**BACKGROUND**

Streptococcus pyogenes, also known as Group A streptococcus (GAS), is responsible for a range of infections including throat infections, skin and wound infections, and more serious diseases such as necrotizing fasciitis and toxic shock syndrome. It is a rapidly growing pathogen that is difficult to treat.

**MATERIALS/METHODS**

Performance of the GAS Test was characterized from throat swabs in both liquid and dry swab matrices. Controls were performed to characterize the sensitivity of both the M1 and M3 GAS strains, analytical specificity across non-target pathogens, and dilution and sensitivity studies by performing a qPCR method comparison study against a commercially available comparator test.

**RESULTS**

The Limit of Detection of the NeuMoDx GAS Test was established to be 70 CFU/mL in both the M1 and M3 GAS strains. Sensitivity was determined to be 97.56% with 0% false positives. The clinical sensitivity and specificity of the NeuMoDx GAS Test were confirmed using the GAS M1 and M3 strains.

**Analytical Sensitivity (LoD)**

The Limit of Detection of the NeuMoDx GAS Test was determined to be 70 CFU/mL in both the M1 and M3 GAS strains. Sensitivity was determined to be 97.56% with 0% false positives.

**Method Comparison**

The clinical sensitivity and specificity of the NeuMoDx GAS Test was determined to be 97.56% and 97.56% respectively.

**NeuMoDx GAS Test Work Flow**

1. **Dry Liquid Amies Collection**
2. **Transport to Laboratory**
3. **Liquid Amies (500 μL)**
4. **Place 1-D barcode on Liquid Amies tube**
5. **Load on NeuMoDx Molecular System & Send to Test**

**NeuMoDx Molecular System Streamlined Testing**

- **Features**
  - Integrated Operation: Automates all steps of molecular diagnostics starting from specimen to reporting time PCR results to fully-automated processes
  - True Random Access: Ability to mix specimens in any order
  - Large Walkaway Window: Up to 288 samples loaded with 48 samples per hour
  - Leak tight swab tubes for N288, ISO DNA tests in an 8 hour shift for the N288, ISO DNA tests in an 8 hour shift for the N96
  - Fast Time to Fast Results: ~40 min for the N288, 96 samples for the N96
  - Continuous Loading of Specimens: Specimens and Reagents can be loaded/processed and real-time PCR.

- **Performance**
  - Detection was also determined to be 97.56% with 0% false positives. The clinical sensitivity and specificity of the NeuMoDx GAS Test were confirmed using the GAS M1 and M3 strains.

- **Usage**
  - Used for clinical throat swabs collected in liquid Amies from GAS infected patients.

- **Accuracy**
  - The clinical sensitivity and specificity of the NeuMoDx GAS Test was determined to be 97.56% and 97.56% respectively.

**CONCLUSIONS**

The NeuMoDx GAS Test is a rapid, easy-to-use test for direct detection of Group A streptococci from throat samples, providing results in ~40 minutes.

**Acknowledgements**

The authors gratefully acknowledge the help and support provided by all members of the NeuMoDx team. We would also like to thank our collaborators: XCR Diagnostics, Salt Lake City, UT. *Full list of acknowledgments included.*