**INTENDED USE**

The StrongStep® Strep A Rapid Test Device is a rapid immunoassay for the qualitative detection of Group A Streptococcal (Group A Strep) antigen from throat swab specimens as an aid to the diagnosis of Group A Strep pharyngitis or for culture confirmation.

**PRINCIPLE**

The Strep A Rapid Test Device has been designed to detect Group A Streptococcal antigen through visual interpretation of color development in the internal strip. The membrane was immobilized with Rabbit anti Strep A antibody on the test region. During the test, the specimen is allowed to react with another rabbit anti-Strep A antibody colored particles conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough Strep A antigens in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

**KIT COMPONENTS**

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individually packed test devices</td>
<td>20</td>
</tr>
<tr>
<td>Bottle of Extraction Buffer A</td>
<td>5ml</td>
</tr>
<tr>
<td>Bottle of Extraction Buffer B</td>
<td>5ml</td>
</tr>
<tr>
<td>Extraction tubes</td>
<td>20</td>
</tr>
<tr>
<td>Workstation</td>
<td>1</td>
</tr>
<tr>
<td>Positive control swab (on request only)</td>
<td>1</td>
</tr>
<tr>
<td>Negative control swab (on request only)</td>
<td>1</td>
</tr>
</tbody>
</table>

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Timer
- Buffer solution containing 4.0 M Acetic Acid with white cap.
- Buffer solution containing 1.0 M Sodium Nitrite with yellow cap.
- Acetate Buffer Solution (Nitrite with yellow cap).
- Acid with white cap.
- 20 Extraction tubes for specimens preparation use.
- Place for holding buffer vials and tubes.
- For operation instruction.
- Contains inactivated Group A Streptococcal and sodium azide. For External control.
- Not contain Group A Streptococcal. For external control.

**STORAGE AND STABILITY**

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

**SPECIMEN COLLECTION AND STORAGE**

Use only Dacron or Rayon tipped sterile swabs with plastic shafts. It is recommend to use the swab supplied by the kits manufacturer(The swabs are not contained in this kit, for the ordering information, please contact the manufacturer or local distributor, the cataloge number is 207000). Swabs from other suppliers have not been validated. Swabs with cotton tips or wooden shafts are not recommended.

- Collect throat swab specimens by standard clinical methods. When swabbing the throat, be careful not to touch the tongue, sides or top of the mouth with the swab. Rub the swab on the back of the throat, on the tonsils and in any other area where there is redness, inflammation or pus. Bloody specimens can create an interfering background and can cause an invalid result. Consult reference procedures such as the collection method described by Facklam.
- Do not place the swab in any transport device containing medium since transport medium interferes with the assay and viability of the organisms is not required for the assay. Put the swab to the extraction tube, if the test may be run immediately. If immediate testing is not possible, the patient samples should be placed in a dry transport tube for storage or transportation. The swabs may be stored for 24 hours at room temperature (15-30°C) or 1 week at 4°C or 6 month at -20°C. All specimens should be allowed to reach room temperature of 15-30°C before testing.
- Do not use 0.9% sodium chloride to treat swabs before collecting specimens.

**PROCEDURE**

**Extraction Procedure:**

1. Provide 4 drops of Extraction Buffer A to the extraction tubes.
2. Add 4 drops of Extraction Buffer B to the tube and mix the liquids thoroughly.
3. Immediately place the swab specimen in the tube. Use a circular motion to roll the swab against the side of the Extraction Tube so that the liquid is squeezed out from the swab and reabsorb again for 2 minutes.
4. At the end of the extraction the swab should be squeezed totally to remain as much liquid as possible in the extraction tube. The swab must be discarded according the local guidelines for handling infectious agents and chemical reagents.

**Test Procedure**

5. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
6. Add 3 drops (approximately 100 µl) of extracted sample from the
Extraction Tube to the sample well on the test cassette. Avoid trapping air bubbles in the specimen well (S), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

**INTERPRETATION OF RESULTS**

<table>
<thead>
<tr>
<th><strong>RESULT</strong></th>
<th><strong>DESCRIPTION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POSITIVE RESULT:</strong></td>
<td>Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).</td>
</tr>
<tr>
<td><strong>NEGATIVE RESULT:</strong></td>
<td>Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).</td>
</tr>
<tr>
<td><strong>INVALID RESULT:</strong></td>
<td>Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.</td>
</tr>
</tbody>
</table>

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. But the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

**QUALITY CONTROL**

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered as an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- External procedural controls may provided(on request only) in the kits to ensure that the test are functioning properly. Also, the Controls may be used to demonstrate proper performance by the test operator. To perform a positive or negative control test, complete the steps in the Test Procedure section treating the control swab in the same manner as a specimen swab.

**LIMITATIONS OF THE TEST**

1. The Strep A Rapid Test Device is for professional in vitro diagnostic use, and should be used for the qualitative detection of Group A Streptococcal only. There is no meaning attributed to line color intensity or width.
2. Respiratory infections, including pharyngitis, can be caused by Streptococcus from serogroups other than Group A as well as other pathogens. The Strongstep® Strep A test will not differentiate asymptomatic carriers of Group A Streptococcus from those exhibiting Group A Streptococcal infection.
3. In rare cases, test specimens heavily colonized with Staphylococcus aureus can yield false positive results.
4. Test results must always be evaluated with other data available to the physician. A negative test result might occur if the level of extracted antigen in a sample is below the detection level of the test.
5. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

**PERFORMANCE CHARACTERISTICS**

**Table: Strep A Rapid Test vs. Culture**

<table>
<thead>
<tr>
<th>Culture</th>
<th>StronStep® Strep A Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>103</td>
</tr>
<tr>
<td>-</td>
<td>3</td>
</tr>
</tbody>
</table>

**Cross reactivity with other organisms has been studied using suspensions of 10⁷ CFU/ml. The following organisms were detected using the test:**

- Arcanobacterium haemolyticum
- Candida albicans
- Escherichia coli
- Fusobacterium necrophorum
- Haemophilus influenzae
- Haemophilus parahaemolyticus
- Klebsiella pneumoniae
- Moraxella catarrhalis
- Moraxella lacunata
- Neisseria gonorrhoeae
- Neisseria lactamica
- Neisseria meningitidis
- Neisseria sicca
- Neisseria subflava
- Proteus vulgaris
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus (Cowan’s serotype 1)
- Staphylococcus haemolyticus
- Staphylococcus epidermidis
- Streptococcus Groups B, C, D, F, G
- Streptococcus mitis
- Streptococcus mutans
- Streptococcus oralis
- Streptococcus pneumoniae
- Streptococcus salivarius
- Streptococcus sanguis
- Yersina enterocolitica
- diphtheriae
- Escherichia coli
- Fusobacterium necrophorum
- Haemophilus influenzae
- Haemophilus parahaemolyticus
- Klebsiella pneumoniae
- Moraxella catarrhalis
- Moraxella lacunata
- Neisseria gonorrhoeae
- Neisseria lactamica
- Neisseria meningitidis
- Neisseria sicca
- Neisseria subflava
- Proteus vulgaris
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Staphylococcus epidermidis
- Streptococcus Groups B, C, D, F, G
- Streptococcus mitis
- Streptococcus mutans
- Streptococcus oralis
- Streptococcus pneumoniae
- Streptococcus salivarius
- Streptococcus sanguis
- Yersina enterocolitica
- diphtheriae

**LITERATURE REFERENCES**


**GLOSSARY OF SYMBOLS**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catalog number</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>Consult instructions for use</td>
<td>Batch code</td>
</tr>
<tr>
<td>In vitro diagnostic medical device</td>
<td>Use by</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Contains sufficient for ≤&lt;n&gt; tests</td>
</tr>
<tr>
<td>Do not reuse</td>
<td>Authorized representative in the European Community</td>
</tr>
</tbody>
</table>

Liming Bio-Products Co., Ltd, No. 12 Huaysan Road, Nanjing, Jiangsu, 210042 P.R. China. Tel: (086)25 85476723 Fax: (086)25 85476387 E-mail: sales@limingbio.com Website: www.limingbio.com www.stdtdiagnostics.com www.stidiagnostics.com

WellKang Ltd.(www.CE-marking.eu) Tel: +44(20)79934346 29 Harley St., London WIG 9QR, UK Fax: +44(20)76811874