Role of Rapid Antigen Test in the Diagnosis of COVID-19 in India

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Authors’ contributions

This work was carried out in collaboration among all authors. Author AM designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author AK managed the analyses of the study. Authors SK and VH managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

In the current world scenario where we are seeing of an alarming increase in the number of SARS-CoV-2 infections, it is necessary that in addition to RT-PCR assays, there is development and standardization of other rapid and efficient diagnostic tests. In relation to the total number of confirmed cases, India ranks second only behind the United States and according to forecasts it will not be long before it reaches the first place. As in developing countries, such as India, it is difficult to implement molecular biology facilities in all centres, the creation of rapid antigen tests is increasingly common in the detection and diagnosis of cases of COVID-19 in an early stage limiting the spread of infection.”

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1. INTRODUCTION

In December 2019, the world for the first time came to know about a cluster of patients with pneumonia of unknown cause. It was epidemiologically linked to wholesale seafood market in Wuhan, Hubei Province, China [1]. After an unbiased deep sequencing analysis of the lower respiratory tract samples of these patients, a previously unknown beta coronavirus was discovered and named as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) whereas disease was given the name COVID-19 by WHO [2,3]. Soon it turned out that the virus has rapid dissemination and it will be difficult to control its spread. Finally it was declared a pandemic in March 2020 [3]. Initially India had witnessed only imported cases of COVID-19 with limited local transmission to their immediate contacts. But with time this has changed and now we are on the verge of community transmission. Till date, India has reported 56, 46,010 cases and is ranked only second behind to the United States of America [4]. In view of the SARS-CoV-2 virus and reported high morbidity, early diagnosis was the need of the hour and therefore Indian Council of Medical Research (ICMR) issued testing strategies. These strategies have undergone several changes and have been evolving simultaneously with changes in stage of transmission. This has had a major impact on the various clinical microbiology laboratories in the country over the past six months.

For SARS-CoV-2 detection, different PCRs are being used in routine diagnostics throughout the country. Although, Real Time RT-PCR is the gold standard test for detection, the average time required for result is more than 24 hours and is an expensive instrument. Moreover, it cannot be performed in each and every laboratory due to lack of molecular virology facilities and technical expertise. Serological antibody tests were introduced, but they were not found suitable for diagnosis as these antibodies only appear after two weeks of onset of symptoms and cannot detect acute infection. As a result these antibody based assays were only indicated for surveillance purpose [5]. In view of the above, there was a need to develop a reliable point-of-care rapid antigen test (RAT). Theoretically, viral antigen is the specific marker of the virus and precedes antibody appearance within the infected people. Therefore, detection of viral antigen can play a rapid screening effect and help us to detect this deadly disease at an early stage and achieve the purpose of early diagnosis.

The first of these to be validated by ICMR was the STANDARD Q COVID-19 antigen detection kit of SD Biosensor (South Korea) [6]. This lateral flow test is based on immunochromatography for the qualitative detection of specific antigens to SARS-CoV-2 present in the human nasopharynx. It was found to have high specificity (99.3%-100%) and relatively low sensitivity (50.6%-84%) in two different evaluations. The sensitivity of the test correlated with the viral load of the patient in both the evaluations. On this basis, ICMR recommended its use as a rapid point of care test in combination with RT-PCR. Rapid antigen test (RAT) is the first test to be performed before RT-PCR or True Nativ containment zones/hotspots as well as for screening at points of entry. Ideally in cities which gave reported widespread transmission of infection, the entire containment zone population must be tested using RAT. The latest recommendations for the use of RAT are as follows:

1. All symptomatic ILI (Influenza like illness) symptoms cases including health care workers and frontline workers.
2. All asymptomatic direct and high-risk contacts of a laboratory confirmed case to be tested once between day 5 and day 10 of coming into contact.
3. All asymptomatic high-risk individuals in containment zones.

This test is easy to use, easy to interpret and gives results in less than 30 minutes. Unlike RT-PCR it does not require a BSL-II laboratory with high-end expensive instruments. Till date ICMR has validated 25 antigen based rapid kits, out of which only four were found to be satisfactory (Table 1). One of these (COVID-19 Antigen Respistrip) is different from the rest as here the sample has to be put in the viral transport medium (VTM) vial and then transported to a BSL-II laboratory. Therefore unlike other approved kits it cannot be employed as a point of care test. Rest 19 antigen based kits were not found acceptable for use [7].

2. STANDARD Q COVID-19 Ag TEST

Currently the STANDARD Q COVID-19 antigen detection kit (South Korea) is the only test kit
being used throughout the country for rapid antigen testing. Every kit comes with an inbuilt COVID antigen test device, sterile swab for collecting the sample, viral extraction tube with viral lysis buffer in order to inactivate the virus and a nozzle. The sample has to be collected by a trained healthcare worker maintaining complete infection control practices which includes wearing complete personal protective equipment. Once the nasopharyngeal swab is taken, it is immersed into the viral lysis buffer and squeezed. After mixing thoroughly, the buffer tube cap is replaced with a nozzle. This sample buffer mixture is only stable for one hour and therefore the test needs to be performed at the site of sample collection. It is not recommended to transport this to a laboratory for further processing. 2-3 drops of the sample with buffer are put into the well of the test strip and then observed for 15 minutes for the appearance of the control and test lines. The maximum duration for interpretation of a positive or negative result is 30 minutes. The interpretation of the test is easy and does not require any specialized instruments (Table 2).

As per latest testing advisory issued by ICMR on 04th September 2020, any positive antigen test will be reported as COVID-19 positive irrespective of the presence or absence of symptoms in the patient. There is no need to confirm such results by RT-PCR in any case.

Whereas if the antigen test is negative, it needs to be confirmed by RT-PCR immediately if the patient is symptomatic (fever, cough, sore throat). For asymptomatic individuals, the RAT or RT-PCR will be done only if such patients develop symptoms (Fig. 1).

### Table 1. List of Rapid antigen kits validated and approved by ICMR

<table>
<thead>
<tr>
<th>Sl no</th>
<th>Name of company</th>
<th>Name of kit</th>
<th>Sample used</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>SD Biosensor, South Korea/India</td>
<td>STANDARD Q COVID-19 Ag</td>
<td>Nasopharyngeal swab</td>
</tr>
<tr>
<td>2.</td>
<td>LabCare Diagnostics Ltd, India</td>
<td>COVID-19 Lateral Antigen Test Device</td>
<td>Oropharyngeal swab</td>
</tr>
<tr>
<td>3.</td>
<td>Trivitron Healthcare Pvt Ltd, India</td>
<td>BIOCARD Pro COVID-19 Rapid antigen Test Kit</td>
<td>Nasopharyngeal swab</td>
</tr>
<tr>
<td>4.</td>
<td>CorisBioconcept, Belgium</td>
<td>COVID-19 antigen Respistrip</td>
<td>Oropharyngeal swab</td>
</tr>
</tbody>
</table>

### Table 2. Interpretation criteria for standard Q COVID-19 Antigen kit

<table>
<thead>
<tr>
<th>Result</th>
<th>Control line</th>
<th>Test line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antigen Positive</td>
<td>Present(Strong/Faint)</td>
<td>Present(Strong/Faint)</td>
</tr>
<tr>
<td>Antigen Negative</td>
<td>Present</td>
<td>Absent</td>
</tr>
<tr>
<td>Invalid</td>
<td>Absent</td>
<td>Present</td>
</tr>
</tbody>
</table>

*Presence of any line, both in the control and test region, no matter how faint will be considered positive

Fig. 1. Algorithm for interpretation of COVID-19 rapid antigen test results(Source -ICMR)
3. CONCLUSION

In conclusion, although these RAT cannot replace the gold standard RT-PCR assays, they have helped us immensely in detecting and diagnosing COVID-19 at its early stage and also by large scale screening of communities residing in hot-spot areas with high incidence of disease. These can additionally be used to gain deeper insights into infectivity and course of infection to develop more advanced testing and treatment strategies [8].

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES


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