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Comparison of the RapidFor™ Strep A Rapid Antigen Test with the Culture Method in Throat Swab Specimens: A Prospective Diagnostic Accuracy Study

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Ethical Approval
This study was approved by the Ümraniye Training and Research Hospital Scientific Research Ethics Committee, February 27, 2024; Decision No. 81.
All research procedures were conducted in accordance with the Declaration of Helsinki.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The RapidFor™ Strep A Rapid Test Kits were provided free of charge by Vitrosens. The company had no role in study design, data analysis, interpretation of results, manuscript preparation, or the decision to submit the manuscript for publication.

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Abstract

Background/Aim: Group A beta-hemolytic streptococci (GAS) are among the most common bacterial causes of pharyngitis. Throat culture is the reference diagnostic method, whereas rapid antigen tests offer faster results. This study aimed to evaluate the diagnostic performance of the RapidFor™ Strep A Rapid Antigen Test compared with throat culture in throat swab specimens.
Methods: Throat culture and rapid antigen testing were performed on specimens from 322 patients aged 2 years or older who presented to Maltepe University Faculty of Medicine Hospital between March and May 2024 with suspected upper respiratory tract infection and for whom GAS testing was planned. A single throat swab was used sequentially for culture and rapid antigen testing. Demographic information was recorded, and sensitivity, specificity, and accuracy were calculated using throat culture as the reference method.
Results: Among the 322 patients evaluated, 74.84% were younger than 18 years. GAS was detected by culture in 97 patients (30.12%). Both tests were positive in 94 patients, both tests were negative in 225 patients, and culture was positive but the rapid antigen test was negative in 3 patients. No false-positive results were observed. Sensitivity, specificity, and accuracy were 96.91%, 100%, and 99.07%, respectively.
Conclusion: The RapidFor™ Strep A Rapid Antigen Test demonstrated high diagnostic performance relative to throat culture in this cohort and provided a rapid testing option.

Keywords: rapid antigen test, throat culture, group A streptococci

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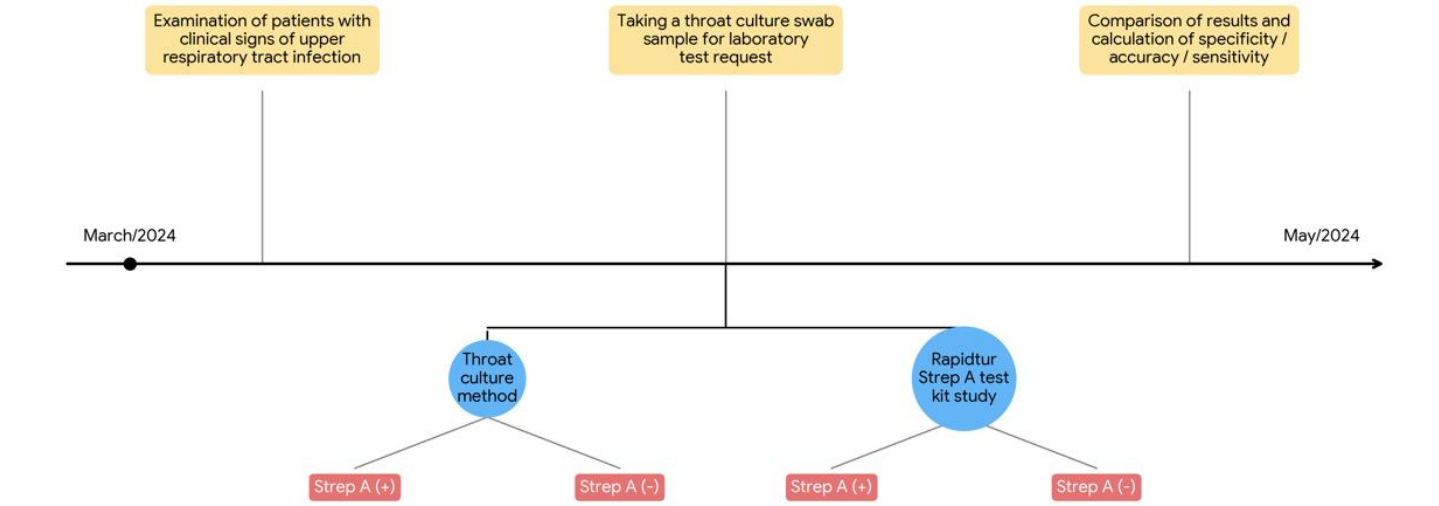
Figure 1. Study Flowchart



Abbreviations: GAS: group A streptococci.

Introduction

Streptococcus pyogenes is a Gram-positive, nonmotile organism belonging to the group A beta-hemolytic streptococci (GAS). The organism commonly colonizes the throat, nose, and skin and represents a major bacterial cause of pharyngitis [1, 2]. Streptococcal pharyngitis commonly manifests with fever above 38 °C and sore throat and may be associated with cryptic tonsils. In the absence of treatment, symptoms generally resolve within 4–5 days. GAS accounts for approximately 5–15% of acute pharyngitis cases in adults and 20–30% of cases in children [2, 3].

Throat culture performed on blood agar is widely used as the reference method for diagnosing streptococcal pharyngitis. Although culture permits identification of non-streptococcal organisms and subsequent antimicrobial susceptibility testing, obtaining a result generally requires 24–48 hours. Rapid diagnostic assays, in contrast, can detect GAS antigens within approximately 5–10 minutes and therefore provide faster diagnostic information. Despite their generally high specificity, the sensitivity of these assays may vary; consequently, negative rapid test results may require confirmation with throat culture [4]. The RapidFor™ Strep A Rapid Test Kit is an immunochromatographic assay intended for the qualitative detection of GAS antigens in throat swab specimens. This study aimed to compare the performance of the RapidFor™ Strep A Rapid Test Kit with that of throat culture, the reference method for detecting GAS in throat swab specimens, in accordance with the CLSI EP12-A2 guideline [5].

Materials and methods

Study Design, Participants, and Ethics

This prospective diagnostic accuracy study was conducted at Maltepe University Faculty of Medicine Hospital between March and May 2024 and is reported in compliance with the Standards for Reporting Diagnostic Accuracy Studies (STARD) 2015 guidelines [6].

Patients aged 2 years or older who presented consecutively to the outpatient clinics or emergency department with clinical features suggestive of an upper respiratory tract infection, including fever >38 °C, sore throat, tonsillitis, or pharyngitis, were assessed for study eligibility. Demographic characteristics, including age and sex, and the results of the rapid antigen test and throat culture were recorded. Eligibility for inclusion required clinical suspicion of GAS infection by the attending physician and a request for diagnostic testing as part of routine patient evaluation. To fully reflect real-world outpatient clinical practice, no exclusion criteria were applied based on disease severity, clinical presentation, or prior medication history (including antibiotic use). No formal prospective sample-size calculation was performed. All 322 enrolled participants underwent both diagnostic evaluations, allowing a paired comparison of the index rapid test and the reference culture method.

The study protocol was approved by the Ethics Committee of Ümraniye Training and Research Hospital (February 27, 2024; Decision No. 81). Written informed consent was obtained from all adult participants, or from the parents or legal guardians of the pediatric patients, before enrollment and data collection, with assent additionally obtained from children where developmentally appropriate in accordance with the approved protocol. The participant pathway is summarized in Figure 1.

Specimen Collection and Diagnostic Workflow

The decision to perform GAS testing was made by the attending physician as part of routine clinical evaluation. A single throat swab was collected from each participant and used sequentially for the two diagnostic procedures. The specimen was initially inoculated onto blood agar and was subsequently used for the RapidFor™ Strep A Rapid Antigen Test. This standardized sequence was followed for all participants to avoid repeated specimen collection and minimize patient discomfort. Rapid antigen testing was performed after culture inoculation in every case. The results of the two tests were recorded independently, and the personnel performing each procedure were blinded to the result of the other test.

Reference Standard: Throat Culture

For the reference standard, the throat swab was inoculated onto blood agar and incubated at 37°C for 24–48 hours. Beta-hemolytic colonies with Gram-positive and catalase-negative characteristics were further evaluated for streptococcal group identification using the Prolex™ Streptococcal Grouping Latex Kit. GAS infection was considered culture-positive when the organism was identified according to these procedures. Samples in which GAS was not detected were classified as

culture-negative. No contaminated, equivocal, unreadable, or otherwise indeterminate culture results occurred during the study period.

Index Test: RapidFor™ Strep A Rapid Antigen Test

The RapidFor™ Strep A Rapid Test Kit is an immunochromatographic assay for the qualitative detection of GAS antigen in throat swab specimens. The test was performed in accordance with the manufacturer's instructions. Results were interpreted at 5 minutes; readings obtained after 15 minutes were considered invalid. No invalid rapid antigen test results were recorded during the study period.

Statistical Analysis

Diagnostic performance was evaluated using throat culture as the reference standard. Results were classified as true positive (TP), false positive (FP), true negative (TN), or false negative (FN). Sensitivity, specificity, overall accuracy, positive predictive value (PPV), and negative predictive value (NPV) and their 95% confidence intervals (CIs) were calculated in accordance with Clinical and Laboratory Standards Institute (CLSI) guideline EP12-A2 [5]. The primary diagnostic metrics were calculated using standard formulas:

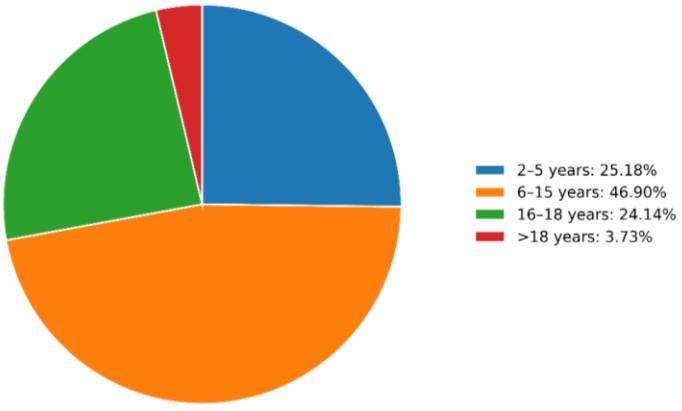
Sensitivity = TP / (TP + FN); specificity = TN / (TN + FP); accuracy = (TP + TN) / (TP + TN + FP + FN).

PPV was defined as the proportion of patients with positive rapid test results who were culture-positive [TP / (TP + FP)]; NPV was defined as the proportion of patients with negative rapid test results who were culture-negative [TN / (TN + FN)]. Statistical analyses and 95% confidence intervals were calculated using MedCalc Statistical Software version 20.0 (MedCalc Software Ltd, Ostend, Belgium) via the Clopper-Pearson exact binomial method.

Results

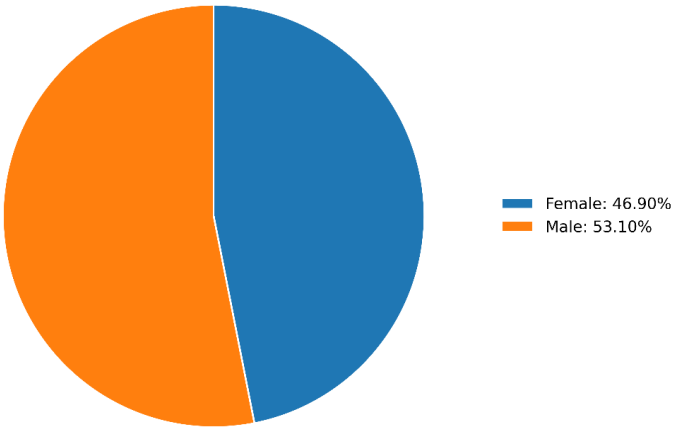
Among the 322 patients with clinically suspected GAS infection, 97 (30.12%) were culture-positive. Patients younger than 18 years accounted for 74.84% of the cohort, and 85.10% of culture-positive cases occurred in patients younger than 18 years. The distributions by age and sex are shown in Figures 2 and 3, respectively.

Figure 2. Distribution of Patients by Age Group



Note: 18-year-olds are included in the 16–18 group, making the pediatric proportion <18 years clear.

Figure 3. Distribution of Patients by Sex



Of the 322 patients, 94 tested positive for GAS by both culture and the rapid antigen test, and 225 tested negative by both methods. The remaining 3 patients were culture-positive but rapid antigen test-negative, representing the only discordant results. No false-positive results were documented. The paired test results and the derived diagnostic performance metrics are summarized in Tables 1 and 2, respectively.

Table 1. Paired Throat Culture and Rapid Antigen Test Results

Rapid Antigen Test Result	Culture Positive	Culture Negative	Total
Positive	94	0	94
Negative	3	225	228
Total	97	225	322

Abbreviations: GAS: group A streptococci.

Table 2. Diagnostic Performance of the RapidFor™ Strep A Rapid Antigen Test

Diagnostic Metric	Value	95% Confidence Interval
Sensitivity	96.91%	91.23%–99.36%
Specificity	100.00%	98.37%–100.00%
Accuracy	99.07%	97.30%–99.81%
Positive Predictive Value (PPV)	100.00%	96.15%–100.00%
Negative Predictive Value (NPV)	98.68%	96.19%–99.73%

Abbreviations: CI: confidence interval, PPV: positive predictive value, NPV: negative predictive value.

Discussion

The diagnostic performance of commercially available Strep A test kits has been evaluated in several studies. In a 2018 study using a double-swab method, the test demonstrated a sensitivity of 92.1%, specificity of approximately 99% (based on the reported data counts), and accuracy of 98.8% [7]. Another study employing double swabs reported sensitivity, specificity, and accuracy values of 84.1%, 100%, and 98.2%, respectively, compared with culture [8]. In a study using a single-swab method, sensitivity was 52% and specificity was 100% [9]. Another investigation evaluated three rapid antigen test kits using dual throat swab samples and reported sensitivities of 92.5% (95% CI, 83.4–97.5), 71.6% (95% CI, 59.3–81.9), and 74.6% (95% CI, 62.5–84.4), respectively. The corresponding specificity values were 97.0% (95% CI, 93.1–99.0), 94.6% (95% CI, 90.1–97.5), and 92.9% (95% CI, 87.8–96.2), with the highest overall accuracy being 95.7% [10].

In comparison to these literature findings, the RapidFor™ Strep A Rapid Test Kit showed sensitivity, specificity, and accuracy relative to culture of 96.91%, 100%, and 99.07%, respectively. These findings indicate that the RapidFor™ Strep A Rapid Test Kit demonstrated high diagnostic performance in the present study, despite the use of a single throat swab specimen.

The small number of discordant results is noteworthy. Three patients had positive culture results but negative rapid

antigen test results, while no false-positive results were observed. However, this study was not designed to determine the reasons for these false-negative findings. Factors such as specimen collection quality and bacterial burden may represent possible pre-analytical explanations, but these cannot be established from the available data. Several studies have addressed unnecessary antibiotic use. One study conducted in Turkey reported that antibiotics are frequently prescribed in primary care at inappropriate doses or durations or without a valid medical indication [11]. Factors contributing to this practice may include the use of findings such as fever, abnormal lung sounds, or visible tonsillar crypts as sufficient grounds for antibiotic prescribing, particularly when physicians have limited time for detailed assessments. In addition, clinicians may choose this less time-consuming approach when faced with patients or relatives who insist on medication. Higher rates of antibiotic prescribing have also been reported in primary care settings with high patient volumes [12, 13].

Rapid antigen testing provided results substantially faster than throat culture while demonstrating high diagnostic performance in this cohort. Therefore, incorporating rapid antigen tests into appropriate clinical diagnostic algorithms may support timely, evidence-based clinical decision-making and may have potential value for antibiotic stewardship. Furthermore, the utilization of a single swab offers an important practical benefit, as it simplifies the collection procedure, optimizes the clinical workflow, and may reduce the need for repeated specimen collection and associated patient discomfort compared with dual-swab approaches. However, because antibiotic prescribing behaviors and longitudinal patient management outcomes were not assessed in this study, a direct reduction in antibiotic utilization cannot be concluded from our findings.

Limitations

This study was conducted at a single center with a relatively short recruitment period (March–May 2024), which may limit the generalizability of the findings. The study population was predominantly pediatric, and no age-specific or subgroup analyses of diagnostic performance were performed. A single throat swab was used sequentially for culture and rapid antigen testing, with culture performed first; although this standardized approach was applied to all participants, a potential effect of the testing sequence on antigen detection cannot be completely excluded. Only three false-negative results were observed, limiting the assessment of factors associated with discordant results. Diagnostic performance may also vary according to GAS prevalence and the clinical spectrum of the study population. Pre-enrollment antibiotic use was not documented; although prior antibiotic therapy may produce false-negative results in both culture and rapid testing, the inclusion of consecutive patients reflects the unselected nature of clinical practice in this outpatient setting.

Conclusion

In individuals with suspected GAS infection, rapid antigen testing provided results considerably faster than throat culture and demonstrated high diagnostic performance in this cohort. These findings suggest that rapid antigen testing may support timely clinical decision-making and may contribute to appropriate antibiotic use when incorporated into an appropriate diagnostic algorithm; however, antibiotic prescribing was not directly assessed in this study.

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