

Evaluation of the Performance Characteristics of RSV Rapid Test in Comparison to RT-PCR Method

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Abstract

Respiratory syncytial virus (RSV) is a common viral pathogen that causes respiratory tract infections across a spectrum of ages, from infants and young children to the elderly. The significance of rapid and accurate RSV diagnosis is crucial for early treatment and prevention of further transmission. The RSV rapid test cassette from Hangzhou AllTest Biotech Co., Ltd is a lateral flow immunoassay that detects RSV antigens in respiratory specimens, including nasopharyngeal swabs and nasal aspirates. The performance of the RSV rapid test cassette (nasopharyngeal swab/nasal aspirate) has been evaluated using patient specimens, with RT-PCR serving as the benchmark reference method.

Patients displaying respiratory symptoms provided nasopharyngeal swab and nasal aspirate specimens. Each patient's sample was tested using the RSV rapid test and RT-PCR molecular assay and the results were compared. The RSV rapid test's performance was calculated for sensitivity, specificity, and accuracy.

When testing nasopharyngeal swab specimens, the RSV rapid test cassette resulted in a sensitivity of 92.7%, a specificity of 98.0%, and an accuracy of 95.6%. When testing nasal aspirate specimens, the RSV rapid test cassette showed a sensitivity of 92.6%, a specificity of 98.5%, and an accuracy of 96.0%.

Overall, the RSV rapid test cassette demonstrated high sensitivity and specificity for RSV detection, comparable to that of the RT-PCR assay. The RSV rapid test cassette offers a quick and easy-to-use alternative to the RT-PCR, making it a valuable screening tool for point-of-care diagnosis of RSV infections. The continued development and evaluation of rapid diagnostic tests for RSV are critical for improving patient outcomes and reducing transmission rates.

Keywords: RSV; Rapid test; RT-PCR

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Introduction

About RSV

Respiratory syncytial virus (RSV) is a common viral pathogen, known for causing respiratory tract infections across diverse age groups, with a pronounced impact on infants and young children [1]. Notably, RSV is a leading cause of lower respiratory tract infections, including conditions like bronchiolitis and pneumonia. Its influence extends to substantial rates of hospitalization and mortality on a global scale. While RSV infections primarily surge during the fall and winter months in temperate regions, they can manifest year-round within tropical regions.

As a member of the Paramyxoviridae family, RSV is an enveloped, single-stranded RNA virus characterized by negative-sense genetic material. RSV's antigenic landscape is structured around two

principal subgroups A and B. The virus propagates via respiratory secretions, such as saliva and nasal mucus, and is transmitted through direct contact with infected individuals or contaminated surfaces.

Currently, there are no specific treatments or therapeutic interventions for RSV infections. Clinical management predominantly adopts supportive measures such as oxygen therapy and mechanical ventilation used in severe cases. Given the treatment gap, the prevention of RSV infections is critical, particularly among high-risk populations. Preventative measures include diligent hand hygiene practices and the isolation of infected individuals.

The continued study of RSV is critical for improving our understanding of the virus and developing effective prevention and treatment strategies. The development and evaluation of rapid

diagnostic tests for RSV are also necessary for improving patient outcomes and reducing transmission. Rapid diagnostic tests allow for quick and accurate diagnosis of RSV infections, enabling prompt treatment and prevention of further transmission.

Symptoms

Among low-risk patients, RSV infections generally present with mild, relatively nonspecific respiratory symptoms. These manifestations emerge following a brief incubation period, typically materializing as upper respiratory symptoms between days 4 to 6 post-infection. Initial symptoms include loss of appetite and runny nose. Subsequently, most patients will exhibit coughing, wheezing, and sneezing, and may become febrile [2]. During this phase, supportive care aimed at alleviating symptoms and promoting comfort is often administered. The contagious phase spans 3 to 8 days, with fully resolution of infection occurring within 1 to 2 weeks.

In contrast, the trajectory of infection in high-risk patients exhibits distinctive characteristics. This group is markedly susceptible to developing complications like lower respiratory infections, bronchiolitis, and pneumonia [2]. While early symptoms might mirror those observed in low-risk patients, high-risk individuals are considerably more predisposed to advancing towards severe manifestations such as notable dyspnea, pronounced coughing or wheezing, and the development of cyanosis. In instances necessitating inpatient care, administration of oxygen and intubation may be considered.

Treatment

Presently, no specific targeted treatment for RSV exists, necessitating the need for supportive care. This approach is aimed at bolstering patient comfort and well-being. Components of supportive care may include rest, hydration, and the alleviation of symptoms through over-the-counter medications like acetaminophen or ibuprofen. Notably, supportive care interventions have demonstrated remarkable efficacy in reducing hospitalization rates for RSV infections among children aged less than 2 years.

In select cases of severe RSV infections, particularly among infants, young children, or individuals at elevated risk for complications, antiviral medications like ribavirin and palivizumab may be administered. These drugs are employed to curtail the progression of severe RSV cases. Severe cases of RSV infection may require more intensive interventions. For patients that require hospitalization resulting from severe respiratory distress, hypoxemia, apnea, and dehydration, they will receive treatment, monitoring and supportive care in hospital-based care facilities.

Prevention

Among low-risk patients, no pharmacologic methods emerge as a cornerstone of disease prevention. According to prior research, hand-washing and cohorting significantly reduce the incidence of nosocomial RSV infection [3]. Pharmacists play an important role in educating patients and caretakers on proper hand-washing techniques, the containment of secretions during coughing or sneezing, patient's isolation, and sanitization of household

surfaces [4]. This is particularly important in households with young children, who are prone to exploratory habits involving touching mucous membrane and surfaces and putting household items in their mouth. An important precaution involved advising parents and caregivers to abstain from kissing their child during periods of illness, thereby reducing risk of acquiring or spreading infection. Pharmacists, uniquely positioned, offer guidance on the transmission of RSV through oral and nasal secretions and provide specific prevention measures like hand washing and covering one's nose.

Environmental factors are sources of RSV exposure, potentially increasing children's susceptibility. When a child interacts with two or more non-immediate relatives, whether a daycare, school, or similar setting, the likelihood of contracting RSV increases dramatically. High-risk patients require more personalized preventive interventions relative to their low-risk counterparts.

RSV testing plays an important role in prevention and control strategies. Measures that facilitate rational antibiotic use, reduce unnecessary diagnostic procedures, together provide valuable information to caregivers and clinicians regarding the cause of a child's symptoms [5]. Consequently, RSV rapid tests can be a valuable tool in the management of pediatric respiratory infections and can contribute to better patient outcomes and reducing healthcare costs.

Evaluation of AllTest RSV Rapid Test Cassette

Objective

The main purpose of this evaluation report was to assess the reliability and performance of the RSV rapid test cassette (nasopharyngeal swab/nasal aspirate) for the rapid diagnosis of respiratory syncytial virus (RSV) infections.

Method

The study aimed to evaluate the performance of the RSV rapid test for point-of-care diagnosis. Respiratory specimens were collected from patients with respiratory symptoms, and the RSV rapid test was performed according to the manufacturer's instructions. The test detects RSV antigens in respiratory specimens using a lateral flow immunoassay. The RT-PCR test, a real-time PCR assay that detects RSV nucleic acid, was used as the reference standard. Sensitivity, specificity, and accuracy were calculated.

Materials

The materials provided for the RSV 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

To collect a sample from the posterior nasopharynx, insert a sterile swab into the patient's nostril until it reaches the surface of the posterior nasopharynx, and swab over the surface 5-10 times.

Table 1. Performance characteristics of RSV rapid test.

RSV Rapid Test Cassette	Nasopharyngeal Swab Specimen			Nasal Aspirate Specimen		
	RT-PCR		Total	RT-PCR		Total
	Positive	Negative		Positive	Negative	
Positive	76	2	78	87	2	89
Negative	6	99	105	7	128	135
Total	82	101	183	94	130	224
Relative Sensitivity	92.7% (95%CI*: 84.8%-97.3%)			92.6% (95%CI*: 85.3%-97.0%)		
Relative Specificity	98.0% (95%CI*: 93.0%-99.8%)			98.5% (95%CI*: 94.6%-99.8%)		
Accuracy	95.6% (95%CI*: 91.6%-98.1%)			96.0% (95%CI*: 92.5%-98.1%)		

*Confidence Intervals

Nasal aspirate sample

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 RSV rapid test cassette (nasopharyngeal swab/nasal aspirate) is a lateral flow immunoassay that detects Respiratory Syncytial Virus nucleoproteins in nasopharyngeal swab or nasal aspirate specimens. The test line region of the cassette contains antibody specific to the Respiratory Syncytial Virus nucleoproteins. During the test, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that is coated onto particles. The resulting mixture migrates up the membrane to react with the antibody to Respiratory Syncytial Virus on the membrane, generating one colored line in the test region. A positive result is indicated by the presence of a colored line in the test region. To serve as a procedural control, a colored line will always appear in the control region if the test has been performed properly.

The performance of the RSV rapid test cassette (nasopharyngeal swab/nasal aspirate) has been evaluated using patient specimens, with RT-PCR used as the reference method. Specimens were

considered positive if RT-PCR indicated a positive result, and negative if RT-PCR indicated a negative result (**Table 1**).

Reaction with various serotypes of respiratory syncytial virus

The current test kit is able to detect the following serotype of the Respiratory Syncytial Virus: Subtype A (A2, long), Subtype B(9320, wild-type)

Summary

The comparison experiments in Table 1 against the benchmark RT-PCR method showed the RSV rapid test cassette from Hangzhou AllTest Biotech Co., Ltd performed well and showed high standards of product quality in terms of specificity, sensitivity, and accuracy. In addition, the RSV rapid test is simple to perform, provides results within 15 minutes and is stable at room temperature for 24 months. It should be noted the RSV POCT does not require use of any laboratory equipment or a trained lab technician to achieve reliable results.

The results of the tested samples validate the accuracy and quality of the AllTest RSV rapid test cassette and meet the requirements of the intended use for professional in vitro diagnostic use. The RSV rapid test can be used to aid in the rapid differential diagnosis of RSV viral infections.

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