LIMING BIO

Strep A

Rapid Test Device

REF	500150	Specimen: Swab
Language: English		Version: 01
Effective Date: 2011-10		

For professional *in vitro* diagnostic use only.

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.

INTRODUCTION

Beta-haemolytic Group B Streptococcus is a major cause of upper respiratory infections in humans. The most commonly occurring Group A Streptococcal disease is pharyngitis. The symptoms of this, if left untreated, can become more severe and further complications such as acute rheumatic fever, toxic shocklike syndrome and glomerulonephritis can develop. Rapid identification can facilitate clinical management to prevent disease progression.

Conventional methods used to identify Group A Streptococcus involve the isolation and subsequent identification of the organisms, which can take 24-48 hours to complete.

The *StrongStep*® Strep A Rapid Test Device detects Group A Streptococci directly from throat swabs so that more rapid results are achieved. The test detects bacterial antigen from swabs, therefore it is possible to detect Group A Streptococcus, which may fail to grow in culture.

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 particals 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

20 Individually packed test devices	Each device contains a strip with colored conjugates and reactive reagents pre-coated at the corresponding regions.
1 bottle of Extraction Buffer A - 5ml	Buffer solution containing 1.0 M Sodium Nitrite with yellow cap.
1 bottle of Extraction Buffer B - 5ml	Buffer solution containing 0.4 M Acetic Acid with white cap.
20 Extraction tubes	For specimens preparation use.
2 Workstation	Place for holding buffer vials and tubes.
1 Package insert	For operation instruction.
1 Positive control swab (on request only)	Contain inactived Group A Streptococcal and sodium azide. For External control.
1 Negative control swab (on request only)	Not contain Group A Streptococcal. For external control.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer	For timing use.

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled observing the usual safety precautions (do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to performing any tests.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Humidity and temperature can adversely affect results.
- When the assay procedure is completed, dispose the swabs carefully after autoclaving them at 121°C for at least 20 minutes. Alternatively, they can be treated with 0.5% sodium hypochloride (or house-hold bleach) for one hour before disposal. The used testing materials should be discarded in accordance with local, state and/or federal regulations.
- **Do not use cytology brushes with pregnant patients.**

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 swab 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[3].
- 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 transport. 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

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.

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 disposed 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.

7. 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

POSITIVE RESULT: 	Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
NEGATIVE RESULT: 	Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T).
INVALID RESULT: 	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.

NOTE:

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

Relative Sensitivity: 97.2% (92.0%-99.4%)* **Relative Specificity:** 98.7% (96.7%-99.7%)* **Overall Agreement:** 98.3% (96.6%-99.3%)* ***95% Confidence Interval**			**Culture**		
			+	**-**	**Total**
	***StrongStep*® Strep A Test**	**+**	103	4	107
		-	3	306	309
			106	310	416

Cross reactivity with other organisms has been studied using suspensions of 10^7 CFU/ml. The following organisms were detected using the test:

Arcanobacterium haemolyticum	Bordetella pertussis
Candida albicans	Corynebacterium 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 aureus (Cowan ' s serotype 1)	Staphylococcus epidermidis
Staphylococcus haemolyticus	Staphylococcus saprophyticus
Streptococcus Groups B, C, D, F, G	Streptococcus mitis
Streptococcus mutans	Streptococcus oralis
Streptococcus pneumoniae	Streptococcus salivarius
Streptococcus sanguis	Yersina enterocolitica

LITERATURE REFERENCES

1. Ruoff K., Streptococcus. In: Manual of Clinical Microbiology, Murray P.R., ed. 6th Edition, 1995, 23: 301.
2. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition. U.S. Department of Health and Human Services, CDC, NIH, Washington, D.C. (1999).
3. Facklam R.R., and Washington II, J.A., Streptococcus and Related Catalase-Negative Gram-Positive Cocci. In: Manual of Clinical Microbiology, Balows A., ed. 5th Edition, 1991, 29: 241.
4. American Academy of Pediatrics. Group A Streptococcal Infections. In: 1994 Redbook: Report of the Committee on Infectious Diseases. Peter G. ed. 23rd Edition, Elk Grove, IL, 1994, p 433.
5. Wannamaker L.W., New England Journal of Medicine, 1970, 282: 23–31.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse	EC REP	Authorized representative in the European Community
CE	CE marked according to IVD Medical Devices Directive 98/79/EC		

Liming Bio-Products Co., Ltd,
No. 12 Huayuan Road,Nanjing, Jiangsu, 210042
P.R. China.
Tel: (0086)25 85476723 Fax: (0086)25 85476387
E-mail: sales@limingbio.com
Website: www.limingbio.com
www.stddiagnostics.com
www.stidiagnostics.com

EC REP WellKang Ltd.(www.CE-marking.eu) Tel: +44(20)79934346
29 Harley St., London W1G 9QR,UK Fax: +44(20)76811874