Results are as follows:

<table>
<thead>
<tr>
<th>Culture</th>
<th>46</th>
<th>1</th>
<th>47</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>50</td>
<td>143</td>
<td>193</td>
</tr>
</tbody>
</table>

Sensitivity: 97.9% (95% CI, 98.7% to 99.9%)
Specificity: 97.3% (95% CI, 99.1% to 99.9%)
Overall Agreement: 97.4% (95% CI, 94.1% to 99.1%)

EXPECTED VALUES
It is believed that approximately 19% of all upper respiratory tract infections are caused by Group A Streptococcus. Infection is most prevalent in winter and early spring, with most cases arising in patients living in highly populated areas.

LIMITS OF DETECTION
Group A Streptococci organs were grown and tested at different concentrations. The test was capable of detecting 1.5 x 10^5 organisms per test.

SPECIFICITY
To confirm the specificity of the CLIAwaived™ Inc. Rapid Strep A Test, bacterial cultures likely to be found in the respiratory tract were tested at 3.0 x 10^5 to 2.8 x 10^9 organisms/test and all yielded negative results. The organisms tested are listed below:

- Streptococcus pneumoniae
- Neisseria meningitidis
- Neisseria gonorrhoeae
- Branhamella catarrhalis
- Neisseria subflava
- Haemophilus influenzae
- Staphylococcus aureus
- Strep. pyogenes
- Strep. suis
- Streptococcus salivarius
- Streptococcus bovis
- Staphylococcus enterotoxin B
- Staphylococcus epidermidis

To further confirm the specificity, the following eleven strains of Group A Streptococcus were tested and positive results were detected at 1.5 x 10^9 organisms/test.

<table>
<thead>
<tr>
<th>SS-410</th>
<th>SS-496</th>
<th>SS-634</th>
<th>SS-721</th>
<th>SS-799</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capable of detecting 1.5 x 10^5 organisms per test.</td>
<td>Tested at different concentrations. The test was living in highly populated areas.</td>
<td>SS-410, SS-496, SS-634, SS-721, SS-799</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Lay Person User Study
Individuals having diverse educational backgrounds evaluated the CLIAwaived™ Inc. Rapid Strep A Test at three different sites. Each site tested a coded panel evaluated at three different sites. Each site tested a coded panel consisting of a negative, low positive and high positive. There was greater than ninety-seven percent (97%) agreement (175/180) of the expected results.

REFERENCES

SUMMARY AND EXPLANATION
Group A Streptococcus (Streptococcus pyogenes) is the principal cause of respiratory tract infection in humans. Streptococcal pharyngitis, which primarily affects children and young adults, can lead to serious complications such as rheumatic fever or acute glomerulonephritis. The rapid and accurate detection of Group A Streptococcus is important to the early initiation of antibiotic therapy in the treatment of Streptococcal pharyngitis. Traditional diagnostic tests have relied on overnight culture with confirmation by serological or biochemical methods. Newer methods based on immunochromatographic detection of Streptococcal antigen have been developed, which do not require growth of the organism, nor do these methods require viable organisms for detection of the antigen.

For the presumptive in vitro qualitative detection of Group A Streptococcal antigen from throat swab specimens

FOR TECHNICAL ASSISTANCE
Call 1-888-882-7739

P/N: CLIA-ST-501
Rev.: CLIA 11.16.11

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REAGENTS & MATERIALS PROVIDED
1. Test dipsticks containing gold conjugated with Uni-strep antibody specific for Group A Streptococcal antigen.
2. Reagent A (7.5% Sodium Nitrite 2.0M), avoid contact.
3. Reagent B (7.5%Acetic Acid 0.5M), avoid contact.
4. Positive control (1 ml-inactivated Group A Streptococcus in solution with 0.1% Sodium Azide). Mix well before use.
5. Negative control (1 ml-inactivated Group B Streptococcus in solution with 0.1% Sodium Azide). Mix well before use.
7. Extraction Tubes.
8. Package Insert.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer.

STORAGE
The kit and components can be stored at room temperature before use.
If refrigerated, the components must be brought to room temperature before use.

PRECAUTIONS
1. For in vitro diagnostic use only.
2. Do not re-use reagents or dipsticks from different lots.
3. Swabs from other suppliers have not been validated.
4. Do not mix reagents or dipsticks from different lots.
5. The kit and components can be stored at room temperature before use.
6. Test dipsticks must remain in the closed canister until ready for use. Record the date the canister is first opened in the place provided on the label. The test strips should not be used beyond 3 days after opening the canister. Dipsticks from a pouch must be used immediately after the pouch is opened.
7. Be careful not to touch the tongue, cheeks, or lips with the swab. Sampling in these areas, as well as excess saliva, may affect the performance of the kit.
8. In accordance with the principles of Good Laboratory Practice it is strongly recommended that all samples be processed intact without prior contamination and handled with all necessary precautions.

SPECFICM COLLECTION & PREPARATION
1. Only sterile rayon collection swabs, supplied with the kit, should be used. Swabs from other suppliers have not been validated. Using swabs other than those provided with the kit may affect performance of the test.
2. Do not use cotton, wooden shaft or calcium alginate swabs.
3. A throat swab should be obtained using a standard collection method such as outlined by Finegold and Martin in the sixth edition of Diagnostic Microbiology.
4. Depress the patient’s tongue with a blade or spoon and rub the swab firmly over the back of the throat, on both tonsils, and any areas of redness. Be careful not to touch the tongue, cheeks, or lips with the swab.
5. Swabs may be transported using modified Stuart’s media or equivalent. Do not use transport media containing peptone or charcoal.
6. Test swabs must remain in the closed canister until ready to use for 24 hours. Record the date the canister is first opened in the place provided on the label. The test strips should not be used beyond 3 days after opening the canister. Dipsticks from a pouch must be used immediately after the pouch is opened.

LIMITATIONS OF THE PROCEDURE
1. The quality of the swab specimen is extremely important to the accuracy of the test. False negatives may result from improper collection or storage. When there is suspicion of having Step 3 performed incorrectly, additional testing may be done using cultures.
2. This CLIAwaived™ Inc. Rapid Strep A Test should only be used with properly collected throat swabs. The use of specimens from other sites or the use of other samples such as saliva, sputum or urine has not been validated or validated.
3. This test will not distinguish between a carrier state and those individuals with an active disease state. Pharyngitis may be caused by organisms other than Group A Streptococcus. In rare cases, specimens heavily colonized with Streptococcus pyogenes can give false positive results. If test results are inconsistent with clinical presentation, a follow-up throat swab should be obtained for culture confirmation. All results should be evaluated in conjunction with all clinical and laboratory findings.
4. A negative test result means there is no detectable amount of extracted Group A Streptococcus antigen on the throat swab. A negative result may be obtained if no Group A Streptococcus is present in the specimen or if the amount of extracted antigen is below the detection limit of the test.
5. The American Academy of Pediatrics (1994 Redbook, p. 445) recommends that cultures be performed on throat-swab specimens with negative antigen results.
6. Some Group D and Group C streptococci of Streptococcus gans Block positive results in clinical trials.

TEST PROCEDURE

Step 1
Add 2 drops of a to the Extraction Tube. Step 3
Add 2 drops of reagent A to the Extraction Tube.

Step 2
Add 2 drops of Reagent B to the Extraction Tube.

Step 4
Arrange the test strip from the extraction tube and then squeezing the swab between the flexible sides. Discard the swab in a biohazard container.

INTERPRETATION OF RESULTS

Negative Results
The test is negative if only one pink colored line appears in the control zone (see illustration). A negative test means that the assay did not detect any antigen to Group A Streptococcus in the specimen or the levels of antigen are below the detection level of the assay. The specimen should be cultured for up to 48 hours to rule out absence of Group A Streptococcus infection. If clinical symptoms are not consistent with results, other results should be obtained, and another specimen culture for culture.

Positive Results
The test is positive if two pink colored lines appear. One pink colored line will appear in the specimen zone and one in the control zone (see illustration). Any pink colored line in the specimen zone should be considered positive. The pink line in the control zone may be lighter or darker than the specimen line. A positive test means that the assay detected antigen to Group A Streptococcus in the specimen.

Invalid Results
The test is invalid if no pink colored line appears in the control zone even if a pink colored line is present in the specimen zone.

Quality Control Testing Procedure
1. Follow instructions in the test procedure for preparation of Extraction Reagents.
2. Add 1 drop of control.
3. Place a clean swab in the test tube.
4. Follow instructions in test procedure (steps 3 through 6) to complete test.

PERFORMANCE CHARACTERISTICS

Comparison Study
A multi-site evaluation of the CLIAwaived™ Inc. Rapid Strep A Test was carried out to determine the clinical performance characteristics of the test relative to another commonly available test. Two throat swabs were collected from patients presenting with symptoms of pharyngitis. A total of 104 patients were tested.

<table>
<thead>
<tr>
<th>Available Test</th>
<th>Commercially Available Test</th>
<th>Other Commercially Available Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLIAwaived™ Inc. Rapid Strep A Test</td>
<td>vs.</td>
<td>vs.</td>
</tr>
<tr>
<td>Total</td>
<td>104</td>
<td>104</td>
</tr>
</tbody>
</table>

The CLIAwaived™ Inc. Rapid Strep A Test had an overall agreement of 93.9% to that of the other commercially available test. The four (4) samples that were found to be CLIAwaived™ Inc. Rapid Strep A Test negative were also considered negative by the other commercially available test positive (+) were confirmed positive (+) by culture. The sample that was otherwise commercially available test positive (+) was confirmed positive (+) by culture. The sample that was otherwise commercially available test positive (+) was confirmed positive (+) by culture.

External Controls
Each kit contains a set of Positive and Negative controls to be used for external quality testing of the reagents and dipsticks.

External controls should be used according to individual quality assurance guidelines. If the controls do not work as expected, repeat the test or contact Technical Assistance.