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/mBdaOHJWxI4

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 ≥ 38°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**.*