## PACKAGE INSERT

A rapid test for the qualitative detection of Strep A antigens in throat swab specimens.
For near-patient and laboratory professional in vitro diagnostic use only.

## INTENDED USE

The Strep A Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens in throat swab specimens. The Strep A Rapid Test is for near-patient and laboratory professional in vitro diagnostic use only and is intended to be used as an aid in the diagnosis of Group A Streptococcal infections. The test provides preliminary test results, negative results will not preclude Strep A infection and they can't be used as the sole basis for treatment or other management decision.
Not for Self-testing use.

## SUMMARY

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.1 Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.2 Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.3
The Strep A Rapid Test is a rapid test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigens in a throat swab specimen.

## PRINCIPLE

The Strep A Rapid Test a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A
carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a colored line in the test line region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

## REAGENT

The test contains Strep A antibody and Biotin-BSA coated particles, Streptavidin-Rabbit IgG and Strep A antibodies coated on the membrane.

## WARNINGS AND PRECAUTIONS

Please read all the information in this package insert before performing the test.
For near-patient and laboratory professional in vitro diagnostic use only.
Do not use after the expiration date.
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.
The used test should be discarded according to local regulations.
Humidity and temperature may adversely affect results.
Do not use test if pouch is damaged.
Extraction reagent 1 contains NaNO2. If the solution contacts the skin or eye, flush with large volumes of water.
Do not interchange reagent bottle caps.
Do not interchange external control solution bottle caps.
Wash hands thoroughly before and after handling.
Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority.
Components provide in the kit are approved for use in the Strep A Rapid Test. Do not use any other commercial kit component.

## STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date. Note: It is suggested to use test cassette within one hour after removing it from the foil pouch.

## SPECIMEN COLLECTION AND PREPARATION

Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
Testing should be performed immediately after the specimens have been collected. If swab are not processed immediately, it is highly recommended the swab specimens is stored into a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8 °C.
If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test.

## MATERIALS Materials Provided

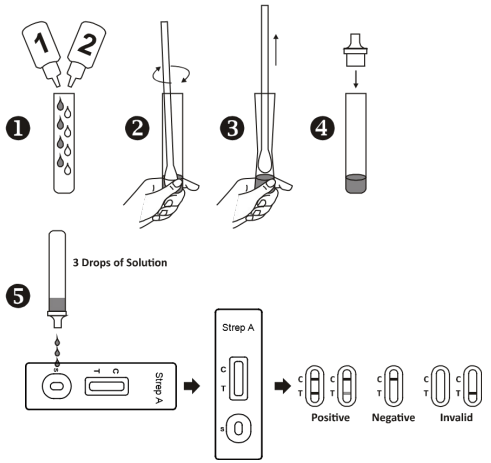
| | Kit size | 20T/ kit |
|---|---|---|
| Components | Test cassettes | 20 |
| | Package insert | 1 |
| | Extraction tubes | 20 |
| | Sterile swabs | 20 |
| | Workstation | 1 |
| | Dropper tips | 20 |
| | ⚠ Extraction reagent 1 10 mL (13.8% $NaNO_2$,0.0004% Phenol red), Red cap | 1 |
| | Extraction reagent 2 10 mL (0.5184% Citric acid, 0.02% Proclin 300), Yellow cap | 1 |
| | Positive control 0.5 mL (Non-viable Strep A, 0.02% Proclin 300, 0.5%BSA), Blue cap | 1 |
| | Negative control 0.5 mL (Non-viable Strep C, 0.02% Proclin 300,PBS), Green cap | 1 |

### Materials Required But Not Provided

- Timer

## DIRECTIONS FOR USE

**Allow the test, reagent, throat swab specimen, and/or controls to reach room temperature (15-30 °C) prior to testing.**
1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch. 2. Insert the extraction tube into the workstation, hold the Extraction Reagent 1 bottle vertically and add 4 full drops (approximately 240 µL) of Extraction Reagent 1 to an extraction tube. Extraction Reagent 1 is red in color. Hold the Extraction Reagent 2 bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow. See illustration 1.
Immediately add the swab into the extraction tube, agitate the swab vigorously 15 times, and leave the swab in the extraction test tube for 1 minute. See illustration 2.
Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab. See illustration 3
Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. Add 3 drops of the solution (approx. 100 µL) to the sample well(S) and then start the timer.
Read the result at 5 minutes. Do not interpret the result after 10 minutes. See illustration 4 and illustration 5.
Note: It is suggested not to use the Extraction Reagent 1 and Extraction Reagent 2 beyond 6 months after opening the vial.




## INTERPRETATION OF RESULTS

(Please refer to the illustration above)
**POSITIVE:*** Two colored lines appear. One colored line should be in the control line region (C) and another colored line should be in the test line region (T). A positive result indicates that Strep A was detected in the specimen.
***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Strep A present in the specimen.
**NEGATIVE:** One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture.
**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

## QUALITY CONTROL Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. External Quality Control
It is recommended that a positive and negative external control be run every kit, and as deemed necessary by internal laboratory procedures. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A Streptococcus reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

### Procedure for External Quality Control Testing

Add 4 full drops of Extraction Reagent 1 and 4 full drops of Extraction Reagent 2 into an extraction tube. Tap the bottom of the tube gently to mix the liquid.
Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
Fit the dropper tip on top of the extraction tube. Place the test on a clean and level surface. Add 3 drops of the solution (approx.100 µL) to the sample well and then start the timer.
Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not interpret the result after 10 minutes. See illustration 5.
If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.
Note: The POSITIVE CONTROL and NEGATIVE CONTROL are qualitative reagents and are not to be used as quantitative calibrators. This control can only be used to validate the performance of Strep A Rapid Test manufactured by the company.

## LIMITATIONS

The Strep A Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
A negative result should be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth4 and any bleeding areas of the mouth with the swab when collecting specimens.
As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

## PERFORMANCE CHARACTERISTICS Accuracy

Clinical test has been conducted on altogether 361 throat swab Specimens. The tests were parallel comparison studied with the culture.
For the Field user study, 103 specimens were found to be positive by culture and 99 were also positive by the Strep A Rapid Test; 258 specimens were found to be negative by culture and 252 were also negative by the Strep A Rapid Test. Based on this data, the Accuracy is 97.2% for the Strep A Rapid Test.
For the Professional study, 103 specimens were found to be positive by culture and 99 were also positive by the Strep A Rapid Test; 258 specimens were found to be negative by culture and 252 were also negative by the Strep A Rapid Test. Based on this data, the Accuracy is 97.2% for the Strep A Rapid Test.

| Method Comparison | | Field User | | | Professional | | |
|---|---|---|---|---|---|---|---|
| | | Culture | | Total | Culture | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Strep A Rapid Test | Positive | 99 | 6 | 105 | 99 | 6 | 105 |
| | Negative | 4 | 252 | 256 | 4 | 252 | 256 |
| | Total | 103 | 258 | 361 | 103 | 258 | 361 |
| Relative sensitivity | | 96.1% (95%CI*: 90.4%-98.9%) | | | 96.1% (95%CI*: 90.4%-98.9%) | | |
| Relative specificity | | 97.7% (95%CI*: 95.0%-99.1%) | | | 97.7% (95%CI*: 95.0%-99.1%) | | |
| Accuracy | | 97.2% (95%CI*: 95.0%-98.7%) | | | 97.2% (95%CI*: 95.0%-98.7%) | | |

*Confidence Intervals

### Sensitivity

The Strep A Rapid Test can detect levels of Strep A as low as 1E+07 org/ mL (1E+05 org/test).

### Hook

There is no dose hook effect with the test, when the Strep A level is no more than 1E+12 org/mL (1E+10 org/test).

### Precision

Precision has been determined by using seven specimens: 0.5%BSA-PBS negative specimen, 5E+06 org/ml, 1E+07 org/mL, 1.5E+07 org/mL, 2E+07 org/mL, 2.5E+07 org/mL, 1E+08 org/mL positive specimens. The study was performed 6 replicates per day for 5 consecutive days in 3 different sites using 3 separate lots of Strep A Rapid Test (one lot per site), and three operators per site. The precision results got high accuracy at 0.5% BSA-PBS, 5E+06 org/mL, 1E+07 org/mL, 1.5E+07 org/mL, 2E+07 org/mL, 2.5E+07 org/mL, 1E+08 org/mL.

### Cross Reactivity

The following organisms were tested at 1E+07org/mL and were all found to be negative when tested with the Strep A Rapid Test. No mucoid-producing strains were tested.

| | | |
|---|---|---|
| Group B Streptococcus | Neisseria meningitidis | Serratia marcescens |
| Group F Streptococcus | Neisseria sicca | Klebsiella pneumoniae |
| Streptococcus pneumoniae | Branhamella catarrhalis | Bordetella pertussis |
| Streptococcus mutans | Group C Streptococcus | Neisseria gonorrhea |
| Staphylococcus aureus | Group G Streptococcus | Neisseria subflava |
| Corynebacterium diphtheria | Streptococcus sanguis | Hemophilus influenza |
| Candida albicans | Staphylococcus epidermidis | Pseudomonas aeruginosa |
| Enterococcus faecalis | | |

### Interfering Substances

The following compounds have also been tested using the Strep A Rapid Test and no interference was observed.

| | |
|---|---|
| Cherry Halls cough drops | Vicks Chloraseptic spray |
| Menthol Halls cough drops | Cepacol Chloraseptic spray |
| Robitussin cough syrup | Listerine mouthwash |
| Dimetapp cough syrup | Scope mouthwash |

## BIBLIOGRAPHY

Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C., 1995, p. 299-307.
Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Pediatrics (Feb 1998), 101:2, 2.
Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999),
491-492

### Index of Symbols

| | | | |
|---|---|---|---|
| | Manufacturer | | Imported by |
| LOT | Lot number | REF | Product code |
| CE | In vitro diagnostic medical device compliant with Regulation (EU) 2017/746 | EC REP | Authorized representative in the European community |
| | Don't use if package is damaged | | Consult instructions for use |
| | Expiration date | | Disposable device, do not re-use |
| Σ | Contains sufficient for <n> test | | Temperature limit |
| IVD | In vitro diagnostic medical device | | Warning |
| UDI | Unique device identifier | | |

**GIMA WARRANTY TERMS**
The Gima 12-month standard B2B warranty applies.

GIMA
PROFESSIONAL MEDICAL PRODUCTS

# *STREP A RAPID TEST*

REF **IST-N502 (GIMA 24520)**

Hangzhou AllTest Biotech Co., Ltd.
#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou - 310018, P.R. China
Made in China

EC REP MedNet EC-REP GmbH
Borkstrasse 10 - 48163
Muenster, Germany

**Gima S.p.A.**
Via Marconi, 1 - 20060 Gessate (MI) Italy
gima@gimaitaly.com - export@gimaitaly.com
**www.gimaitaly.com**

*M24520-Rev.0-03.23*

CE 0123

IVD 30°C 2°C