The Journal of Medical Research

Dynamic characteristic of SARS-CoV-2 and its antibody detection

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Abstract

To prevent excess morbidity and mortality of Covid-19, a prompt and accurate diagnosis is crucial. Antibody-based rapid diagnostic test (RDT) is a rapid, fairly reliable, and useful diagnostic testing solution for COVID-19. As a point-of-care test with fast turnaround time, the kit permits quick screening in hospitals to avoid the crowding of specimen collection. However, available RDTs kits have different sensitivity, specificity, and accuracy profiles due to antigen and antibody variability because of the sequence mutation of the SARS-CoV-2 gene. Therefore, it is strongly recommended to either re-measure the accuracy of a rapid test before using it in a different country or use tests developed based on local viral characteristics.

Keywords: SARS-CoV-2, Rapid Diagnostic Test, Target gene mutation.

INTRODUCTION

The World Health Organization (WHO) declared Coronavirus disease 2019 (COVID-19) as a global pandemic on March 11, 2020. To prevent excess morbidity and mortality, prompt and accurate diagnosis is crucial. Hence, research institutes and medical companies have attempted to develop and approve tests to detect current viral infection and immunity to SARS-CoV-2.

SARS-CoV-2 detection in the respiratory specimen using real-time reverse transcription-polymerase chain reaction (rRT-PCR) is considered the gold standard for the diagnosis of COVID-19. However, this technique requires certified laboratories, expensive equipment, and trained technicians [1].

Antibody-based rapid diagnostic test (RDT) is a rapid, fairly reliable, and useful diagnostic testing solution for COVID-19. As a point-of-care test with fast turnaround time, the kit permits quick screening in hospitals to avoid the crowding of specimen collection for molecular detection. Additionally, rapid antibody tests can aid in cases presenting with a discrepancy between the clinical/radiological feature and rRT-PCR results [2].

Currently, available RDTs kits have different sensitivity, specificity, and accuracy profiles due to antigen and antibody variability [3]. In addition, Hofman *et al*. (2020) and Li *et al*. (2020) studied the same rapid test with different sensitivity and specificity results on COVID-19 detection. Hofman *et al*. (2020) found 100% specificity for both IgM and IgG, while the sensitivity was 87.9% for IgM and 97.2% for IgG [4]. The results by Li *et al*. (2020) showed an overall testing sensitivity of 88.7% and 90.6% specificity [5].

These discrepancies could be caused by the variability of antigen and antibodies, antibody rising time (time of testing), cross-reactivity with other coronaviruses, or the limited number of samples for testing. Therefore, a combination of nucleic acid rRT-PCR and the IgM-IgG antibody test can provide a more accurate SARS-CoV-2 infection diagnosis [5].

Another reason for the discrepancy is the sequence mutation of the target gene. SARS-CoV-2 is an enveloped, RNA virus, belonging to the betacoronavirus genus. RNA virus mutation rate is dramatically high, up to a million times higher than their hosts and this high rate is correlated with virulence modulation, traits considered beneficial for viruses [6]. Wang C *et al*. (2020) reported the mutation of the SARS-CoV-2 virus on positions nt28144 in ORF 8 and nt8782 in ORF 1a with respective mutation rates of 30.53% and 29.47% [7]. Additionally, Cardoso *et al*. (2020) found the mutation of the amino acid at position 614 of the viral spike, which may affect the receptor-binding site of the antigen to the antibody [8].

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The biological characteristics of these viral mutations provide precious insight for designing new vaccines, antiviral drugs, and diagnostic assays [7,8].

Studies on patients` immunological response against the SARS-CoV-2 is also important to generate accurate rapid tests. Antigen-antibody based rapid tests should be designed to target the immune response towards conserved epitope regions. Although, many B and T cell epitopes are highly conserved between SARS-CoV-2 and SARS-CoV [9] the structure and function of these regions may change by the mutation of SARS-CoV-2. These changes could affect the accuracy of the rapid test. Unfortunately, information regarding the target epitope region of most kits is mainly unavailable. Therefore, it is strongly recommended to either re-measure the accuracy of a rapid test before using it in a different country or use tests developed based on local viral characteristics in order to attain more reliable results.

Conflicts of Interest

The authors declare no conflicts of interest.

Funding

None.

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