**RapidTech Strep A Test**

**INTENDED USE**
The RapidTech Strep A Test is a lateral flow, one-step immunoassay for the rapid, qualitative detection of Group A Streptococcal antigen from throat swabs. The test is intended for use as an aid in the diagnosis of Group A Streptococcal infection.

**SUMMARY AND EXPLANATION**
Beta-hemolytic Group A Streptococcus is a major cause of upper respiratory infections such as tonsillitis, pharyngitis, and scarlet fever. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications, such as rheumatic fever and glomerulonephritis (1).

Conventional methods used for the detection of the disease depend on the isolation and subsequent identification of the organism (1,2). These methods often require 24-48 hours to complete. Recent development of immunological techniques (3,4) which can detect Group A Streptococcal antigen directly from throat swabs allow physicians to diagnose and administer therapy immediately.

**TEST PRINCIPLE**
The RapidTech Strep A Test utilizes a two-site sandwich immunoassay technology for the detection of Group A Streptococcal antigen. The test consists of a membrane strip which was precoated with rabbit anti-Strep A antibody on the test band region and goat anti-rabbit antibody on the control band region. A colored rabbit anti-Strep A antibody-colloidal gold conjugate pad is placed at the end of the membrane. During testing, the Strep A antigen is extracted from the throat swab using Extraction Reagents. The test strip is then immersed in the extracted sample. The mixture then moves chromatographically on the membrane to the immobilized rabbit anti-Strep A antibody at the test band region. If Strep A antigen is present in the specimen, a colored sandwich of solid phase/Strep A antigen/gold conjugate is formed on the test band region. Absence of the colored band at the test band region indicates a negative result. Regardless of the presence of Strep A antigen, as the extracted mixture continues to move laterally across the membrane to the immobilized goat anti-rabbit antibody control band region, a colored band at the control region will always appear. The presence of this colored band serves as: 1) verification that sufficient volume has been added, 2) verification that proper flow is obtained, and 3) reagent control.

**STORAGE AND STABILITY**
All reagents included in the RapidTech Strep A Test can be stored at room temperature (15-30°C) or refrigerated (2-8°C) until the expiration date printed on the outer box. Do not freeze.

**PRECAUTIONS**
1. For in-vitro diagnostic use only.
2. Do not mix reagents from different lots.
3. Do not use after stated expiration date.
4. Extraction Reagent is slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.

5. If the Extraction Tube is missing the tablet, discard and use another test pack.
6. Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions, always flush with copious amounts of water to prevent azide buildup.
7. Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. All contaminated waste such as swabs, Strep A Test strips and extracts should be properly disposed of.
8. To obtain accurate results, package insert instructions must be followed.

**REAGENTS AND MATERIALS SUPPLIED**
1. 25 test packs: each pack includes one test strip and one tablet in the Extraction Tube. Each tablet contains 40 mg of sodium nitrite.
2. 1 Extraction Reagent (0.5 M acetic acid.)
3. 25 Sterile Throat Swabs.
4. Positive Control: Heat-killed Group A Streptococcus in solution (1 x 10^6 organisms/ml) with 0.1 % sodium azide as preservative (2 ml).
5. Negative Control: Heat-killed Group B Streptococcus in solution (1 x 10^6 organisms/ml) with 0.1 % sodium azide as preservative (2 ml).
6. Instruction insert.

**SPECIMEN COLLECTION AND HANDLING**
Use only Dacron® or rayon tipped sterile swabs with plastic shafts. The tongue should be held down with a tongue depressor to obtain a specimen. The tongue should not be touched with the swab. Both tonsils, the posterior pharynx and any areas of inflammation, ulceration or exudation should be sampled. Review standard clinical methods such as those described by Facklam (1) and Ross (5).

It is recommended that swab specimens be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a sterile, dry, tightly capped tube or bottle and refrigerated. If a liquid transport method is employed, use Modified Stuart's Transport Media as outlined in the manufacturer’s instructions. Do not use transport media formulations including charcoal or agar. Swabs can be stored at room temperature (15-30°C) up to 4 hours or refrigerated (2-8°C) up to 24 hours.

If a bacteria culture is desired, lightly streak the swab on a 5% sheep blood agar plate before using it with the RapidTech Strep A Test. Extraction Reagents kill the bacteria on swabs and make them impossible to culture. Alternatively, a subsequent second swab sample may be taken for culture procedure.

**ASSAY PROCEDURE**
Review “specimen collection” instructions. Do not open pouches until ready to perform the assay. Test reagents and specimens should be brought to room temperature before testing.

**INTERPRETATION OF RESULTS**

- **Positive:** Two pink colored bands appear. In addition to a pink-colored band in the control (C) region, a pink-colored band will also appear in the test band (T) region. Absence of the control line is an indication of procedural error or possible reagent deterioration. A new test should be performed.

- **Negative:** Only one pink colored band appears in the control (C) region. No pink colored band is visible in the test band (T) region. This indicates that no Strep A antigen has been detected.

- **Invalid:** No pink colored bands appear. An absence of the control line is an indication of procedural error or possible reagent deterioration. A new test should be performed.
The results are summarized as follows:

<table>
<thead>
<tr>
<th>Culture Classification</th>
<th>RapidTech/Culture</th>
<th>Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>102/104</td>
<td>98%</td>
</tr>
<tr>
<td>1 + (&gt; 10 colonies)</td>
<td>1/3</td>
<td>33.3%</td>
</tr>
<tr>
<td>2 + (11-50 colonies)</td>
<td>8/0</td>
<td>80%</td>
</tr>
<tr>
<td>3 + (&gt; 50 colonies)</td>
<td>19/19</td>
<td>100%</td>
</tr>
<tr>
<td>4 + (predominant growth)</td>
<td>9/9</td>
<td>100%</td>
</tr>
</tbody>
</table>

Sensitivity 90.2%  Specificity 98.1%

Overall Accuracy 95.8%

REFERENCES

Genix Technology
Vancouver, Canada.

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