Potential Use of Antigen-Based Rapid Test for SARS-CoV-2 in Respiratory Specimens in Low-Resource Settings in Egypt for Symptomatic Patients and High-Risk Contacts

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ABSTRACT

Objective: Because of the rapidly emerging SARS-CoV-2 pandemic and its wide public health challenges, rapid diagnosis is essential to decrease the spread. Antigen-based rapid detection tests are available; however, insufficient data about their performance are available.

Methods: The lateral-flow immunochromatographic BIOCREDIT COVID-19 antigen test was evaluated using nasopharyngeal swabs in a viral transport medium from patients with confirmed infection, contacts, and exposed healthcare professionals at Fayoum University Hospital in Egypt. Test performance was determined in comparison to the SARS-CoV-2 real-time reverse-transcription polymerase chain reaction (RT-PCR) test.

Results: Three hundred ten specimens from 3 categories—patients with confirmed diagnoses of COVID-19, contacts, and exposed healthcare professionals—were included; 188 specimens were RT-PCR-positive, from which 81 were detected by rapid antigen test. Overall sensitivity was 43.1%. Sensitivity was significantly higher in specimens with high viral loads.

Conclusion: Poor sensitivity of the BIOCREDIT COVID-19 test does not permit its use for diagnosis, and it can only be used in conjunction with RT-PCR for screening.

Keywords: antigen-based rapid test, COVID-19, RT-PCR, SARS-CoV-2
tests in antigen detection for SARS-CoV-2 requires further evaluation, and the tests are not recommended for clinical diagnosis.8,9

The aim of this study was to assess the performance of the BIOCREDIT COVID-19 Ag test as a frontline test in comparison to the molecular RT-PCR technique to evaluate the potential of its use during the peak period of the pandemic, especially in high-risk symptomatic populations such as healthcare workers, reducing the need for expensive molecular confirmatory testing.

Materials and Methods

Patient Selection

This study was performed at Fayoum University Hospital in Egypt and was approved by the Fayoum University Research ethics committee, which is a member of the Egyptian Network Research Ethics Committee. The study included 310 specimens: 160 from patients who tested positive for SARS-CoV-2 by RT-PCR and 150 from exposed healthcare workers and patient contacts. Specimens were all collected during May 2020.

Specimens

Nasopharyngeal (NP) specimens were obtained using flocked NP swabs and transported to the laboratory in universal viral transport media (UTM-RT System, Copan Diagnostics, Murrieta, CA) within 1 to 2 hours of collection.

RT-PCR for SARS-CoV-2

The RT-PCR technique used the SARS-CoV-2/SARS-CoV Multiplex real-time PCR detection kit, DNA technology in the instrument RT-PCR DTlite 4 (Russia), and the extraction was done using the LabTurbo 48C (Taiwan).

BIOCREDIT COVID-19 Ag

PCR-characterized specimens (universal transport medium with swabs) were kept at 4°C and tested within 24 hours by the BIOCREDIT COVID-19 Ag, which is a lateral-flow immunochromatographic assay that uses a dual-color system for the qualitative detection of the SARS-CoV-2 antigen from NP swab specimens. The recommended specimen volume of the BIOCREDIT COVID-19 Ag kit was 90 to 150 μL. To unify the specimen volume, a 100 μL specimen volume average was used.

Statistical Analysis

All statistical calculations were done using SPSS software version 18 under Windows 7. Qualitative data were statistically expressed in the form of frequency and percentages. Numerical data were statistically represented in terms of range, mean, and standard deviation. The Pearson χ² and t-test were used for comparing categorical variables. A probability value (P value) >.05 was considered significant.

Results

A total of 310 specimens were included. Of those, 188 were RT-PCR-positive for SARS-CoV-2 RNA, and 122 were RT-PCR-negative. Among tested patients, 59.4% were men and the median age was 42 years. Positive specimens from patients were taken during the initial phase of the disease with a median duration of symptoms of 3 days. The median cycle threshold (Ct) value of positive RT-PCR specimens was 20.2 (range, 15.8–32.3). All false negative results according to the RAD test (n = 107) corresponded to specimens with

Table 1. Demographic and Laboratory Features of Included Patients

|                | All   | PCR-Positive | PCR-Negative |
|----------------|-------|--------------|--------------|
| Total          | 310   | 188          | 122          |
| Sex            |       |              |              |
| Male           | 184 (59.4) | 103 (54.8) | 81 (66.4)    |
| Female         | 126 (40.6) | 85 (45.2)  | 41 (33.6)    |
| Age (y), median| 42    | 42           | 42           |
| Ct value       |       |              |              |
| Median         | 20.2  |              |              |
| Range          | 15.8–32.3 |            |              |
| Mean           | 22    |              |              |

Ct, cycle threshold of RT-PCR; PCR, polymerase chain reaction. Data represent absolute numbers (%).
RT-PCR Ct values >28. All specimens that tested positive according to the RAD test tested positive according to RT-PCR testing.

Discussion

Different diagnostic test manufacturers have developed rapid tests based on SARS-CoV-2 protein detection in respiratory specimens.7 The analytical performances of rapid antigen tests depend on different factors including the viral load, the quality of the specimen, and the setting of the people tested.

Rapid tests have different advantages, including low cost, short turnaround time, simple noncomplicating test performance, and the lack of a need for special equipment or skills compared with molecular techniques.10

In this study, we assessed the performance characteristics of the rapid antigen test BIOCREDIT COVID-19 Ag for detecting SARS-CoV-2 in respiratory specimens and compared the results with RT-PCR testing. Our data indicated that (i) RAD testing for SARS-CoV-2 had a lower sensitivity than RT-PCR testing, (ii) negative results could not exclude the possibility of SARS-CoV-2 infection with confidence, and (iii) therefore, results should be confirmed by further RT-PCR testing. We also noted that the RAD test can detect SARS-CoV-2 with a high viral load (Ct <25.5), but the sensitivity declines substantially when the viral load decreases with Ct values >28, which is often the case in patients with COVID-19. In this study, the overall sensitivity of the BIOCREDIT COVID-19 Ag test was 43.1%. A similar study revealed an overall sensitivity of 30.2% in 106 SARS-CoV-2 RT-PCR-positive specimens.6

Although the RAD test was positive for corresponding RT-PCR-confirmed COVID-19 infection, we recommend checking the specificity more by using the RAD test for other viruses that could cross-react with other human coronaviruses, eg, severe acute respiratory syndrome coronavirus (SARS-CoV) and the Middle East respiratory syndrome coronavirus, which can each cause severe acute respiratory illnesses because of their genetic relationship with SARS-CoV-2.

Conclusion

In summary and based on our data, the application of the RAD test alone in clinical settings is not recommended in favor of continued molecular diagnostics and should not be considered for use in the screening of asymptomatic individuals or for population-based surveillance studies. However, the balance between cost, turnaround time, ease of performance, and sensitivity in adopting an antigen-based assay should be considered in symptomatic patients with a high pretest probability of having COVID-19. The use of these tests should be considered when there is a need for immediate clinical decisions and infection control measures, and negative results in this scenario should be confirmed with a laboratory-based molecular test. LM

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