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Performance Evaluation of the Strep A Rapid Test Cassette (Throat Swab) for Point-of-Care Testing via Clinical Validation

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Abstract: The Strep A Rapid Test Cassette (Throat Swab) is a chromatographic immunoassay designed for the qualitative detection of Group A Streptococcus (GAS) antigens from human throat swab specimens, aiding in the diagnosis of streptococcal pharyngitis. This study aimed to evaluate the clinical performance of the CITEST DIAGNOSTICS INC. Strep A Rapid Test by comparing its results with the reference method of bacterial culture. A total of 526 throat swab specimens collected from individuals with suspected strep A infection were tested concurrently with the rapid test and culture. The results demonstrated that the rapid test had a relative sensitivity of 95.1% (95% CI: 89.6%–98.2%), a relative specificity of 97.8% (95% CI: 95.8%–99.0%), and an overall accuracy of 97.1% (95% CI: 95.3%–98.4%) compared to culture. The test exhibited no cross-reactivity with a panel of common oropharyngeal flora and potential interfering organisms. The device remained stable under recommended storage conditions (2–30 ℃). These findings confirm that the Strep A Rapid Test Cassette is a reliable, rapid and practical tool for the detection of GAS antigens in throat swabs, facilitating timely diagnosis and management of streptococcal pharyngitis in point-of-care settings.

1. Introduction

Streptococcus pyogenes or Group A Streptococcus (GAS), is a Gram-positive bacterium responsible for a significant burden of bacterial pharyngitis, particularly in children aged 5-15 years [1]. Left undiagnosed and untreated, GAS pharyngitis may lead to serious suppurative complications such as peritonsillar abscess and retropharyngeal abscess, as well as non-suppurative sequelae including acute rheumatic fever and post-streptococcal glomerulonephritis [2,3]. The accurate and timely diagnosis of GAS pharyngitis is therefore critical for initiating appropriate antibiotic therapy, which can alleviate symptoms, prevent transmission and reduce the risk of complications [4].

The traditional gold standard for GAS detection remains throat swab culture on sheep blood agar plates, a method characterized by high sensitivity and specificity [5]. However, this technique

requires 24 to 48 hours for results, necessitating a return visit or a delayed treatment decision, which can lead to unnecessary antibiotic use in the interim or a delay in effective therapy [6]. Rapid antigen detection tests (RADTs) were developed to provide results within minutes, enabling point-of-care diagnosis and immediate treatment decisions [7]. Early RADTs were criticized for their variable and often lower sensitivity compared to culture [8]. However, technological advancements have significantly improved their performance, with many modern immunoassays demonstrating sensitivity and specificity exceeding 95% [9,10].

The principle of these tests is based on the immunochromatographic detection of the group-specific Lancefield group A carbohydrate antigen extracted from the bacterial cell wall [11]. The Strep A Rapid Test Cassette (Throat Swab) evaluated in this study utilizes antibodies specific for this antigen to provide a qualitative result within 5 minutes.

This study aims to conduct a comprehensive clinical validation of the Strep A Rapid Test Cassette (Throat Swab) by comparing its performance against the reference standard of culture, in accordance with established guidelines for the evaluation of in vitro diagnostic devices. The evaluation encompasses the assessment of sensitivity, specificity, accuracy and cross-reactivity, providing evidence for its clinical utility in diagnosing GAS pharyngitis.

2. Materials and Methods

2.1 Specimen Collection

A total of 526 throat swab specimens were collected from patients presenting with signs and symptoms suggestive of streptococcal pharyngitis (e.g., sore throat, fever, tonsillar exudate, anterior cervical lymphadenopathy). The study was conducted following ethical guidelines and informed consent was obtained where required. Specimens were collected using sterile swabs provided in the test kit. For culture confirmation, the swab was first rolled onto a selective sheep blood agar plate (e.g., Columbia CNA agar with sheep blood) before being used for the rapid test, or a second swab was collected simultaneously for culture. Specimens intended for the rapid test were processed immediately or stored in a clean, dry container at room temperature for up to 8 hours before testing, as per the manufacturer's instructions.

2.2 Test Kits and Procedures

The evaluated device was the CITEST DIAGNOSTICS INC. Strep A Rapid Test Cassette (IST-502). The reference method was bacterial culture, performed as outlined in standard microbiological procedures. The test procedure was followed precisely as per the manufacturer's package insert. All components, including test cassettes, reagents, and specimens, were equilibrated to room temperature (15–30 ℃) before testing.

The testing procedure was conducted as follows: the extraction tube was placed on a flat surface, and Extraction Reagent 1 (approximately 260 µL, red) was added vertically into the tube, followed by the vertical addition of Extraction Reagent 2 (approximately 160 µL, colorless). Upon mixing, the solution turned from red to yellow. The throat swab specimen was immediately inserted into the extraction tube and vigorously agitated approximately 18 times, after which the swab was left in the tube. Following a brief standing period as specified, the extracted solution was transferred using the provided dropper into the sample well of the test cassette. Results were interpreted at 5 minutes: the appearance of both a control line (C) and a test line (T) indicated a positive result, while only the control line (C) indicated a negative result; the test was considered invalid if the control line did not appear.

3. Results and Discussion

3.1 Performance Characteristics

3.1.1 Sensitivity, Specificity, and Accuracy

The performance of the Strep A Rapid Test Cassette was evaluated against the culture method using 526 clinical specimens. The results showed that among the 122 culture-positive specimens, the rapid test correctly identified 116 as True Positives, while among the 404 culture-negative specimens, 395 were correctly identified as True Negatives, yielding 6 false-negative and 9 false-positive results. These consolidated data is summarized in Table 1.

Table 1: Clinical Study Result (IST-502).

Method		Culture		Total Results
Strep A rapid test Cassette (Throat Swab)	Results	Positive	Nagative	
	Positive	116	9	125
	Nagative	6	395	401
Total Results		122	404	526
Relative Sensitivity		95.1% (95%CI*: 89.6%-98.2%)		
Relative Specificity		97.8% (95%CI*: 95.8%-99%)		
Totally Accuracy		97.1% (95%CI*: 95.3%-98.4%)		

The high sensitivity (95.1%) suggests that the test is highly effective at ruling in GAS infection when positive, while the high specificity (97.8%) minimizes false positives, thereby reducing unnecessary antibiotic prescriptions. The performance metrics meet and exceed the acceptable thresholds for rapid strep A tests, which have historically been a concern

3.1.2 Cross-reactivity and Interference

To assess specificity further, cross-reactivity studies were performed. The Strep A Rapid Test Cassette was tested with high concentrations ($\geq 10^{\wedge 8}$ CFU/mL) of pure cultures of various organisms commonly found in the oropharynx or that could potentially cause cross-reaction. All tested organisms yielded negative results with the rapid test. The list of non-reactive organisms included: Group B Streptococcus, Group C Streptococcus, Group F Streptococcus, Streptococcus pneumoniae, Streptococcus mutans, Streptococcus salivarius, Staphylococcus aureus, Staphylococcus epidermidis, Neisseria meningitidis, Neisseria sicca, Neisseria gonorrhoeae, Moraxella catarrhalis, Haemophilus influenzae, Pseudomonas aeruginosa, Klebsiella pneumoniae, Serratia marcescens, Enterococcus faecalis, Candida albicans, and Bordetella pertussis. The lack of cross-reactivity confirms the high specificity of the antibodies used in the test cassette and reinforces the low rate of false positives observed in the clinical study.

3.1.3 Precision

The test demonstrated consistent performance showed sensitivity of 95.1%, specificity of 97.8% and accuracy of 97.1%. These performance metrics, consistent with other lots tested, indicate excellent lot-to-lot reproducibility and manufacturing robustness. Furthermore, the device maintains its stability when stored in the sealed pouch at 2-30℃ throughout the shelf life indicated on the packaging, ensuring reliable performance in various storage conditions.

3.2 Discussion

3.2.1 Performance Characteristics

The results of this clinical validation demonstrate that the Strep A Rapid Test Cassette is a highly reliable tool for the rapid detection of GAS. With a sensitivity of 95.1% and specificity of 97.8%, its performance is comparable to, if not superior to, many currently marketed rapid strep tests and aligns with the performance of modern high-sensitivity immunoassays. The high negative predictive value makes it particularly useful for ruling out GAS pharyngitis in a low-to-moderate prevalence setting, potentially allowing for the immediate discontinuation of empiric antibiotics if symptoms are mild.

The test's procedural control ensures the validity of each test run, and the simple, rapid procedure (results within 5 minutes) makes it highly suitable for busy clinical settings such as primary care clinics, emergency departments, and school health offices. The ability to test transported swabs stored in modified Stuart's medium further enhances its flexibility.

3.2.2 Limitations

As with all rapid antigen tests, the primary limitation is its qualitative nature; it does not provide information about bacterial load. Furthermore, no test is 100% sensitive. The observed false-negative rate of approximately 5% underscores the importance of clinical correlation. Guidelines, such as those from the Infectious Diseases Society of America (IDSA), recommend that negative rapid tests in children and adolescents be backed up by a throat culture due to the risk of rheumatic fever. The 9 false positives could be attributed to persistent antigen after resolved infection or potentially very low levels of colonization below the detection threshold of culture. Furthermore, the test performance can be affected by improper specimen collection technique (e.g., not swabbing the tonsillar areas and posterior pharynx) or deviations from the test procedure. Operators must be adequately trained.

3.2.3 Comparison with Other Diagnostic Methods

Compared to the 24-48 hour turnaround time for culture, the rapid test offers a decisive speed advantage, enabling same-visit diagnosis and treatment. While molecular methods like PCR offer exceptional sensitivity and specificity, they are generally more expensive, require specialized equipment, and have a longer turnaround time than RADTs, making them less practical for routine point-of-care use. The evaluated Strep A Rapid Test strikes a favorable balance between performance, speed, cost, and ease of use.

4. Conclusion

In summary, the Strep A Rapid Test Cassette (Throat Swab) demonstrates strong potential as a valuable point-of-care diagnostic tool for managing acute pharyngitis. Its ability to deliver results within a clinically relevant timeframe of approximately 5 minutes enables immediate therapeutic decision-making directly at the patient's side. This rapid turnaround is crucial for facilitating the timely initiation of appropriate antibiotic therapy for confirmed GAS infections, which can accelerate symptom resolution and help prevent potential complications.

The test's operational characteristics further enhance its clinical utility. Its straightforward procedure and minimal requirement for instrumentation make it readily deployable across diverse healthcare settings, from primary care clinics to school health offices and emergency departments. When integrated with a thorough assessment of clinical signs and symptoms, a positive result

provides strong support for targeted antibiotic prescription. Conversely, a negative result, especially in low-prevalence settings, offers substantial confidence to safely withhold antibiotics, thereby making a meaningful contribution to antimicrobial stewardship efforts and helping to curb unnecessary antibiotic use for viral infections.

Therefore, the Strep A Rapid Test Cassette effectively addresses the critical need for a rapid, reliable, and accessible diagnostic solution for streptococcal pharyngitis. By bridging the gap between delayed laboratory results and the immediate demands of clinical practice, it empowers clinicians to make evidence-based decisions at the point of care. This capability ultimately streamlines patient management, promotes better health outcomes, and supports the broader goal of rational antibiotic utilization.

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