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SARS-CoV-2 Rapid Antigen Kit Efficacy in Comparison with Quant Studio 12 PCR

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ABSTRACT

COVID-19 is an acute respiratory disease that has profoundly affected the way we test for disease and monitor viral infection. COVID-19 is caused by the novel coronavirus, SARS CoV-2. This virus is rapidly spread from person to person through contact with sputum particles, even when the infected individual is asymptomatic. Testing for the disease relies heavily on PCR molecular assays, and during the COVID-19, pandemic at-home rapid antigen test kits became widely available to improve the convenience of diagnosing the disease and increase the access to testing capabilities. COVID-19 rapid antigen kits have been a cornerstone of COVID-19 testing as a supplement for PCR testing. Rapid antigen kits can determine the presence of SARS CoV-2 using a lateral flow assay that targets the nucleocapsid protein of the virus for a qualitative result. This study aims to determine the efficacy of the rapid antigen kit by analyzing 105 rapid antigen results and comparing them with Quant Studio 12 PCR cycle threshold values. The results indicate that the lateral flow assay can detect SARS CoV-2 in samples that have a cycle threshold of 28.92 out of 40 cycles. Relative to other at-home antigen kits, the findings in this study imply that this kit is especially sensitive and able to detect low levels of viral load within patients.

Keywords

SARS-CoV-2, Rapid Antigen Kit, Respiratory diseases, PCR.

Introduction

SARS-CoV-2 is the virus that causes COVID-19, an acute respiratory disease that resulted in a pandemic outbreak in 2020. Due to its rapid spread, the World Health Organization (WHO) recognized the disease as a global pandemic on March 11, 2020 [1]. The overwhelming infection rates and devastating fatalities catalyzed an urgent need to increase the diagnostic capabilities to better identify those who have been infected by the virus, and ultimately decrease the spread of the disease. The rapid necessity for treatment and protection has led the scientific community to partly focus on antibody response and exploring the ability to protect the body from disease via antibodies. Individuals infected with SARS-CoV-2 may have a range of symptoms from asymptomatic infection to severe respiratory illness and even death. The virus is spread primarily from person to person through respiratory particles, even by individuals without symptoms. Testing for this disease has become increasingly more important to decrease the spread, making the need for reliable at-home testing kits prevalent.

Due to the high pathogenicity and rapid transmission across

communities and congregated groups, early and reliable detection for SARS-CoV-2 presence is critical [2]. COVID-19 diagnostic techniques either use clinical samples to directly evaluate presence of virus particles, nucleic acids, or antigens, or serological assays for antibodies against SARS-CoV-2 [3]. Reverse transcriptase polymerase chain reaction (RT-PCR) is considered the gold standard for detecting presence of SARS-CoV-2 through nasopharyngeal swabs, saliva, nasal fluids, or bronchoalveolar lavage fluid [4]. While this is considered the most precise and accurate way to diagnose COVID-19, testing requires extensive laboratory work including experienced laboratory technicians and expensive equipment [5]. Although considered to be less sensitive, studies have shown rapid antigen testing can provide an alternative to RT-PCR, and are more practical due to the ease of use, cost effectiveness, and the early detection of the virus early after symptoms appear [6].

Antigen diagnosis identifies live virus proteins such as the nucleocapsid protein, spike protein, or both [7]. Antigen testing is both cost effective, and easy to use due to the nature of testing that does not require laboratory facilities or experienced technicians. Rapid antigen kits can determine the presence of SARS CoV-2 using a lateral flow assay that targets the nucleocapsid protein of the virus for a qualitative result. These tests can also be used for a wide range of patients, increasing the accessibility for the vast and dynamic population that is susceptible to viral infection. Additionally, these tests do not require analyzers, readers, and are cost effective and portable [8]. Despite the benefits, there has been ambiguity about the sensitivity of rapid antigen kits as there are many manufactures and are considered inferior to molecular assays [9].

In the present study, we examine the at home rapid antigen kit results and compare them to RT-PCR cycle threshold values to determine the accuracy and efficacy of the test. This test is authorized for non-prescription home use with self-collected anterior nasal (nares) swab samples from individuals aged 15 years or older who are symptomatic. Additionally, the test is authorized for individuals aged 2 years or older with symptoms of COVID-19 within the first seven days of symptom onset with or without other epidemiological reasons to suspect COVID-19 when tested twice over three days with at least 24 hours (and no more than 48 hours) between tests.

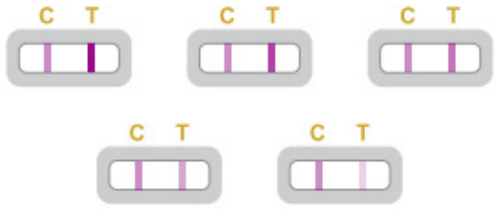
The test targets the SARS-CoV-2 nucleocapsid protein antigen protein. The antigen is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with a past medical history and other diagnostic information is necessary to determine infection status.

It is important to note that positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease. Individuals who test positive for the COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary. Negative results are presumptive, however, do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

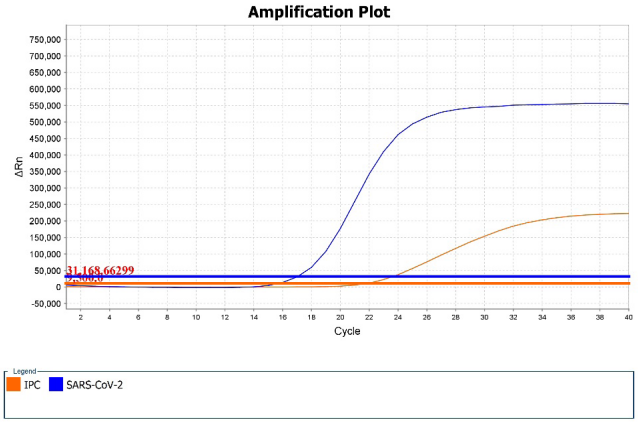
Materials and Methods

To determine the accuracy and efficacy of the rapid antigen kit, we examined 105 rapid antigen test results and compared them to RT-PCR cycle threshold values. Cycle threshold (Ct) values represent the amount of virus that is detectable in a certain sample. Since Ct values tell us how many cycles are necessary for the virus' genetic material to be detected, they can provide insight to the sensitivity and efficacy of a diagnostic test. Viral load is inversely proportional to a sample's Ct value, meaning the lower the Ct value correlates with a higher concentration of a viral RNA in the sample.

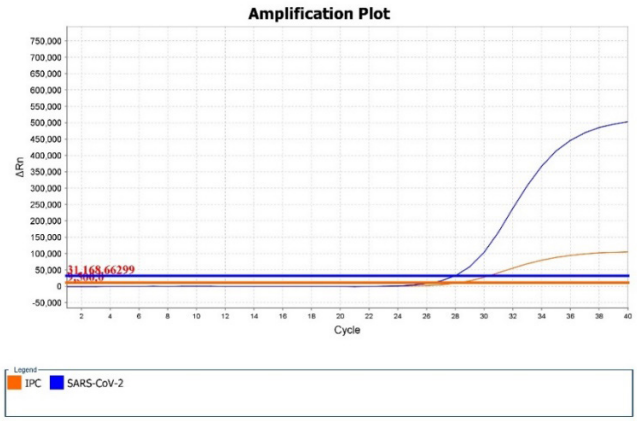
Rapid antigen kits were performed using the inserted "instructions for use" that is present with the kit. Results are interpreted using a pictured guide, supplied with the kit. See (Figure 1A) Quant Studios 12 by ThermoFisher is a thermocycler that is capable of high throughput real time-PCR. Procedures and methods supplied by the manufacturer were used to perform the experiments. Results are interpreted by a technician and confirmed by a licensed clinical laboratory scientist. See (Figure 1B). The IPC (internal positive control) serves as a control to determine if the patient was swabbed well enough to get an accurate reading. If only IPC is present, the patient is considered negative see (Figure 2B).



A: Positive Result as Depicted on the Rapid Kit.



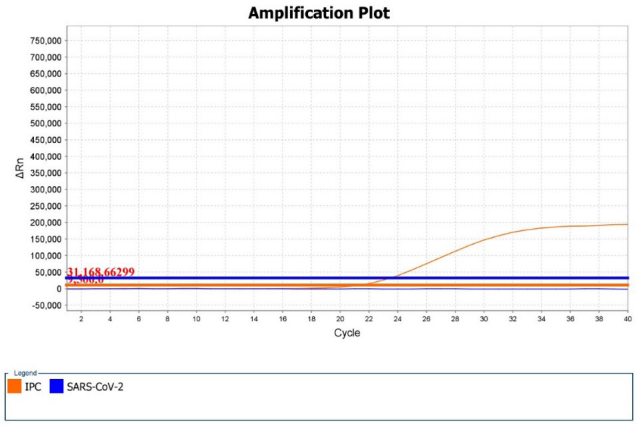
B: High positive as depicted on Quant PCR.



C: Low positive as depicted on Quant PCR.

Figure 1: Positive Results.

A: Negative Result as Depicted on the Rapid Kit.



B: Negative as Depicted on Quant PCR.

Figure 2: Negative Results

Invalid Result: Invalid Results are Depicted by Marking Just the "T" or No Mark at all.

Results

Ct values were obtained from the Quant Studios 12 PCR test and compared with results on the rapid antigen assay. 105 samples tested on the rapid antigen molecular assay. Ct values as low as 16 and as high as 28.91 were obtained from the PCR test. 54 out of 54 that were within that range confirmed positive and 51 out of 51 were confirmed negative. The positive percent agreement (PPA) is 100% and the negative percent agreement (NPA) is 100%. These results indicate that the lateral flow assay can detect SARS CoV-2 in samples that have a cycle threshold of 28.92 out of 40 cycles.

Discussion

Although the colloidal-gold conjugate with the monoclonal antibody is highly sensitive to the nucleocapsid protein of SARS CoV-2, there remains speculation about the sensitivity and efficacy of rapid antigen test kits. The rapid antigen kit evaluated in this study shows high sensitivity and can efficiently detect low levels of SARS CoV-2. Ct values obtained from PCR testing indicate what cycle number the amplification became high enough to break the threshold baseline [4]. Lower Ct values indicate a higher viral load collected, and higher Ct values indicate a lower viral load collected [2,3].

Many studies have shown Ct values to be a correlate to disease severity. One study found that out of 678 patients who were hospitalized from COVID-19, 35% of those with a Ct value of 25 or less died, compared to 17.6% of patients with a Ct value of 25 to 30 and 6.2% with a Ct value above 30 [13]. Additionally, they surmised that the risk of death increased with decreasing Ct values and the risk of intubation was greater with Ct values less than 27 compared with Ct values greater than 27. Similarly, another study examined Ct values of 875 patients with COVID-19 and found that those with a Ct value of 25 or below were more likely to have severe disease or die [14].

In the present study, Ct values as low as 16 and Ct values as high as 28 can be detected with clarity using this rapid antigen kit. This is a significant range that is highly effective for testing individuals during the COVID-19 global crisis. If a rapid antigen test can produce results from samples with lower Ct values, patients with high viral loads will be able to mitigate their risks of complications from COVID-19 due to the accessibility of this test. Conversely, if a rapid antigen test can produce accurate results from patients with higher Ct values; this will allow patients to seek medical guidance prior to the disease advancing. It has also been shown that Ct values can allow clinicians to screen patients most at risk for severe disease and death [12].

Some limitations include asymptomatic infections that would require serial testing to accurately determine infection. Additionally, viral load is determined by how infectious the patient is and how well they are sampled or swabbed. The test cannot be used to determine at what stage of infection the patient is, and results should be used in conjunction with physical examination and recommendations to manage COVID-19 infections. PCR remains the best way to detect a SARS CoV-2 infection in patients but is not practical for in home use by the public. The recent pandemic has highlighted a need for more sensitive at home kits that are comparatively just as accurate or sensitive as PCR.

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