

Comparison of the BioStar Antigen Test, Gen-Probe Direct Probe and Culture for Detection of Group A *Streptococcus*

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ABSTRACT

Group A *streptococcus* (GAS) antigen testing has become a routine point-of-care (POC) test. Concern about performance parameters (PP) has resulted in various recommendations regarding follow-up of antigen negative GAS tests. There were two goals in this study: first; to evaluate our current GAS rapid antigen test (RAT) (BioStar, Boulder, CO) and the GAS Direct probe (Gen-Probe, San Diego, CA) compared to culture; second, to evaluate the probe as an alternative to culture for confirmation of negative GAS antigen tests. 520 patients presenting with symptoms of pharyngitis were evaluated using a double-swab collection device (Copan, Corona, CA). One swab was used for the antigen test; the second for the probe test and the plegette in the collection device for culture on 5% sheep blood agar incubated 24-48 h anaerobically. After discrepant analysis: sensitivity (S), specificity (SP), positive predictive value (PPV) and negative predictive value (NPV) were: 94.8, 100, 100 and 96.9% for the probe and 86.1, 97.1, 93.7 and 93.4% for the antigen test, respectively. S for culture was 99.4 (163/164). Colony counts for false negative tests were higher for the antigen assay than the probe test. False positive (FP) antigen results were often seen from patients previously diagnosed and/or treated for GAS. No FP results were seen with the probe in these same patients. Compared to culture and probe, the Biostar offered a rapid result and acceptable PP for POC testing. The probe offered excellent PP compared to culture and could be used as the primary test or as the backup to negative antigen tests. The GAS probe offers the additional advantage over culture of same day reporting for expedited and appropriate antibiotic therapy.

INTRODUCTION

In 1998, the National Center for Health Statistics reported 12.2 million patient visits for cases of pharyngitis. 2.4 million of these were due to streptococcal sore throat, the *only common* form of acute pharyngitis for which antibiotic therapy is indicated. As a result, the use of rapid tests for the diagnosis of Group A *streptococcal* (GAS) pharyngitis has become common in many office and clinic settings. Given good performance parameters, a point of care (POC) test where the results are directed to the physician before the patient leaves the healthcare setting has many benefits. Positive results allow appropriate and directed therapy, are satisfying to the patient, and eliminate phone calls about follow-up results.

However, depending on the collection technique, type of test used, technician performing the test, and history of the patient, performance of GAS antigen tests vary widely. This concern is reflected in the flip-flopping of recommendations of the American Academy of Pediatrics and the American Thoracic Society on rapid antigen negative patients that present with acute pharyngitis.

OBJECTIVE

- One purpose of the study was to evaluate the rapid GAS antigen test currently used among our institution for POC testing, the Strep A OIA test (BioStar), and the GAS Direct probe (Gen-Probe, Inc.) compared to GAS culture.
- The second purpose was to evaluate the use of the probe as an alternative to culture for either primary testing or confirmation of negative GAS rapid antigen tests.

RESULTS

- 520 patient samples were evaluated.
- 172 patients were considered infected for GAS based on positive culture and one additional patient based on a positive RAT and positive probe.
- A total of 173 infected GAS patients resulted in a disease prevalence of 33% during the study period.
- Results for performance of the RAT and the GAS probe compared to culture are shown in Table 1.
- Colony counts for the culture positive/antigen negative tests and culture positive/probe negative specimens are footnoted at the bottom of table 1.
- Sensitivity, specificity, positive predictive value and negative predictive value based on the infected patient status as described above, for the BioStar test was 86.1, 97.1, 93.7, and 93.4% and 94.8, 100, 100, and 96.9% for the GAS Direct probe, respectively. Culture was 99.4% sensitive.
- False positive results with the antigen test were seen in 10 patients. 5 were from patients previously treated and seen because of continued upper respiratory infection symptoms.
- No false positive results were noted with the probe, including those patients that were previously treated and reviewed.
- False negative results were seen with all methods, 24 with the BioStar OIA, and 9 with the GAS probe and 1 with culture. Colony counts for the false negative antigen and probe results were distributed throughout the colony count range evaluated.

CHARTED RESULTS

Table 1. Comparison of Test Methods (%)

	GAS Direct probe	OIA rapid antigen	Culture
Sensitivity	94.8	86.1	99.4
Specificity	100	97.1	100
PVP	100	93.7	
PVN	96.9 ^a	93.4 ^b	
Total tested	520		

^a False negative probe specimens had colony counts on plates of <10 (3), 10 - 25 (5), 25 - 50 (1)

^b False negative OIA specimens had colony counts on plates of <10 (6), 10 - 25 (8), 25 - 50 (8), < 50 (2)

CONCLUSIONS

- FN results were seen for all methods
- While culture was the most sensitive, the TAT was the least favorable for clinical utility and overall cost
- FP results were seen with the RAT
- 50% were in patients previously treated for GAS
- RATs should not be performed as a follow-up test in patients previously diagnosed with GAS
- FP results were not seen with the GAS Direct in previously treated patients
- The RAT worked well as a POC test with acceptable sensitivity and allowed immediate appropriate therapy. Clinical discretion is warranted when testing RAT negative patients with a more sensitive follow-up test method
- GAS Direct can be used as an alternative to culture for either direct diagnosis of GAS or as a back-up to less sensitive RATs. TAT at Lahey is within 24 hours. Further data is needed on recently treated patients that return with pharyngitis. Results of this study do not show residual rRNA to be a factor for false positive results.
- Costs as calculated for Lahey for each test were:
 - Throat culture \$2.13
 - GAS Direct probe \$2.40
 - OIA RAT \$2.90

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