchers/ entrepreneurs to come up with such testing kits, which are accurate and useful. Efforts are being made to validate such kits and make multiple options available for use.

5. With the use of antigen tests, more and more tests are being carried out. It is absolutely necessary that all such testing data is uploaded on the ICMR database and all positive cases are brought to the attention of district/ municipal authorities for isolation/ quarantine/ treatment, as the case may be. It is expected that to provide safe healthcare services, all Govt. hospitals/ labs as well as all private NABH/NABL hospitals/labs may initiate antigen testing and also apply for obtaining login credentials for data entry into the ICMR portal. ICMR has been receiving multiple requests from various public sector units, small private/ government facilities, temples, etc. for initiating this testing.

6. In a further effort to **facilitate and further liberalize testing**, ICMR has generated **five common login credentials for each district of your State/ UT**, which may be shared with all Government and private facilities selected for antigen testing. You may nominate a **nodal person from your State/ UT**, who could **contact the ICMR team for obtaining login credentials**. The request for login credentials may be sent at:

ag-govthosp@icmr.gov.in

7. In this CoVid-19 pandemic, to ensure that testing is further enhanced and reporting of the same is done seamlessly, you are advised to take the following steps:

- Respective State/ UT governments should identify/ approve all government and private facilities who would be providing COVID-19 diagnosis through antigen-based assays;
- The common login credentials should be shared with all government and private facilities approved by the state. Individual organizations should not separately approach ICMR now for obtaining logins for antigen testing. **However, ICMR / Mentor Institutes will continue to review and approve all applications for RT-PCR based testing**
- Attached algorithm for interpreting the antigen test should be followed wherein all positives can be labelled as true positives and symptomatic negatives should be subjected to RT-PCR;
- The states should ensure that all the antigen testing points are appropriately linked with RT-PCR facility, where symptomatic negatives will be tested; and
- District-wise login credentials should be shared with all antigen testing sites (Govt. and Private) so that data can be entered into the ICMR portal on a real time basis.

8. May I request you to kindly ensure afore-mentioned steps to tackle the COVID-19 pandemic, so that precious lives are saved, and livelihoods are protected too.

With best regards

Yours sincerely

(Balram Bhargava)

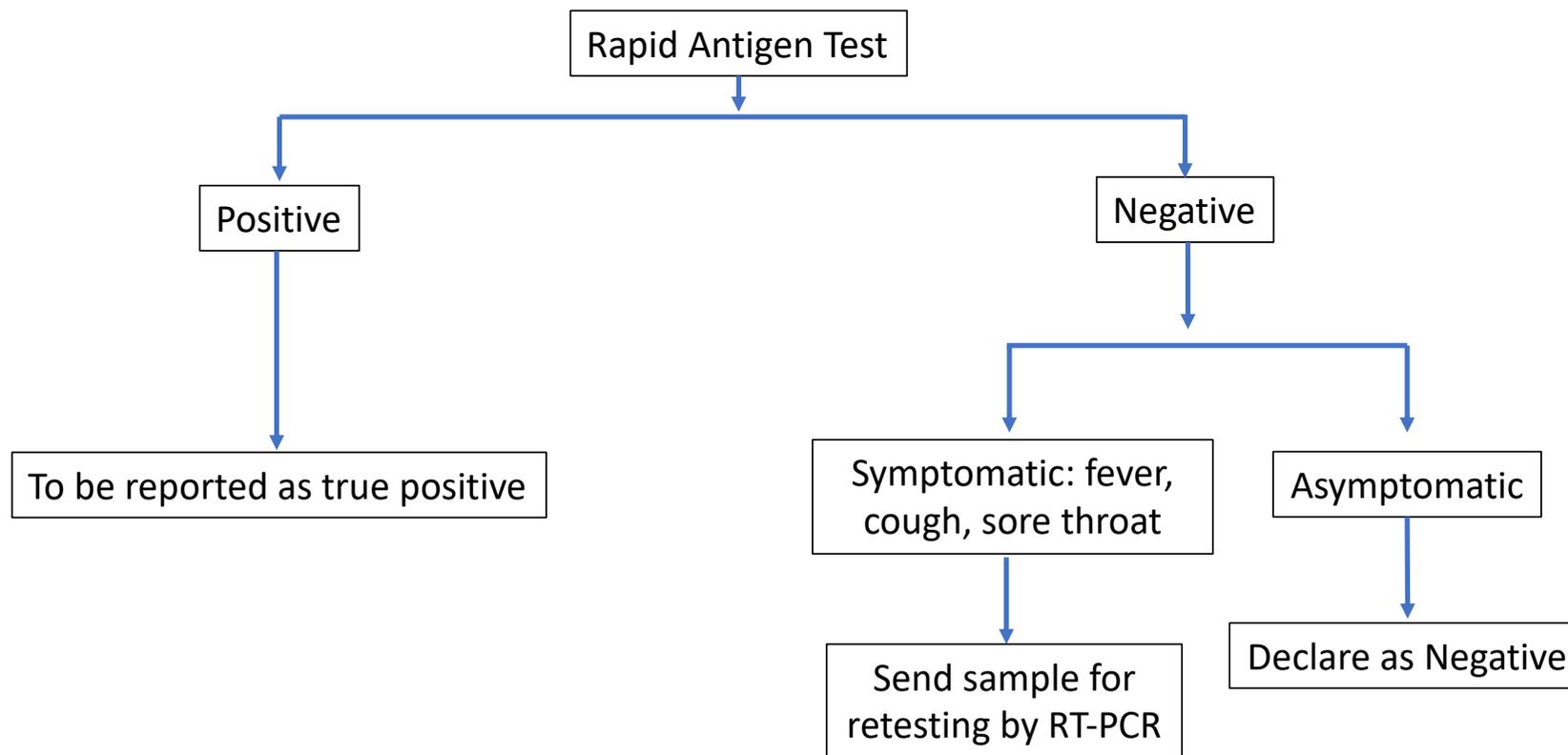
To

All Chief Secretaries

All States / UTs

Enclosed: As above

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



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



Date: 22/07/2020

List of Companies / Vendors of Rapid Antigen Test Kits for COVID-19 validated / being validated by ICMR

S. No	Name of the kit	Name of company	India/ Other countries	Name of the supplier	Current status at validation centre
1.	STANDARD Q COVID-19 Ag	SD Biosensor	South Korea / India	SD Biosensor	Validated, Approved
2.	COVID-19 Antigen Lateral Test Device	LabCare Diagnostics Ltd.	India	MyLab Discovery Solutions	Validated, Approved
3.	COVID-19 Ag Respi Strip	Coris Bioconcept	Belgium	Vishat Diagnostics Pvt. Ltd, Mumbai	Validated, Approved
4.	COVID-19 Antigen Rapid Card Test	Bhat Bio-Tech India, Bangalore	India	Invex Health, India	Validated, Not Approved
5.	COVID FIA Antigen Test	SD Biosensor	South Korea / India	SD Biosensor	Validated, Not Approved
6.	Q-Line Rapid COVID-19 Rapid Antigen Test	POCT Services Pvt Ltd	India	POCT Services Pvt Ltd	Validated, Not Approved
7.	Makesure Covid-19 Antigen Rapid Card	HLL Lifecare Ltd	India	HLL Lifecare Ltd	Validated, Not Approved
8.	AAG Q COVID-19 N-Antigen rapid test	Agappe Diagnostics, Kochi	India	Agappe Diagnostics, Kochi	Validated, Not Approved
9.	Formosa One Sure SARS-COV-2 Ag rapid Test Kit	Formosa Biomedical Technology Corp.	Taiwan	Intai Lifesciences LLP, India	Validated, Not Approved
10.	Biocredit COVID-19 Ag	Rapigen Inc	South Korea	Imperial Life Sciences, Gurgaon	Validated, Not Approved
11.	Camtech COVID-19 rapid Antigen Test	Camtech Diagnostics	Singapore	Althea Pharma Pvt. Ltd, Mumbai	Under Validation
12.	COVID-19 Antigen Rapid Test	M/s Medsource Ozone Biomedicals Pvt. Ltd	India	M/s Medsource Ozone Biomedicals Pvt. Ltd	Under Validation
13.	V Strip COVID-19 Antigen rapid Test	Panion & BF Biotech, Taiwan	Taiwan	Tricell Biologics, Chennai	Under Validation