Introduction: Clinical studies of streptococcal pyrogenic exotoxin (SPE) infection can result in serious sequelae if not treated; however, the current diagnostic methods are limited in sensitivity and require additional confirmatory culture to identify the species. We have previously reported on a novel method for direct detection of streptococcal pyrogenic exotoxin (SPE) in the SPEx™ assay that is highly sensitive and can detect SPE in as little as 18 to 24 hours, which may cause treatment delay. In an effort to provide an alternative solution for SPE detection, we developed a real-time PCR assay that detects group A streptococci (GAS) directly from throat swabs in approximately 1 hour. The SPE assay is capable of identifying the species and typing the specimen specifically.

Methods: The Simplexa Group A Strep Direct Assay (Simplexa assay) targets the conserved exotoxin B gene of S. pyogenes. For each assay, a series of pre-mixed tube strips (G1 and M1) of Simplexa assay were prepared. Negative controls were run in parallel with the Simplexa assay in the 384-well plate during the amplification with the 384-well thermal cycler. Absence of amplification was assumed when there was no visible band 

Results: For prospective specimens, the assay agreed in 97.4% of positive results and 95.2% of negative results. For fresh, retrospective specimens, the assay agreed in 97.1% of positive results and 95.4% of negative results. 

Conclusions: Compared to the Simplexa Group A Strep Direct Assay provides quick turn-around time without sacrificing performance and can be used for rapid detection of streptococcal pyrogenic exotoxin.

Rapid Detection of Streptococcus pyogenes Using the Simplexa® Group A Strep Direct Assay

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