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Review Article

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Utilizing a COVID-19 Antigen Rapid Test to Screen Specific Populations Facilitates: 'Early Detection' of Omicron Variants

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Abstract

Background: COVID-19 is caused by the SARS-CoV-2 virus. It is part of the coronavirus family, which includes Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS). Like many other respiratory viruses, coronaviruses are transmitted mainly through person-to-person contact with an average incubation period of about 4 days.

Since the World Health Organization (WHO) declared the SARS-CoV-2 pandemic, the virus of COVID-19 has spread to 223 countries, with over 593 million confirmed cases and over 6 million reported deaths worldwide. The most recent WHO epidemiological report states that more than 200 countries worldwide have reported worrisome variants of SARS-Co-V-2, including Omicron VOC (Variant of Concern). Omicron VOC is currently reported as the predominant circulating VOC since November 2021. However, morbidity and mortality rates are influenced by factors such as age, underlying pre-existing medical conditions and disease severity, and vary significantly between countries.

The clinical spectrum of COVID-19 ranges from asymptomatic or oligosymptomatic forms to clinical conditions characterized by acute respiratory failure, infectious shock and multi-organ failure. It is estimated that between 17.9% and 33.3% of infected patients will remain asymptomatic. In contrast, most symptomatic patients usually present with fever, cough and shortness of breath, and less commonly with sore throat, loss of smell, taste disturbances, anorexia, nausea, malaise, myalgia and diarrhea.

On serology, the initial infection is characterized by elevated specific IgM antibodies within 3 days-7 days of onset and elevated IgG antibodies 5 days-10 days later. Therefore, Polymerase Chain Reaction Techniques (RT PCR) or SARS-CoV-2 nuclear capsid protein antigen testing are used within the first 5 days to diagnose neocoronavirus.

Objective: The main objective of this study is to investigate the performance of the Citest COVID-19 antigen rapid test kit for the qualitative detection of SARS-CoV-2 virus in self-collected nasal swab specimens from symptomatic/asymptomatic individuals as an aid to the diagnosis of COVID-19 infection in suspected patients.

Methods: Run a rapid chromatographic immunoassay to detect SARS-CoV-2 nucleocapsid protein antigen in human nasal swab specimens and compare with the gold standard RT-PCR (nasopharyngeal swab) test for performance verification.

Results: 97.0% Sensitivity-In total 665 PCR confirmed positive samples: 645 PCR confirmed positive samples were correctly detected by Citest COVID-19 antigen rapid test. There are 20 false negative cases.

>99.9% Specificity-In total 332 PCR confirmed negative samples: 332 PCR confirmed negative samples were correctly detected by Citest COVID-19 antigen rapid test. There are 0 false positive case.

98.0% Accuracy-In total 997 PCR confirmed samples, 977 PCR confirmed samples were correctly detected by Citest COVID-19 antigen rapid test.

Conclusion: The COVID-19 antigen rapid test (Swab) is a qualitative membrane-based Immunoassay for the detection of SARS-CoV-2 nucleocapsid protein Antigens in human nasal swab specimens.

The test kit is simple to use and has been validated against the RT PCR test, the gold standard for nucleic acid detection. Results are available 15 minutes after testing. The results of 997 nasal specimens tested in clinical trials show an overall accuracy of 98.0%, a relative specificity of >99.9% and a relative sensitivity of approximately 97%. Patients can use the test kit to obtain accurate results and determine whether they are infected with SARS-CoV-2.

Keywords: Antigen; COVID-19; SARS-CoV-2; Rapid test; Omicron

Introduction

About SARS-CoV-2

SARS-CoV-2 is a positive-stranded single-stranded RNA β family coronavirus that is genetically similar to SARS coronavirus and bat SARS coronavirus. Each virus particle has a diameter of 50-200 nm [1-3]. It consists of four structural proteins, named S (Spines), E (Envelope), M (Membrane) and N (Nucleocapsid). The N protein contains the RNA genome of the virus, and the S, E and M proteins together form the viral envelope. Recent studies suggest that bats may be a potential natural hosts for SARS-CoV-2, while Malayan pangolins may be potential intermediate hosts [4].

Despite global vaccination efforts, mitigation strategies including masking and social distancing, vaccination and treatment, millions of cases are likely to occur globally, many of which are currently undocumented in immunized populations, allowing variants with immune evasion characteristics to continue to have the opportunity to emerge.

Omicron appears to be at least more infectious than Delta and Delta variants, and 50%-70% more infectious than earlier variants (including the Alpha variant). Severe infections remain more common in unimmunized populations with risk factors and in those with poor vaccine response [5].

Materials and Methods

Transmission of SARS-CoV-2

The primary mode of transmission of SARS-CoV-2 is through close contact with respiratory droplets carrying the infectious virus, or through droplets from presymptomatic, asymptomatic, or symptomatic individuals carrying the virus.

Aerosol-producing airborne transmission has also been associated with the spread of COVID-19. However, data on airborne transmission of SARS-CoV-2 in the absence of aerosol-producing procedures are emerging and being evaluated. However, this mode of transmission is not universally recognized.

Contaminant transmission of SARS-CoV-2 contaminating inanimate surfaces has been well characterized based on numerous studies reporting SARS-CoV-2 viability on a variety of porous and nonporous surfaces.

The U.S. Centers for Disease Control and Prevention (CDC) recently issued an update stating that individuals can be infected with SARS-CoV-2 through contact with surfaces contaminated with the virus, but the risk is low and it is not the primary route for virus transmission. Epidemiologic data from several case studies report the presence of live virus in the feces of SARS-CoV-2 infected patients, suggesting the possibility of fecal-oral transmission. Transmission *via* respiratory droplets is also possible in prolonged indoor exposure and poorly ventilated areas. The risk of transmission from contaminants is considered very low. Six feet distance remains the conventional recommended distance for socialization but is largely not followed in many settings where mitigation strategies are no longer promoted.

Prevention and diagnosis for COVID-19

Vaccination against SARS-CoV-2 infection: The WHO has proclaimed “everyone, everywhere, should have access to COVID-19 vaccines”.

In addition to the importance of implementing public health and infection control measures to prevent or reduce the spread of SARS-CoV-2, the most critical step to contain the global pandemic is to prevent SARS-CoV-2 infection in communities around the world through vaccination.

Different types of vaccines provide protection in different ways. However, with all types of vaccines, the body leaves behind a "memory" of t and b lymphocytes that will remember how to fight the virus in the future.

After vaccination, it usually takes a few weeks for the body to produce t-lymphocytes and b-lymphocytes. Therefore, it is possible for a person to become infected with the virus that causes COVID-19 before or after vaccination and then become sick because the vaccine did not have enough time to provide protection.

In some instances after vaccination, the process of building immunity can cause symptoms such as fever. These symptoms are normal signs that the body's immunity is building.

Results and Discussion

COVID-19 diagnostic methods

Real time reverse transcription polymerase chain reaction (real-time RT-PCR): Real-time RT-PCR is an example of Nucleic Acid Amplification Tests (NAATs), which amplify nucleic acids for subsequent sequence analysis and are the gold standard for the diagnosis of current infection with COVID-19 [6,7].

Real-time RT-PCR not only has high sensitivity and specificity, but also enables quantitative analysis of RNA. It is currently the most used technique to detect SARS-CoV-2 RNA from respiratory samples [8].

However, since viral load depends on disease progression and specimen type, false negative results can still occur. In addition, because SARS-CoV-2 is an RNA virus that is more susceptible to inactivation and degradation, preservation and handling methods for samples can be more difficult. On the other hand, these technical factors such as mutation of viral target region, PCR inhibition, and cross-contamination between samples can also affect the accuracy of the results.

Computed Tomography (CT) scan: Computed tomography (CT) is a medical imaging technique that generates cross-sectional images

by combining multiple x-ray measurements of the patient's chest at different angles. It helps in the diagnosis of lung lesions and reveals radiological changes in the lungs.

It is a non-invasive detection method that offers convenience for patients with sampling difficulties, but at the same time requires a higher level of medical care in the community.

Rapid antigen testing for COVID-19: COVID-19 antigen test generally refers to the novel coronavirus antigen test. The advantage of this method is the rapid test is simple to perform and generally produces a test result in 15 minutes. It can also be used for primary screening of large populations. Almost all COVID-19 antigen tests use the neo-coronavirus capsid protein as the target, and are therefore less likely to be affected by variant strains and have a higher accuracy rate.

Evaluation of Citest COVID-19 antigen rapid test (Swab)

Materials and directions for use: The COVID-19 antigen rapid test (Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Nucleocapsid protein Antigens inhuman nasal swab specimen.

Materials provided in the test kit include a test cassette, extraction buffer, sterile swab, tube holder, package insert and an optional biosafety bag.

Directions for use state to wash hands thoroughly before testing. Then, remove the cover of the tube containing the extraction buffer. Place the tube in the tube holder. Insert a cotton swab into the nostril, but do not exceed 2 cm, and use the swab to make a circular motion around the inner wall of each nostril and wipe hard 5 times-10 times. Do not insert the swab deeper if strong resistance or pain is felt during sample collection. Nasal swab collection is not recommended when the nasal mucosa is damaged or bleeding.

Performance characteristics of Citest COVID-19 antigen rapid test (Swab)

The COVID-19 antigen rapid test Kit (Swab) has been evaluated on fresh nasal swab specimens obtained from symptomatic and asymptomatic individuals. Excellent performance in Table 1 of the test kit has been confirmed by leading RT-PCR (nasopharyngeal swab) tests.

Sample	RT-PCR (nasopharyngeal swab) confirmed	Correct identified
Positive sample	665	645
Negative sample	332	332
Total	997	977
Relative sensitivity	97.0% (95%CI:95.4%-98.2%)	
Relative specificity	>99.9% (95%CI:98.9%-100%)	
Accuracy	98.0% (95%CI:96.9%-98.8%)	

Table 1: Performance of citest COVID-19 antigen rapid test (Swab).

Clinical performance

A clinical evaluation was conducted comparing the results obtained using the COVID-19 antigen rapid test with RT-PCR (nasopharyngeal swab) test results. The clinical trial included 997 nasal specimens. The results demonstrated 97.0% sensitivity and >99.9% specificity with an overall accuracy of 98.0%.

Conclusion

Novel coronavirus pneumonia, is an acute infectious pneumonia. The initial symptoms of patients are mostly fever, malaise and dry cough, and gradually develop severe manifestations such as respiratory distress, which can lead to death in severe cases.

Once symptoms of suspected viral infection appear, self-testing can be performed using the COVID-19 antigen test, with or without symptoms. Currently, there are thousands of known variants, with Omicron being the most infectious. Highly accurate antigen detection kits have clearly become one of the most effective and rapid methods for initial screening of COVID-19.

Diagnostic testing is the key to an effective response to identifying novel coronaviruses. Regardless of the diagnostic method used to perform the test, it is a sign of responsibility for health. This study has validated the Citest COVID-19 antigen rapid test (Swab) with an accuracy rate of 98% and can meet the requirements of daily testing.

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