**Evaluation of the cobas® Strep A Nucleic Acid Test for Use on the cobas® Liat System for Rapid Detection of Infection with Streptococcus pyogenes**

**1. Abstract**

**Objectives:** Rapid and accurate diagnosis of pharyngitis caused by infection with group A streptococcus is important for patient management. Rapid antigen tests are commonly used to diagnose pharyngitis, but these tests suffer from limited sensitivity. We determined the performance of the cobas® Strep A assay, a rapid automated nucleic acid test performed on the cobas® Liat System for the detection of Streptococcus pyogenes from throat swabs.

**Methods:** 570 throat swabs collected from participants 15 years of age with symptoms characteristic of pharyngitis at 4 collection sites (3 point-of-care or physical office sites). Specimens were collected on dry swabs and stored at 4°C until processed, with 23 being stored for 40 days. The cobas® Strep A assay was performed in parallel to culture on a routine laboratory medium in a blinded fashion. In addition, PCR/sequencing were used for reference for current point-of-care tests. Operators ranged from medical assistants to nurses, laboratory technicians and medical technologists.

**Results:** Compared to culture, the cobas® Strep A assay showed a sensitivity of 100% (95% CI 100% to 100%) and a specificity of 99% (95% CI 99% to 100%).

**Conclusions:** The cobas® Strep A assay demonstrated high accuracy compared to culture. The test detected additional Strep A positive specimens that were reported negative by culture. The test detected all positive samples, including samples with very low concentrations of S. pyogenes. In addition, the test was performed in a point-of-care setting, allowing for rapid and accurate diagnosis of pharyngitis.