Performance Evaluation of the cobas® Strep A Assay for Point-of-care Diagnosis of Streptococcus pharyngitis in CLIA-waived Primary Care Settings

1. Abstract

Background: Group A streptococci are a leading cause of pharyngitis. CLIA-waived rapid antigen tests are commonly performed by non-laboratory trained staff and are subject to operator variability. This may result in misdiagnosis and incorrect antibiotic therapy. The cobas® Strep A nucleic acid assay is a rapid, CLIA-waived PCR test on the cobas® Liat System that requires no laboratory training. It was evaluated here at 5 CLIA-waived sites by 17 non-laboratory trained staff. Results were presented to reference culture. Quidel QuickVue Dipstick, McKesson Strep A Dipstick)

2. Background

• Rapid antigen-based site diagnostic tests (e.g. Consult Strep A, Quidel QuickVue Dipstick, McKesson Strep A Dipstick)

3. Methods

Objective: To evaluate the clinical sensitivity and specificity of the cobas® Strep A assay on the cobas® Liat System in CLIA-waived settings.

3.1 Cobas® Strep A Assay

The cobas® Strep A assay was evaluated at 5 CLIA-waived sites by 17 non-laboratory trained staff. Throat swabs were prospectively collected from patients with signs and symptoms of pharyngitis. For comparison, the cobas® Liat System was used. Using appropriate antibiotic therapy. Rheumatic fever if left untreated.

3.2 Cobas® Liat System

The cobas® Liat System is an easy-to-use, CLIA-waived PCR test on the cobas® Liat System in CLIA-waived settings. To evaluate the clinical sensitivity and specificity of the cobas® Strep A assay for use on the cobas® Liat System in CLIA-waived settings.

4. Results

4.1 Demographics

Demographics for all 20 of the study populations are shown in Table 1.

Table 1: Demographics for all 20 specimens collected.

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of participants</th>
<th>Percentage</th>
<th>Specificity</th>
<th>% 95% CI</th>
<th>Sensitivity</th>
<th>% 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30 yrs</td>
<td>52</td>
<td>100.0 (74.1 - 100.0)</td>
<td>100.0 (91.4 - 100.0)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31-50 yrs</td>
<td>40</td>
<td>100.0 (74.1 - 100.0)</td>
<td>93.1 (78.0 - 98.1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>51-60 yrs</td>
<td>4</td>
<td>100.0 (74.1 - 100.0)</td>
<td>6.7 (0.0 - 76.5)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.2 Cobas® Strep A Assay

The cobas® Strep A assay was easy to perform and can be used by non-laboratory trained point-of-care personnel.

4.3 Operator Ease of Use Questionnaires

Operator Ease of Use Questionnaires of the study populations are shown in Table 2.

Table 2: Operator Ease of Use Questionnaires of the study populations.

<table>
<thead>
<tr>
<th>Age</th>
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</table>

5. Conclusions

The incorporation of an accurate, highly sensitive and specific, and rapid PCR test, such as the cobas® Strep A, provides added value through improved diagnosis of group A streptococcal infection, improved management of patients with suspected pharyngitis, and prevention of complications of untreated infection such as acute rheumatic fever.

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