The NeuMoDx Strep A/C/G Vantage Assay implemented on the NeuMoDx Molecular System is the first and only fully automated test for the detection of Group A and Group C Group B Streptococci simultaneously from throat swab specimens. With ultra-fast turnaround time, minimum user intervention and high-throughput, the NeuMoDx Strep A/C/G Vantage Assay addresses many unmet market needs.

**BACKGROUND**

Group A β-hemolytic streptococci (GAS) are the most frequently isolated pathogens in the diagnosis of streptococcal pharyngitis. In addition, Group C and Group G streptococci (GCS/GGS) have been increasingly recognized as potential causes of non-group A Streptococcal pharyngitis in children. Diagnosis has traditionally been performed through rapid antigenic detection and culture identification methods. Rapidly readable tests for GAS suffer from poor specificity and culture identification takes at least 24–48 hours. The NeuMoDx Strep A/C/G Vantage Assay is a multiplex to result (m2r) nucleic acid test that is fast amplification technology implemented on the fully automated, high-throughput NeuMoDx Molecular Systems. It detects and differentiates DNA of GAS and GCS/GGS simultaneously. All the reagents and consumables used are stable at ambient conditions, do not require any refrigeration, and are made in ready-to-use configurations requiring no user-modified steps.

**METHODS**

Performance of the Strep Assay was characterized from clinical throat swabs in Liquid Amies and in neat liquid Amies. Studies were performed to characterize the analytical sensitivity of both the MS and MS GAS strains, as well as GCS and GGS. Additionally, analytical specificity against non-target organisms, robustness in the presence of interfering substances, and clinical sensitivity and specificity (by performing a method comparison study against commercially available competitor tests) were determined for the NeuMoDx Strep Assay.

**RESULTS**

The Limit of Detection of the NeuMoDx Strep A/C/G Vantage Assay was established to be 50 and 100 CFU/mL for the GAS M1 and M3 strains respectively, 2,567 CFU/mL for GCS and 1,541 CFU/mL for GGS. The assay displayed 100% analytical specificity with no cross-reactivity against any of the 45 phylogenetically similar or co-habiting strains, as well as GCS and GGS. Additionally, analytical specificity against non-target organisms, robustness in the presence of interfering substances, and clinical sensitivity and specificity (by performing a method comparison study against commercially available competitor tests) were determined for the NeuMoDx Strep Assay using 230 clinical residual specimens as a reference test.

**Limit of Detection**

<table>
<thead>
<tr>
<th>GAS Strain</th>
<th>GAS M1</th>
<th>GAS M3</th>
<th>GCS</th>
<th>GGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFU/mL</td>
<td>50</td>
<td>100</td>
<td>2,567</td>
<td>1,541</td>
</tr>
</tbody>
</table>

**Analytical Specificity and Sensitivity**

A total of 230 de-identified retrospective residual throat swab specimens from symptomatic patients at five clinical laboratories (Beaumont General Hospital, Royal Oak, MI; Tampa General Hospital, Tampa Bay, FL) were tested on qualified NeuMoDx Molecular Systems. Results reported from the FOGE-CE/FS cleared tests (Quadra Lyra Direct Strep Assay (Beaumont) and Quadra Lyra Complete Strep Assay (Tampa)) used by the clinical laboratories were utilized to perform the clinical performance analysis. The NeuMoDx Strep A/C/G Vantage Assay had excellent concordance with the FOGE-CE/FS cleared tests, displaying a Clinical Sensitivity of 100% for both the GAS target and Clinical Sensitivity of 95.9% for the GCS/GGS target, and Clinical Specificity of 100% for both targets.

**Method Comparison**

A total of 5 replicates of each strain were tested in neat Liquid Amies and in neat Liquid Amies. Variant strains were prepared independently. The study was performed on the N288 NeuMoDx Molecular System and a N288 NeuMoDx Molecular System. Variant strains were prepared in neat Liquid Amies and 5 replicates of each strain were tested until a ratio of 100% was observed.

**CONCLUSION**

The NeuMoDx Strep A/C/G Vantage Assay implemented on the NeuMoDx Molecular Systems is the first and only fully automated test developed for direct detection of Group A and Group C Group B Streptococci simultaneously from throat swab specimens. With ultra-fast turnaround time, minimum user intervention and high-throughput, the NeuMoDx Strep A/C/G Vantage Assay addresses many unmet market needs.

**ACKNOWLEDGMENTS**

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