

Evaluation of the Norovirus/Rotavirus/Adenovirus Combo Rapid Test Cassette (Feces) for Rapid Diagnosis of Viral Gastroenteritis

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Abstract

Norovirus, rotavirus, and adenovirus are common viruses that can cause gastroenteritis in humans. Rapid tests for the detection of these viruses are crucial for timely diagnosis and treatment. The objective of this study was to assess the performance characteristics of the Norovirus/Rotavirus/Adenovirus Combo Rapid Test Cassette (Feces) for the rapid diagnosis of these infections.

The Norovirus/Rotavirus/Adenovirus Combo Rapid Test Cassette (Feces) is a chromatographic immunoassay that offers a rapid and user-friendly screening tool for the qualitative detection of norovirus, rotavirus, and adenovirus in human feces samples. Fecal specimens were collected from patients exhibiting gastroenteritis symptoms and subsequently subjected to testing using the combo rapid test. The detection of norovirus was compared with other established tests in the industry, while the detection of rotavirus and adenovirus was compared with the latex agglutination method. Subsequently, the combo rapid test's sensitivity, specificity, and accuracy were calculated.

The Norovirus/Rotavirus/Adenovirus Combo Rapid Test Cassette (Feces) exhibited favorable sensitivity, specificity, and accuracy. It serves as a reliable and convenient tool for rapidly diagnosing norovirus, rotavirus, and adenovirus infections in patients presenting with gastroenteritis symptoms. The development and evaluation of rapid diagnostic tests for norovirus, rotavirus, and adenovirus infections are essential for improving patient outcomes and reducing transmission. The Norovirus/Rotavirus/Adenovirus Combo Rapid Test Cassette (Feces) equips healthcare professionals with an effective diagnostic instrument that can contribute to the timely diagnosis and treatment of these infections.

Keywords: Norovirus; Rotavirus; Adenovirus; Rapid test; Diagnosis

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Introduction

Viral gastroenteritis

Viral gastroenteritis is a condition characterized by the inflammation, swelling, and irritation of the gastrointestinal tract instigated by a virus. The virus has the potential to invade the stomach, small intestine, and large intestine, and its prevalence is notably high. Ordinarily, the illness resolves on its own within a few days and typically doesn't necessitate medical intervention; however, the risk of dehydration resulting from bouts of vomiting and diarrhea should not be underestimated. Gastroenteritis can stem from various viruses that are detectable in the vomit and

diarrhea of affected individuals, and these viruses can survive outside the body for an extended duration. Transmission of the virus can occur through contaminated objects, food and beverages, and water tainted by sewage, among other avenues.

Rotavirus, norovirus and adenovirus are the common causes of viral gastroenteritis. Rotavirus is a specific virus that predominantly afflicts infants aged between 3 and 15 months, typically leading to illness duration of 3 to 7 days. Its prevalence notably surges during in the fall and winter months. Classified within the Reoviridae virus family, rotavirus boasts a distinctive double-stranded RNA configuration. Notably, among infants and young children, rotavirus claims the top spot as the most

widespread cause of diarrheal disease [1].

Conversely, Norovirus takes the lead in infecting adults. Symptoms typically endure for 1 to 3 days and can manifest at any point throughout the year. Dubbed the "winter vomiting disease," Norovirus holds the dubious distinction of being the most frequent trigger for gastroenteritis.

Adenovirus, on the other hand, remains active throughout the year and primarily targets children below the age of 2. The associated symptoms can persist for a span of 5 to 12 days.

Prevention

Norovirus

Effective measures for reducing the transmission of norovirus pathogens encompass regular hand washing with soap and water, or the use of alcohol rubs containing $\geq 62\%$ isopropyl alcohol as a supplementary measure [2]. Additionally, the sanitization of surfaces using a solution comprising 1.5% to 7.5% household bleach in water, or alternative disinfectants proven effective against norovirus, can contribute to prevention. The CDC's clinical practice guideline offers evidence-based recommendations for prevention and control of norovirus gastroenteritis outbreaks in healthcare settings. These measures encompass patient isolation precautions, hand hygiene, thorough environmental cleaning, and proactive case identification [3]. Furthermore, researchers are studying methods to develop a vaccine against Norovirus. These vaccine trials employ a virus-like particle composed of Norovirus capsid proteins to emulate the virus's external structure, thus preventing infection.

Rotavirus

Rotaviruses are highly contagious and do not respond to antibiotics or other medications. As enhanced sanitation fails to decrease the incidence of rota viral disease and hospitalization rates persistently remain high despite the utilization of oral rehydrating therapies, vaccination stands as the primary public health intervention [4]. Rotavirus vaccines adopt two distinct approaches. One type employs reasserting viruses, which consist of a combination of human and animal rotavirus, to achieve attenuation [5]. The other approach uses a single attenuated human virus [6]. While neither type vaccine type prevents subsequent rotavirus infection or mild illness, but both effectively prevent severe illness.

Adenovirus

To prevent adenovirus and other respiratory ailments, recommended practices include regular hand washing for at least 20 seconds, refrain from touching the eyes, face, and nose with unwashed hands, and avoiding close contact with individuals exhibiting adenovirus infection symptoms. Individuals with symptomatic adenovirus infection should direct coughs or sneezes into their arm or elbow rather than their hand, abstain from sharing cups and utensils, and avoid kissing others. The application of chlorination in swimming pools can help prevent conjunctivitis outbreaks caused by adenovirus.

Evaluation of all tests Norovirus/ Rotavirus/Adenovirus Combo Rapid Test

Objective

The primary purpose of this evaluation report was to assess the reliability and performance of the Norovirus/Rotavirus/Adenovirus Combo Rapid Test Cassette (Feces) for the rapid diagnosis of norovirus, rotavirus or adenovirus infection.

Method

Fecal samples were collected from patients displaying symptoms of gastroenteritis and subsequently subjected to testing using the Norovirus/Rotavirus/Adenovirus Combo Rapid Test cassette, following the manufacturer's instructions. This test employs specific antibodies to detect the presence of norovirus, rotavirus, and adenovirus within fecal samples. The rapid test's sensitivity, specificity, and accuracy were calculated and compared with alternative methods of norovirus detection, as well as the latex agglutination method, to assess the product's performance.

Materials

The materials provided for the Norovirus/Rotavirus/Adenovirus Combo Rapid Test include test cassettes, package insert, droppers, and specimen collection tubes with extraction buffer.

Specimen collection and preparation

Enhanced viral detection is achieved by collecting specimens at the initial stages of symptom onset. Studies have indicated that the peak excretion of norovirus, rotavirus, and adenovirus in the feces of gastroenteritis patients typically occurs between 3 to 5 days post-symptom onset. Collecting specimens well after the onset of diarrhea symptoms may yield an inadequate amount of antigens, thereby impeding a positive reaction, or the identified antigens might not be directly linked to the bout of diarrhea. It is essential to collect the feces specimen in clean, dry, waterproof containers devoid of detergents, preservatives, or transport media. Before usage, ensure that the required reagents have attained room temperature.

Performance characteristics

The performance evaluation of the Norovirus Rapid Test Cassette has been evaluated with 136 clinical specimens. The results indicate that the Norovirus Rapid Test Cassette (Feces) relative sensitivity exceeds 99.9% and a relative specificity of 98.1% (**Table 1**).

The performance evaluation of the Rotavirus Rapid Test Cassette involved the evaluation of 501 clinical specimens collected from children and young adults, and compared against the latex agglutination method. The results show that the Rotavirus Rapid Test Cassette (Feces) produces a relative sensitivity of 97.3% and a relative specificity of 97.1% (**Table 2**).

The performance of the Adenovirus Rapid Test Cassette has been evaluated with 381 clinical specimens collected from children and young adults in comparison with latex agglutination method.

Table 1. Norovirus rapid test cassette vs other test.

Method	Results	Other Test		Total Results
		Positive	Negative	
Norovirus Rapid Test Cassette	Positive	33	2	35
	Negative	0	101	101
	Total Results	33	103	136

Relative Sensitivity: >99.9% (95%CI:*91.32%-99.92%) *Confidence Intervals

Relative Specificity: 98.1% (95%CI:*93.16%-99.76%)

Relative Accuracy: 98.5% (95%CI:*94.79%-99.82%)

Table 2. Rotavirus rapid test cassette vs latex agglutination.

Method	Results	Latex Agglutination		Total Results
		Positive	Negative	
Rotavirus Rapid Test Cassette	Positive	251	7	258
	Negative	7	236	243
	Total Results	258	243	501

Relative Sensitivity: 97.3% (95%CI:*94.5%-98.9%) *Confidence Intervals

Relative Specificity: 97.1% (95%CI:*94.2%-98.8%)

Relative Accuracy: 97.2% (95%CI:*95.4%-98.5%)

Table 3. Adenovirus rapid test vs latex agglutination.

Method	Results	Latex Agglutination		Total Results
		Positive	Negative	
Adenovirus Rapid Test	Positive	118	6	124
	Negative	6	251	257
	Total Results	124	257	381

Relative Sensitivity: 95.2% (95%CI:*89.8%-98.2%) *Confidence Intervals

Relative Specificity: 97.7% (95%CI:*95.0%-99.1%)

Relative Accuracy: 96.8% (95%CI:*94.6%-98.4%)

The results show that the relative sensitivity of the Adenovirus Rapid Test Cassette (Feces) is 95.2% and the relative specificity is 97.7% (Table 3).

Summary

The comparative experiments conducted with other established tests in the Point-of-Care Testing (POCT) industry and the latex agglutination method have yielded noteworthy results regarding the Norovirus/Rotavirus/Adenovirus Combo Rapid Test developed by Hangzhou AllTest Biotech Co., Ltd. The test has demonstrated high levels of specificity, sensitivity, and accuracy, indicating that it is a high-quality diagnostic product. Additionally, the Norovirus/Rotavirus/Adenovirus rapid tests

offer the advantage of simplicity and user-friendliness, rapid results within 15 minutes, and eliminate the need for specialized laboratory equipment or personnel.

It is important to highlight that this product has the unique capability to simultaneously detect three viruses, a feature that not only reduces cost and time but also enhances testing efficiency.

Drawing from the outcomes of the samples tested, the Norovirus/Rotavirus/Adenovirus Combo Rapid Test cassette from Hangzhou AllTest Biotech Co., Ltd is deemed suitable for professional in vitro diagnostics. Consequently, this rapid test emerges as a valuable effective tool to aid in the prompt diagnosis of norovirus, rotavirus, and adenovirus infections.

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