Research Article

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Evaluation on the Specificity and Sensitivity of a COVID-19 and A+B Influenza Antigen Combo Test for Detection and Application in Rapid Chromatographic Immunoassays

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Abstract

Background: The emergence of COVID-19 and influenza A+B antigen combination diagnostic tests implies a significant increase in their respective prevalence worldwide [1] On the one hand, the emergence of novel coronary pneumonia has had a significant impact on people's lives worldwide since 2019. As a condition consisting of severe acute respiratory syndrome with a high intensity of transmission, COVID-19 poses a threat to human health worldwide. On the other hand, influenza A, which dominates influenza, has increased in activity worldwide.

As of December 14, 2022, the cumulative number of COVID-19 confirmed cases worldwide reached more than 640 million. Of these, 260 million and 180 million have been confirmed in Europe and the Americas, respectively. The number of confirmed cases worldwide will reach a peak in January 2023. In addition, it is estimated that more than six million people worldwide have died from COVID-19. However, this figure is incomplete and to some extent, the data for Africa is not complete and the presence of asymptomatic patients makes it difficult to count. For influenza, North America and Europe have seen a significant increase in influenza activity, while other regions have seen a relatively lower prevalence [4]. In the National Influenza Centre (NIC) study, 97.9% of the 562,000 samples were influenza A viruses, while influenza B viruses accounted for 2.1%.

In clinical manifestations, patients infected with novel coronaviruses mainly present with fever, malaise and dry cough, and some people suffer from a stuffy, runny nose, sore throat, and myalgia diarrhea. The incubation period of the novel coronavirus is 1-14 days, with most people developing symptoms within 3-7 days. In addition, the novel coronavirus is highly contagious and can be transmitted to asymptomatic people. Influenza is also a highly contagious acute respiratory virus that can be transmitted from person to person through droplets containing the virus, such as coughing and sneezing, resulting in infection.

Objective: The main objective of this report is to evaluate and discuss how the COVID-19 and influenza A+B antigen combo tests can be used in practical situations and to analyse their professional performance in terms of response principles and accuracy. The feasibility of its application as a major tool for the rapid diagnosis of COVID-19 and influenza A+B antigens will also be reviewed.

Method: The SARS-CoV-2 nucleotide protein and influenza A + B virus antigens are detected in nasopharyngeal swabs from infected patients by rapid chromatographic immunoassay for the detection of COVID-19 and influenza A+ B viruses in the nasopharynx. As their antigens can be detected during the acute phase of infection, a positive result indicates the presence of antigens in the nasopharynx of the patient, while a negative result does not exclude the possibility of infection and should be confirmed by combining the test results with clinical signs of exposure and presence of associated symptoms in the patient.

Results: The results showed that the ACRO Rapid Test for COVID-19 and A + B influenza antigen combo (nasal swabs) achieved a sensitivity of 97.7%, specificity of 99% and accuracy of 98.6% for the COVID-19 antigen. The sensitivity for Type A influenza was 97%, the specificity 99.4% and the accuracy 99.2%. For Type B influenza, the sensitivity was 94.6%, the specificity 99.4% and the accuracy 99%.

Conclusion: The ACRO COVID-19 and Influenza A+B Antigen Combo (Nasopharyngeal Swab) is a qualitative, membrane-based immunoassay that tests for SARS-CoV-2 nucleotide protein and influenza A and B nucleoproteins by detecting the presence of antigenic viruses in the nasal cavity of a sample using a lateral flow immunoassay, a convenient and rapid test that gives results in less than 15 minutes.

The combination of COVID-19 and influenza A+ B antigen is easy to handle and tests for both antigenic viruses simultaneously with clear and understandable results. In this sample test, the antigen combination can effectively help patients to determine if they have this antigenic virus, and its accuracy and specificity have been thoroughly tested. Patients can use the rapid test kit to make a rapid diagnosis and get a specific assessment of which virus or viruses they are infected with.

Keywords: COVID-19; Influenza A+B; Antigen; Rapid Test

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Introduction

About COVID-19

COVID-19 is spread through droplet transmission where the virus can enter susceptible mucous membranes through coughing, sneezing and talking [2]. A second path of transmission is through contact transmission, where the virus is spread by touching one's mouth, nose or eyes after touching something that has been touched by an infected person [3]. And thirdly, airborne transmission, where the pathogen can remain infectious over long distances. Finally, fecal-oral transmission, where rotavirus is present in the feces of a patient is excreted and often contaminates water, food, clothing, toys, utensils, and other high touch objects. When a healthy person comes into contact with these items, the virus can enter the body through the hand or mouth and cause lesions in the digestive tract [4, 7].

Since 2019, the spread of COVID-19 has posed a public health threat throughout the world, endangering people's lives. It has likewise attracted the attention of the World Health Organization, which has defined it as a global public health emergency of international concern [5] [6].

About influenza A+B

Influenza A is prone to seasonal outbreaks and contains three types of influenza viruses: avian, swine and human influenza. This type of influenza is more contagious, with more severe symptoms and longer-lasting fevers, and more severe systemic symptoms which in some cases can progress rapidly causing respiratory failure and multi-organ damage, and even lead to death.

Influenza B is a small-scale or epidemic disease. Most cases of influenza B have rapid onset with chills and fever and temperature peaks within a few hours to 24 hours. Influenza B is often accompanied by headache, body aches, and fatigue and loss of appetite, but the respiratory symptoms are typically mild.

The high incidence of influenza A usually occurs in the winter and spring, when contacting the disease is relatively high. Treatment should be given promptly, otherwise symptoms may worsen.

Influenza A is a contagious disease, and in winter and spring, when the seasons are changing, individuals with reduced resistance or immunity may be infected by the virus and may show obvious clinical symptoms. Symptoms include sore throat and, in some cases, weakness or a rise in body temperature so that anti-viral medication is required.

Prevention and Diagnosis for COVID-19 and influenza A+B virus

Prevention Method

In the case of COVID-19 and influenza A+B, the movement and aggregation of populations can cause large outbreaks. From the perspective of transmission routes, since droplet transmission is necessary for both transmission routes, wearing masks and washing hands frequently are effective means to prevent infection. According to research, N95 masks are more protective against COVID-19 than normal masks. Limiting aggregation is also an important means to limit the spread of the viruses. The viruses are more likely to survive and spread in crowded places. Therefore, control measures to limit the number of people gathering and intervening in public places are effective [7].

In addition, the development of COVID-19 and influenza A+B vaccines has reduced people's sensitivity to the virus to some extent, and increases the protective barrier for people's immune systems. Studies have shown that the vaccine can effectively reduce the severity of the virus and prevent patients from dying as the infection worsens.

Flu vaccination

The risk of getting influenza is very high after the influenza season, which is a contagious disease of the respiratory system. If this disease is not treated in time, it can cause widespread infection. In order to prevent the occurrence and development of the flu, people can prevent the disease by getting a flu shot. The flu shot can also prevent the development of bronchitis and laryngitis.

Evaluation of ACRO COVID-19 and influenza A+B Antigen Rapid Test Cassette Materials and Directions for Use

Materials included in the ACRO COVID-19 and influenza A+B Antigen Combo Rapid Test include the test kits, sterile swabs, extraction tubes and suction tips (optional), extraction buffers, and product instruction guides.

ACRO COVID-19 and A+B Influenza Antigen Combo Rapid Tests (nasopharyngeal swabs) were qualitatively tested for the presence of viral antigens in the nasal passages of tested patients by membrane-based immunoassay and side-flow immunoassay, respectively.

The main test object was the nasopharynx of the patient. Tests should be performed at room temperature (15-30 degrees Celsius). The sample should be collected using a sterile swab, inserted into the patient's nostril reaching the nasopharynx, then wiped with the nasopharynx and removed from the nasal cavity. Once the sample has been correctly collected, it is placed in the extraction tube with the buffer. Then, the swab should be squeezed and rotated in the tube to release the antigens.

The test box is removed from the sealed aluminium foil bag and should be used within one hour. Next, put three drops (about 75-100µL) of the sample extract into each specimen well (S) and wait 15 minutes to read the results according to the colour display.

Performance Characteristics

Samples from the COVID-19 and influenza A+B antigen combination rapid assay (nasopharyngeal swabs) were evaluated and validated against RT-PCR (nasopharyngeal swabs) as a reference method to compare sensitivity, specificity, and accuracy of the rapid assay (**Tables 1 and 2**).

Confidence Intervals

In addition, for specificity, multiple virus strains were tested and tabulated in the study. None of the multiple strains in the tabulated concentration produced color lines in the test area.

Summary

The COVID-19 and influenza A+B antigen combo rapid tests (nasopharyngeal swabs) demonstrated excellent performance with high accuracy, sensitivity, and specificity in this evaluation. The overall performance of the test kits demonstrate they can be used as an effective diagnostic tool.

The overall evaluation of ACRO rapid tests for COVID-19 and influenza A+B antigen combo (nasopharyngeal swabs) meets the requirements for in vitro diagnosis. The test kit's ability to distinguish between COVID-19 and influenza A+ B viruses illustrates one of the excellent properties of the product and certainly add value to global public health.

Table 1. Performance Characteristics of COVID-19 Test.

COVID-19 and Influenza A+B Antigen Combo Rapid Test	RT-PCR (Nasopharyngeal Swab)		Total
	Positive	Negative	
COVID-19 Antigen	42	1	
	1	43	
Negative	101	102	
Total	43	102	145
Relative Sensitivity	97.7% (95%CI*: 87.7%~99.9%)		
Relative Specificity	99.0% (95%CI*: 94.7%~99.9%)		
Accuracy	98.6% (95%CI*: 95.1%~99.8%)		

Table 2. Performance Characteristics Influenza A+B Test.

COVID-19 and Influenza A+B Antigen Combo Rapid Test		Type A			Type B		
		RT-PCR (Nasopharyngeal Swab)		Total	RT-PCR (Nasopharyngeal Swab)		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	32	2	34	35	2	37
	Negative	1	351	352	2	347	349
Total		33	353	386	37	349	386
Relative Sensitivity		97.0% (95%CI*: 83.4 %~> 99.9%)			94.6% (95%CI*:81.4%~99.4%)		
Relative Specificity		99.4% (95%CI*:97.8 %~> 99.9%)			99.4% (95%CI*: 97.8 %~> 99.9%)		
Accuracy		99.2% (95%CI*: 97.6%~99.8%)			99.0% (95%CI*: 97.3%~99.7%)		

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