HEALTH DEPARTMENT
GOVERNMENT OF HARYANA
INTEGRATED DISEASE SURVEILLANCE PROGRAMME

Website: haryanahealth.nic.in Email: dhs.idspdatam@hry.nic.in

From

Director General Health Services,
Haryana, Panchkula

To

All Civil Surgeons,
Haryana

No. 32/3-IDSP-2020- 3857-78 **Dated:** 25-06-2020

Subject: Regarding Use of Rapid Antigen Detection Test for COVID-19.

With reference to the subject cited above,

2. As you are aware that Real-time i.e. RT-PCR test is considered Gold Standard frontline test for Clinical Diagnosis of SARS-CoV-2, causing COVID-19. Currently many open and closed RTPCR platforms (open system RTPCR Machine, True NAAT and CBNAAT) are being used for covid-19 diagnosis.

3. Further to strengthen the testing strategy for COVID-19, the antigen detection assay based kits i.e. Standard Q COVID-19 Ag detection kit, has been recommended by the ICMR vide its communication dated 14 June, 2020 and 23rd June, 2020 **(Annexed at I).** The same has been evaluated by ICMR and AIIMS, Delhi.

4. For performing this test one Nasopharyngeal swab is to be collected by the use of sample collection swab provided with the kit. After sample collection the swab is immersed in the viral extraction buffer provided with the kit. This buffer in-activates the virus thereby reducing bio-safety and bio-security requirements. This sample is to be stable for 1 hour hence, the testing to be performed within 1 hour at the site of sample collection. This test does not require any specialized Equipments and the duration of interpreting test report is 30 minutes.

5. Hence, looking into some positive impacts of this diagnostic tests like: -

1. The virus inactivated after emerged into the viral extraction buffer.
2. No extra bio-safety and bio-security requirements.
3. Test to be performed at the site of sample collection in the healthcare setting within 1 hour of sample collection.
4. The duration of the test of the interpretation is less i.e. 30 minutes.
5. No special Equipments required.
6. All the required sample collection material and reagents are being provided with the diagnostic kits.

6. Considering the above positive aspects, State has decided to use this rapid Point of Care (PoC) antigen detection test for the early diagnosis and management of the positive cases with the aim to increase the diagnostic capacity of the State.

7. **As per ICMR recommendation the deployment of the Rapid Antigen Test is to be done in the following settings:**

(i) All Central & State Government Medical Colleges and Government hospitals

(ii) All private hospitals approved by National Accreditation Board for Hospitals & Healthcare (NABH).

(iii) All private labs accredited by National Accreditation Board for Laboratories (NABL) and approved by ICMR as COVID-19 testing labs.

(iv) All above mentioned institutes are directed to registered with ICMR to obtain the login credentials for data entry. The request to obtain the login ID, Password may be sent to the following email id's:

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

8. 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.**

9. 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.

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

11. The kit has to be used in following situations:

A. **In containment zone or hotspots: -**

- All symptomatic ILI cases.
- 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:**

(i) All symptomatic ILI patients presenting in Healthcare Centre.

(ii) Asymptomatic high-risk patient, who are hospitalized for: -

- Chemo therapy.
- Immunosuppressed patient including HIV Positive.
- Patient with malignant disease.
- Transplant patient.
- Elderly patient with co-morbidities.

(iii) A symptomatic patient 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.

Recommended by ICMR

C. Sampling of Dead Body in case of suspected COVID-19 Deaths.

Recommended by State

12. Accordingly, the District wise distribution of the Antigen Kits is proposed as under:

Sr. No	Name of the district	Approx. no. of tests which can be conducted
1	Faridabad	30,000

2	Gurugram	30,000
3	Jhajjar	20,000
4	Sonipat	20,000
Total		1,00,000

13. Details of the Storage & Transportation methods, SOPs, details of the reporting format in ICMR Portal etc. is **Annexed at II**.

14. It is once again reiterated that the above said kits may be used in combination with RT PCR. As the ToTs of all the Districts regarding use of Rapid Antigen testing kits has already been conducted by the State Head Quarter in two batches. Further, you all are directed to initiate the testing at the Districts and submit the report to the State head Quarter at covidlabhry@gmail.com and copy to dhs.idspdatam@hry.nic.in.

Director Health Services (IDSP)
O/o Director General Health Services
Haryana, Panchkula.

No. 32/3/IDSP/20/ 3879-80 **Dated:** 25-06-2020

1. A copy is forwarded to the **Director General Medical Education and Research, Haryana** for information and necessary action please.
2. A copy is forwarded to the **Managing Director HMSCL** with the request to distribute kits as per above mentioned distribution. Further, it is also reiterated that out of total 100,000 testing kits, 25,000 testing kits have already been issued to District Gurugram (8,000), Faridabad (8,000), Jhajjar (4,500) and Sonepat (4,500). Hence you are requested to distribute the remaining kits as per the above mentioned Table.

Director Health Services (IDSP)
O/o Director General Health Services
Haryana, Panchkula.

No. 32/3/IDSP/20/ 3881-82 **Dated:** 25-06-2020

A copy is forwarded to the followings for kind information please:

1. Worthy Additional Chief Secretary (Health), Haryana
2. DGHS, Haryana

Director Health Services (IDSP)
O/o Director General Health Services
Haryana, Panchkula.

HEALTH DEPARTMENT
GOVERNMENT OF HARYANA
INTEGRATED DISEASE SURVEILLANCE PROGRAMME
Website: haryanahealth.nic.in Email: dhs.idspdatam@hry.nic.in

STANDARD OPERATING PROCEDURE (SOP)

FOR

USE OF RAPID ANTIGEN DETECTION COVID-19

Background :

Real time RT-PCR is the Gold Standard frontline 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 COVID-19 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. 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.

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.

ADVISORY FOR TESTING :

State in compliance to the Guidelines of ICMR is going to initiate testing of the various categories like:

A. In containment zone or hotspots: -

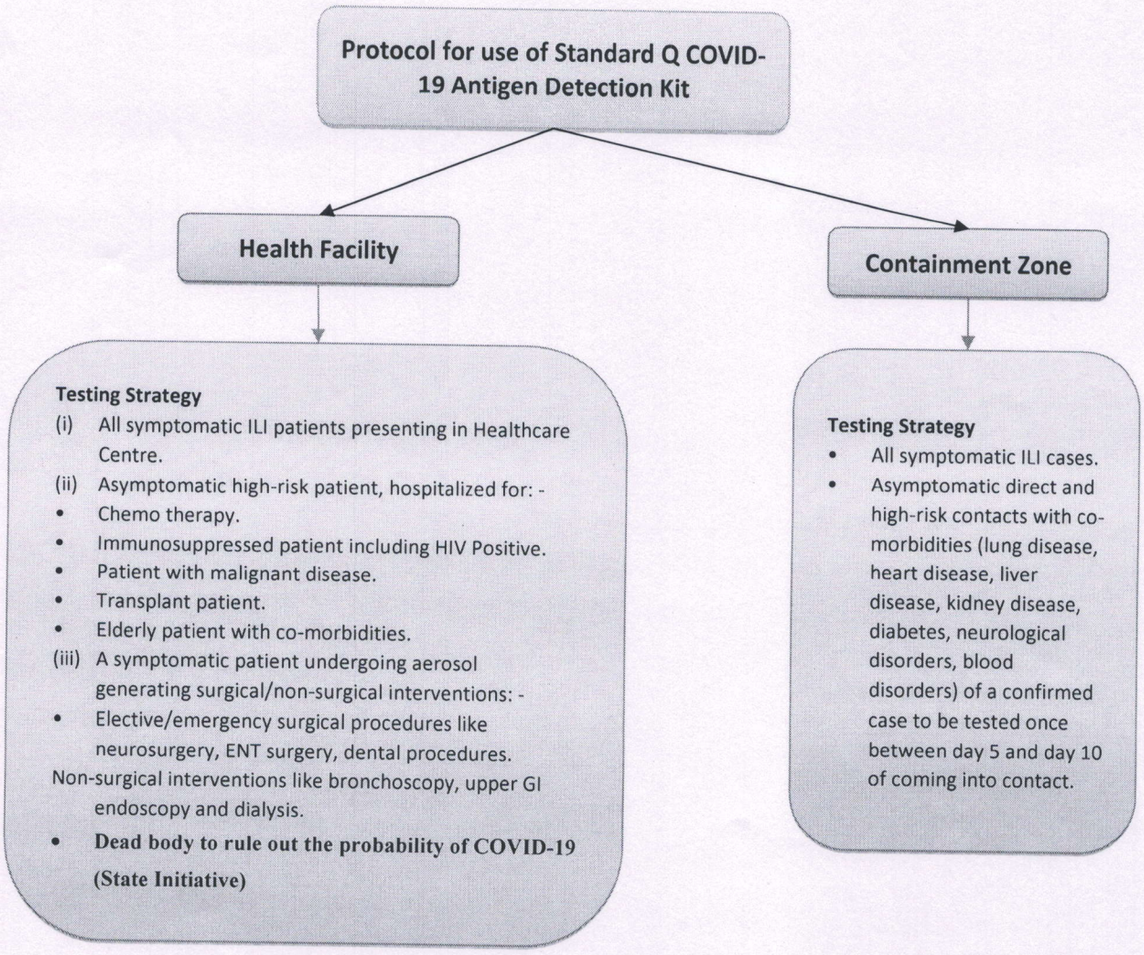
- All symptomatic ILI cases.
- Asymptomatic direct and high-risk contacts with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

B. Healthcare settings:

(i) All symptomatic ILI patients presenting in Healthcare Centre.
(ii) Asymptomatic high-risk patient, who are hospitalized for: -
- Chemo therapy.
- Immunosuppressed patient including HIV Positive.
- Patient with malignant disease.
- Transplant patient.
- Elderly patient with co-morbidities.

(iii) A symptomatic patient 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.

C. Dead body to rule out the probability of COVID-19 (State Initiative)



2. **As per ICMR recommendation the deployment of the Rapid Point of Care Antigen detection Tests to be done 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.

(v) All above mentioned institutes are directed to registered with ICMR to obtain the login credentials for data entry. The request to obtain the login ID, Password may be sent to the following email id's:

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

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

1. **Standard Q COVID-19 Ag detection kit** is a rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2.
2. Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.
3. 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.

4. 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.
5. 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.
6. 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.
7. 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.
8. Maximum duration for interpreting a positive or negative test is 30 minutes. After that the test strip should be discarded.
9. Regarding Validation of the Test:

   - Standard Q COVID-19 Ag detection assay by SD Biosensor was evaluated independently by ICMR & AIIMS and following observations were made:

     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.

     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 selected settings in combination with the Gold Standard RT-PCR test:

General Instructions

1. Each District to setup adequate no. of Antigen Testing Centre (ATC) preferably near Containment Zone, in case of testing in containment area, however, ATC may be established in the facility near flu center, fever clinic or can be clubbed with already available collection center for RTPCR. The ATC room should be conditioned enough to ensure that the preferred temperature of the kits is maintained between 2° to 30° C.
2. The method and PPE to be used for sample collection (Nasopharyngeal swab) for antigen detection kit should remain same as for RTPCR method. Sufficient personal protective equipment (PPE) such as gloves, masks (preferably N-95 masks), apron, etc, should be available to all the personnel involved in the sample collection, testing, and data management.
3. Each ATC should have one qualified Medical doctor for supervision.
4. All the personnel involved in testing should be trained on use of the kit and interpretation of results. Before initiation of testing, all the involved personnel should essentially read the ICMR advisory on rapid antigen testing: https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test_14062020.pdf, and also watch the company video on the proper sample collection and use of the kit.

5. Availability of sufficient disinfectants/ hand sanitizer is mandatory. Hand washing station with soap and water should essentially be available at the ATCs.
6. Overcrowding should be avoided at the ATC during the waiting period and the testing process. Dedicated personnel/volunteers should be available to ensure that overcrowding is avoided at the ATC.
7. The persons to be tested should essentially wear masks at the ATC and should not be allowed to remove masks at any point except at the time of sample collection.
8. The people to be tested should be requested to come to the testing centre on their own, as providing a limited number of vehicles to bring the people to the ATC can lead to spread of the infection.

Materials, reagents, kits required

1. Rapid antigen kit (with cassette, buffer, swab)
2. Personal protective equipment [gloves, masks (preferably N-95), aprons, etc)]
3. Disinfectants/ Hand sanitizer
4. Soap and water (for hand washing)
5. Refrigerator for storing antigen kits
6. 1% sodium hypochlorite for cleaning work surfaces
7. Appropriate biomedical waste management bags for disposal of infectious wastes
8. VTM and swabs (for collection of samples for RT-PCR)
9. Computers with internet access
10. Tables and chairs
11. Paper, pen, watch (to note time), and other stationeries

Sample collection, testing & data entry:

1. Number of personnel per counter (see recommendation for infrastructure at Annexure 1):
    a. 2 nursing/trained staff for sample collection
    b. 2 laboratory personnel for testing
    c. 1 data entry operator for data management
2. Tables, chairs, etc should be available for sample collection, rapid antigen testing and data entry.
3. For each counter, computer with internet access should be available for data entry.
4. The rapid antigen test should be performed as per the manufacturer's instructions. The video link can be accessed at https://youtu.be/mBdaOHJWxI4.
5. Sample collection should be done by trained personnel wearing proper PPE. Only nasopharyngeal swab should be collected from each person. No other sample should be collected.
6. For discarding of the kits and PPE, proper biomedical waste management bags should be available at the ATC.

Interpretation of results, and further action

1. The first reading should be taken at 15 minutes after inoculation of the sample in the cassette.
2. For all the samples, the control line should be visible after 15 minutes. If the control line is not visible, then the test should be considered as invalid.
3. For positive samples, the test line should be visible along with the control line.

4. In case of negative results at 15 minutes, keep the cassette till 30 minutes for final reading.

5. Clinical and demographic details of the patient being tested must be filled up in the Specimen referral form (SRF) for COVID-19 testing. Current version of the SRF available at icmr.gov.in must be used.

6. The copy of SRF is placed at **Annex-I.** It is also mentioned as per the State decision the sampling of dead body if required is to be done by antigen kit and while selecting the category of the patient **"others"** may be selected and detail may be specified. It is pertinent that the additional categrories which are to be catered through antigen kits at the health care settings levels may also be entered by opting the **"other"** columns while selecting the category in SRF.