



New Molecular Test for the Improved Diagnosis of Group A Strep Pharyngitis

Effective August 15, 2016, the Microbiology Department of Laboratory Alliance of CNY will be replacing routine throat culture screens for group A streptococci (GAS) and its GAS Direct non-amplified test with a rapid, highly sensitive, isothermal gene amplification assay for the direct detection of GAS in pharyngeal specimens. The molecular GAS test is more sensitive than culture (98% vs. 93%) with final results available as soon as the same day of specimen receipt instead of 24 to 48 hours by culture.

Clinical Significance

Group A streptococci are the most common bacterial cause of acute pharyngitis. The incidence of disease is highest in children, particularly during the spring and winter months, but adults are susceptible to infection as well.¹ The CDC has estimated that the costs associated with GAS pharyngitis due to medical care and days lost from school and/or work exceed \$500 million each year.²

Most cases of pharyngitis are caused by viruses that do not require antibiotic therapy. However, GAS infection does require therapy and its prompt and reliable diagnosis is important to prevent the suppurative (otitis media and peritonsillar abscess) and non-suppurative (rheumatic fever and glomerulonephritis) complications of infection.^{3,4} As such, prompt treatment with an appropriate antibiotic will not only reduce the severity and duration of symptoms and decrease transmission of the organism to others but will also minimize the risk of patients developing complications from infection. In addition, accurate diagnosis favorably impacts antibiotic stewardship programs resulting in the more appropriate use of antibiotics and minimizing the potential for the development of antibiotic resistance resulting from the unwarranted treatment of viral infections.⁵⁻⁷

The laboratory diagnosis of GAS pharyngitis typically involves the cultural detection and characterization of the organism in a pharyngeal specimen. Culture is a time-dependent process that generally requires 24 to 48 hours for a final result. Rapid antigen detection tests (RASTs) have been developed but the RASTs suffer from poor sensitivity (50% to 80%) and negative tests **must** be reflexed for culture.

Recently, an isothermal gene amplification assay has been developed for the direct detection of GAS in pharyngeal specimens. The results can be generated as soon as the same day of specimen receipt and "negative" results **need not** be reflexed for culture. In addition, the molecular assay is more sensitive than culture (98% versus 93%). For these reasons, the new gene amplification assay, called the "Group A Strep DNA Test" will be replacing throat culture screens for GAS and our "GAS Direct non-amplified Probe" test.

Test:	Group A Strep DNA
Test Code:	GASM
Method:	Nucleic Acid Amplification Test
Specimen Requirement:	Throat swab collected using a White cap Eswab liquid Amies or Red cap liquid Stuart's collector are preferred. Other collectors with liquid Amies or Stuart's are also acceptable.
Unacceptable Specimens:	Collectors using gel transport media or dry swabs
Storage and Transport:	Transport at 23°C to 27°C or 2°C to 8°C. Store at 23°C to 27°C for 2 days, 2°C to 8°C for 6 days, or ≤-15°C or ≤-70°C for 34 days.
Schedule of Testing:	Daily
CPT4 Code:	87651
Billing Code:	3010454

Questions regarding the Group A Strep assay should be directed to Russ Rawling, MS, M(ASCP)SM, RM(NRM)SM, Manager of Microbiology, at 315-410-7060 or russellrawling@lacny.com.

References:

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