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Introduction of Group A Streptococcus (GAS) Testing by Nucleic Acid Amplification

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In an effort to improve patient care and antibiotic stewardship, Marshfield Labs will be replacing the current testing algorithm for GAS (rapid antigen- detection test [RADT] testing confirmed with culture) with a rapid PCR test that provides a definitive result for all samples in < 25 minutes.

Background: Over the last several decades, use of the RADT has become the standard of care in the early diagnosis of GAS pharyngitis. Unfortunately, the sensitivity of most of these tests is 70%–90%, compared with blood agar plate culture [1, 2]. This poor sensitivity necessitates confirmation of negative samples by follow-up culture requiring up to an additional 48 hours before a definitive result is obtained. Introduction of PCR testing for GAS will eliminate the need for culture confirmation and thus should abrogate the practice of empirical antibiotic treatment or unnecessary treatment delays. Therefore, the introduction of PCR testing for GAS will provide a significant enhancement of patient care through timely, appropriate therapy as well as optimal antibiotic stewardship.

Principle of the Test: The assay uses PCR to amplify and detect presence of the speB gene of GAS as well as internal control targets to verify test integrity. A negative result can be obtained in 24 minutes while a positive result may be obtained in as little as 18 minutes through the use of an Early Assay Termination function which provides positive results if the signal from the target DNA reaches a predetermined threshold before the full test time is



exhausted. The manufacturer claims Sensitivity of 99.4-100% and Specificity of 94.1% for this assay.

Testing Details: On the Marshfield campus, instrumentation for testing will be placed in the Pediatrics Department as well as being available 24/7 from the clinical laboratory. Other hospitals and regional centers planning to implement this technology include:

Chippewa Falls Lake Hallie Stevens Point

Clairemont C Rice Lake M Wisconsin Rapids

Colby E Merrill V

Eau Claire Wausau



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Chetek Mosinee Cumberland Oakwood Greenwood Phillips Hayward Stettin Menomonie

At this time, some regional centers with very low testing volumes are not projected to receive this instrumentation, these sites include: Bloomer Cadott Cornell Eagle River Mercer Rhinelander

Ordering Details: This test is designed for the rapid detection of pharyngitis caused by Group A Streptococcus (GAS).

How to order this test:

- > **Test name:** Group A Strep Nucleic Acid Test
- Test Code: GASNAT
- > **Specimen:** Purple top Copan ESwab-Throat
- **Storage:** 15–30 °C for 48 hr or refrigerated up to 6 days
- > Test availability: visit <u>Marshfield Labs' Test Reference Manual.</u>
- > Qualitative interpretation:
- > Reported as Negative, Positive, or Indeterminate
- > **CPT Code:** 87651

Questions:

For additional information, please contact Marshfield Labs Customer Service (1-800-222-5835):

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References:

- 1. Gerber MA, Shulman ST. Rapid diagnosis of pharyngitis caused by group A streptococci. Clin Microbiol Rev. 2004;17:571–80.
- 2. Tanz RR, Gerber MA, Kabat W, Rippe J, Seshadri R, Shulman ST. Performance of a rapid antigen-detection test and throat culture in community pediatric offices: implications for management of pharyngitis. Pediatrics. 2009;123:437–44.