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Evaluation of the Performance Characteristics of Influenza A+B Rapid Test for Point-of-Care Diagnosis Compared with RT- PCR Method

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Abstract

Influenza, commonly referred to as the flu, is a highly contagious respiratory viral infection that spreads through aerosolized droplets resulting from coughing and sneezing. This communicable disease predominantly manifests during the fall and winter months. Type A influenza viruses exhibit higher prevalence compared to type B viruses and correlate with more severe epidemics. The rapid and accurate diagnosis of influenza A and B viral infections is crucial for early treatment and preventing further spread.

The Influenza A+B Rapid Test Cassette, developed by Hangzhou AllTest Biotech Co., Ltd is a lateral flow immunoassay for the detection of influenza A and B antigens in nasopharyngeal swab, throat swab, or nasal aspirate specimens. Its performance has been evaluated using patient specimens, with Reverse-transcription polymerase chain reaction (RT-PCR) as the benchmark reference method. The Influenza A+B rapid test cassette evaluated in this study demonstrated high sensitivity and specificity, comparable to RT-PCR, making it a valuable alternative to traditional laboratory diagnostic methods. By offering a quick and easy-to-use screening tool, this point-of-care test (POCT) facilitates rapid diagnosis of influenza A and B viral infections.

The development and advancement of rapid diagnostic tests targeting influenza A and B viral infections play a pivotal role in improving patient outcomes and mitigating transmission rates. The Influenza A+B rapid test cassette is a reliable and efficient tool for rapid detection of influenza viruses, allowing for prompt treatment and control of outbreaks.

Keywords: Influenza A; Influenza B; Rapid test; RT-PCR

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Introduction

Influenza

Influenza, a contagious illness caused by influenza viruses, presents a spectrum of symptoms ranging from mild to severe. Common symptoms include fever, runny nose, sore throat, muscle pain, headache, coughing, and fatigue. These symptoms usually appear 1-4 days after exposure to the virus (often 2 days) and can last from 2-8 days. Notably, children may experience gastrointestinal symptoms like diarrhea and vomiting. In certain cases, influenza can progress to pneumonia, attributed either to the virus itself or secondary bacterial infections. Other possible complications include acute respiratory distress syndrome, meningitis, encephalitis, and exacerbation of pre-existing health conditions such as asthma or cardiovascular disease.

There are four distinct types of influenza virus: A, B, C, and D. Among these, aquatic birds stand as the primary source of influenza A virus (IAV), a virus that also finds prevalence in various mammals, including humans and pigs [1]. On the other hand, influenza B virus (IBV) and influenza C virus (ICV) predominantly impact humans, whereas influenza D virus (IDV) is commonly observed in cattle and swine. In the human context, both IAV and IBV maintain circulation, leading to seasonal epidemics. In contrast, ICV generally causes a mild infection, largely affecting children. Although IDV can infect humans, it has not demonstrated an ability to cause illness within this population. Transmission of these influenza viruses among humans mainly occur through respiratory droplets expelled during coughing and sneezing. However, transmission through aerosols and contact with contaminated surfaces, are also recognized pathways.

Annually, approximately 5-15% of the global population contracts influenza, with 3-5 million cases reported as severe. Respiratory-

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related deaths attributed to influenza can reach up to 650,000 globally each year [2]. Those most susceptible to influenza-related mortality are individuals categorized as high-risk, including young children, the elderly, and those with chronic health conditions. In temperate climate regions, the incidence of influenza cases generally peak during the winter months, while in tropical areas, influenza can occur throughout the year.

Diagnosis

Rapid influenza diagnostic test (RIDT) is the most common type of flu test. The sample is collected by nasopharyngeal swab, throat swab, or nasal aspirate specimens and tested for influenza viral antigens, which are substances on the virus that can produce an immune response.

Viral culture is the gold standard of laboratory diagnosis. It involves a 14-day cell culture process utilizing a variety of cell lines that can support the growth of influenza virus [3].

Reverse-transcription polymerase chain reaction (RT-PCR) is the most accurate type of flu test, which uses a different process to analyze the genetic makeup of a nasal swab sample. PCR assays deliver results to answer in a few hours and some of these assays can identify the subtype of the influenza virus, whether it's B, A, or a distinct A variant [4].

Prevention

Annual vaccination is the primary and most effective way to prevent influenza and its associated complications, particularly for high-risk groups [5]. Trivalent or quadrivalent vaccines provide protection against H1N1 strain, H3N2 strain, and one or two IBV strains of influenza B virus (IBV) that correspond to the two prevalent IBV lineages.

Administering antiviral drugs as post-exposure prophylaxis, such as orally-taken oseltamivir for those aged three months and above, and inhalable zanamivir for individuals above seven, are effective means to either prevent or reduce the severity of influenza. Chemoprophylaxis is most beneficial for individuals at high-risk for developing complications and those who cannot receive the flu vaccine due to contraindications or lack of effectiveness [5].

Preventing the transmission of influenza viruses originating from animals such as birds and swine is a pivotal aspect of comprehensive control efforts. Employing measures like water treatment, indoor animal husbandry, quarantining infected animals, vaccination, and robust biosecurity protocols are key control measures in curtailing the spread of the virus. To limit contact with wild birds, strategic placement of poultry houses and piggeries on elevated ground, distant from high-density and backyard farms, live poultry markets, and bodies of water, are prudent strategies. Among these measures, the closure of live poultry markets has shown to be effective in controlling the spread of H5N1, H7N9, and H9N2 [6]. Biosecurity measures include cleaning and disinfection of facilities and vehicles, prohibiting visits to poultry farms, avoiding the return of birds intended for slaughter back to farms, adopting clothes changing, implementing disinfecting footbaths, and treating food and water.

In addition to vaccination and antiviral medication, the integration of rapid tests is an additional strategy in preventing the spread of influenza. Quick and accurate diagnosis of influenza A and B infections is crucial for early treatment and prevention of further transmission.

Evaluation of All Test Influenza A+B Rapid Test Cassette

Objective

The main purpose of this evaluation report was to assess the reliability and performance of the influenza A+B rapid test cassette (swab/nasal aspirate) for the rapid diagnosis of influenza A and B viral infections.

Method

To perform rapid tests for influenza A and B, nasopharyngeal swab, throat swab, or nasal aspirate specimens were collected from patients exhibiting flu-like symptoms, and following the manufacturer's instructions. This test employs a lateral flow immunoassay to detect influenza A and B antigens in respiratory specimens. The RT-PCR method is used as a reference standard for detecting influenza A and B nucleic acid in real-time. Sensitivity, specificity, and accuracy are calculated based on these methods.

Materials

The materials provided for the Influenza A+B Rapid Test include test cassettes, extraction reagent, extraction tubes, sterile swabs, package insert, workstation, and extraction tube tips.

Specimen collection and preparation

Nasopharyngeal swab sample

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.

2. Swab over the surface of the posterior nasopharynx 5-10 times.

Throat swab sample

Insert a sterilized swab into pharynx and collect mucoepidermis mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.

Nasal aspirate

Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasal cavity from a nostril, start the aspiration device and then collect nasal aspirate sample. Dip a sterilized swab into the collected nasal aspirate sample and make the specimen cling to the swab.

Performance characteristics

The Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate) is a qualitative, lateral flow immunoassay for the detection of influenza A and influenza B nucleoproteins in nasopharyngeal swab, throat swab or nasal aspirate specimens. In this test, antibodies specific to the influenza A and influenza B nucleoproteins is separately coated on the test line regions of

the test cassette. During testing, the extracted specimen reacts with the antibodies to influenza A and/or influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibodies to influenza A and/or influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate) has been evaluated with specimens obtained from patients. RT-PCR is used as the reference method for the Influenza A+B rapid test. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result (**Tables 1-3**).

Summary

The comparative experiments using the RT-PCR method demonstrated that the Influenza A+B Rapid Test Cassette manufactured by Hangzhou AllTest Biotech Co., Ltd performed as intended, exhibiting very high specificity, sensitivity, and accuracy. The Influenza A+B rapid test offers the advantages of ease of use and low cost. Moreover, the rapid test does not require the use of specialized laboratory equipment or personnel, and provides quick results within 15 minutes.

The test results of the samples indicate that the Influenza A+B rapid test cassette produced by Hangzhou AllTest Biotech Co., Ltd fulfills the intended use requirements for professional in vitro diagnostics. This rapid test can be utilized as a diagnostic aid in the prompt differential diagnosis of influenza A and B viral infections. Its real-world application can enhance the accuracy and timeliness of diagnosis of the flu, and help clinicians make informed medical decisions and provide responsive patient care.

Table 1. Nasopharyngeal swab specimen.

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	100	2	102	85	2	87
	Negative	1	180	181	2	200	202
Total		101	182	283	87	202	289
Relative Sensitivity		99.0%			97.7%		
Relative Specificity		98.9%			99.0%		
Accuracy		98.9%			98.6%		

Table 2. Throat swab specimen.

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	58	1	59	65	1	66
	Negative	3	150	153	4	162	166
Total		61	151	212	69	163	232
Relative Sensitivity		95.1%			94.2%		
Relative Specificity		99.3%			99.4%		
Accuracy		98.1%			97.8%		

Table 3. Nasal aspirate specimen.

		Type A			Type B		
		RT-PCR		Total	RT-PCR		Total
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	46	2	48	94	1	95
	Negative	0	241	241	2	158	160
Total		46	243	289	96	159	255
Relative Sensitivity		100%			97.9%		
Relative Specificity		99.2%			99.4%		
Accuracy		99.3%			98.8%		

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