

EZER™ Strep A Antigen Rapid Test

This kit is designed for testing collected throat swab samples.

INTENDED USE

The **EZER™** Strep A Antigen Rapid Test is a lateral flow, one-step immunoassay for the rapid, qualitative detection of *Group A streptococcus* antigen from throat swabs. The test is intended for use as an aid in the diagnosis of Group A streptococcal infection. It's an *in vitro* diagnostic test for professional use only.

BACKGROUND

Streptococcus pyogenes (*Group A streptococcus*) is a Gram-positive, nonmotile, non-spore forming bacterium that occurs in chains or in pairs of cells, where individual cells are round-to-ovoid cocci, 0.6-1.0 micrometer in diameter. Approximately 5-15% of normal individuals harbor the bacterium, usually in the respiratory tract, yet remain asymptomatic. As normal flora, *S. pyogenes* can infect when defenses are compromised or when the organisms are able to penetrate the constitutive defenses. When the bacteria are introduced or transmitted to vulnerable tissues, a variety of types of suppurative infections can occur^[1].

GAS (*Group A streptococcus*) infection can lead to a wide range of clinical diseases, including non-invasive infections and invasive infections, non-invasive infections such as pharyngeal infections (including pharyngeal / tonsillitis), skin infections (impetigo), etc. Invasive infections include pneumonia, bacteremia, endocarditis, osteomyelitis, Guanchitis, encephalitis, necrotizing fasciitis and streptococcal toxic shock syndrome (STSS)^[2]. Among them, GAS plays an important role in respiratory tract infections in children, mainly including pharyngitis, tonsillitis and pneumonia.

The **EZER™** Strep A Antigen Rapid Test, a lateral flow immunochromatographic assay permits the early diagnosis of *group A streptococcus* infection by simple and rapidly detecting the antigen in throat wipe specimens.

PRINCIPLE

The test uses A highly specific antibody antigen reaction and immunochromatography analysis technology to qualitatively determine whether the throat mucus contains *group A streptococcus* antigen. The kit contains the rabbit antibodies against *group A streptococcus* fixed in the membrane test area (T) and the corresponding antibodies in the quality control area (C).

For testing, three drops of the split extract were added to the addition wells of the reagent plate, and the *group A streptococcus* antigen in the extract was reacted with the rabbit anti-*group A streptococcus* antibody bound to the precoated labeled particles. Then, the mixture is then chromatographed under the capillary effect. If positive, the mixture first binds to the rabbit anti-*group A streptococcus* antibody in the specimen during the chromatography, and then the conjugate is bound by the rabbit anti-*group A streptococcus* antibody on the membrane, and a red band will appear in the test area (T). If no red band appears in the test area (T), the specimen does not contain the *Group A streptococcus* antigen, indicating A negative result. Regardless of the presence the *group A streptococcus* antigen is present in the specimen, the mixture will chromatographically migrate to the control region (C), and a red band appears when the corresponding antibody in the control region reacts with the colloid gold conjugate. The red band appearing in the quality control area (C) is the standard to determine whether the chromatography process is normal, and serves as the internal control standard of the reagents.

CONTENTS

Strep A antigen test devices	20
Sterilized swabs	20
Nozzles	20
Plastic tubes	20
Extraction buffer(A/B)	2
Tube Stand	1
Package Insert	1

STORAGE CONDITIONS

The original packaging should be stored in 2~30℃, in a cool and dry place, avoid freezing.

The validity period is 24 months, the expiration date: see the packaging, the expired products are not available.

WARNINGS AND PRECAUTIONS

1. Strep A Antigen Rapid Test was used only for *in vitro* diagnostics and only for detecting *Group A streptococcus* antigens in throat cotton swab samples.
2. If the sample size is insufficient or the antigen concentration is less than the detection sensitivity. Therefore, the negative results are recommended for confirmation by the culture method.
3. The sterile cotton swabs provided by the kit must be used for specimen collection, and the other cotton

swabs were not verified by this reagent. Independent cotton swabs were used for each sample to avoid cross-contamination.

4. Additional blood or saliva in cotton swabs can interfere with test results and may produce false positive results, so avoid touching the tongue, cheeks, or teeth during sampling.
5. All samples and used accessories should be treated as infectious and discarded according to local regulations.
6. Read the result at 15 min, or up to 30 min. Do not read the result longer than 30 min, because the result might be altered if the device is dry out.
7. The Extraction buffer A is corrosive and avoids contact with skin and eyes during operation.

SAMPLE COLLECTION AND PREPARATION

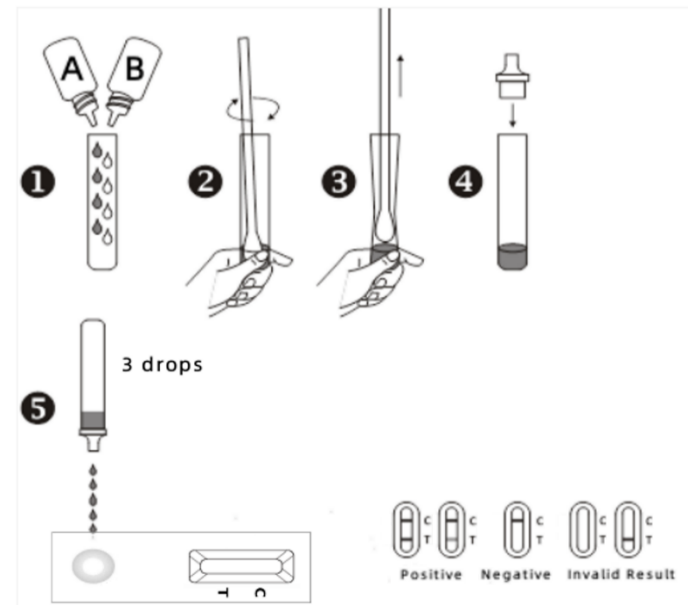
1. Applicable samples: throat swabs.
2. throat swabs
 - Only the reagents and cotton swabs provided in the package box shall be used.
 - Samples were collected at the tonsil or the back wall of the throat with the cotton swab provided in the box to avoid touching the teeth and gums. Tongue and inner cheek surface.
 - It is best to detect specimens immediately after collection. Cotton swabs can be kept at room temperature or at 2~8 °C for 24 hours. Cotton swabs should be restored to room temperature before testing.
3. Note on sample processing:
 - All samples are at risk of infection, please be careful when handling.

PROCEDURE

Reading the service insert before testing and ensuring that the test cartridge and lysate are restored to room temperature (15 to 30°C) before testing.

1. Take out the test card from the original package foil bag and use it within 1 hour.
2. First add 4 drops (around 240ul) of Extraction buffer A (the purple-red one) to the plastic tube vertically, and then add 4 drops (around 160ul) of Extraction buffer B (the colorless one) to the same plastic tube. Shaking the plastic tube slightly to ensure the two buffers are mixed completely, then the color of the mixed buffer will turn light yellow.
3. Put the sampled swab into the buffer immediately when the buffer turned into yellow, stir and squeeze the swab 10 times to ensure the sample on the swab is mixed with the buffer completely, and leave it to stand for around 1 minute, then remove the swab.
4. Insert the attached tip into the upper end of the plastic tube firmly.

5. Squeeze the plastic tube and add 3 drops to the sample window on the test plate.
6. Read the test result within 15 minutes. The result may be invalid after 30 minutes.



INTERPRETATION OF RESULTS

Allow the samples to react according to the procedure and read the red purple lines that appear in the reading area.

Positive

Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T). This indicates that the specimen contains detectable amount of Strep A antigen. The shade of color may vary, but it should be considered positive whenever there is even a faint line.

Negative

Only one reddish band appears on control region of the device. No reddish line is visible next to the Test "T". This indicates that there is no detectable Strep A antigen in the sample.

Invalid Result

No red line appears in the control region (C). The test is invalid even if there is a line in the region (T). Review testing procedures and repeat the test using a new rapid test device.

PRECAUTIONS FOR ASSESSMENT

1. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement, the reaction and color development may slightly continue and progress even after 15 minutes.
2. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present.

Occasionally, broken lines may appear, but the test result is valid as long as a red line is present.

3. If the line is not red at all (e.g., black), the test result is invalid and another test should be performed.
4. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.

QUALITY CONTROL

Internal control :

Each EZER™ Strep A Antigen Rapid Test contains internal/procedural controls. The appearance of a control line at the Control "C" position validates the proper reagent function and assures that the correct test procedure was followed.

PERFORMANCE CHARACTERISTICS

Minimum detection limit

This Test shows positive results when the tests are performed following the specified procedures with positive quality standard solution containing extract of Strep A, CICC10913 (2.0x10⁵CFU/mL).

Cross-reactivity evaluation

The exception of Strep A

No cross reactivity was observed with the following bacteria and fungi :

Group B Streptococcus, Group C Streptococcus, Group F Streptococcus, Group G Streptococcus, Streptococcus pneumoniae, Streptococcus sanguis, Streptococcus mutans, Enterococcus faecalis, Staphylococcus aureus, Staphylococcus, Corynebacterium, Serratia marcescens, Candida albicans, Klebsiella pneumoniae, Pseudomonas, Bordetella pertussis, Neisseria, Neisseria gonorrhoea, Neisseria sicca, Neisseria subflava, Branhamella, Hemophilus influenza.

Clinical Studies

The performance of the EZER™ Strep A Antigen Rapid Test evaluated 525 clinical specimens, 401 patients culture negative and 124 culture positive. The results showed that the Strep A Antigen Rapid Test has A high sensitivity to the *group A streptococcus* antigen, with its relative sensitivity of 93.55%, specificity of 97.26% and accuracy of 96.38%.

Table 1: Performance Summary of the EZER™ Strep A test compared to "Another product" with Percent Agreements

		Another product		
		+	-	Total
EZER™ Strep A Antigen Rapid Test	+	116	11	127
	-	8	390	398
	Total	124	401	525

Positive Percent Agreement: 93.55% (87.68% -97.17%)
 Negative Percent Agreement: 97.26% (95.14% -98.62%)
 Overall Percent Agreement: 96.38% (94.41% -97.81%)

INTERFERING SUBSTANCES

The following endogenous interfering substances did not affect the test performance of Strep A Antigen Rapid Test.

Substance	Concentration with no interference
Whole Blood	4%
Mucin	0.3%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
OTC Throat swab Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
OTC Throat swab Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	1:10 dilution
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	5% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL

LIMITATIONS OF THE PROCEDURE

1. This reagent is only suitable for in vitro diagnostic single use and should not be used for damaged packaging.
2. The test card in the device must be stored in a 15~30°C environment as required until the expiration date, and the expired reagents should not be used.
3. This test only represents the presence of *Group A streptococcus* antigen in the sample and cannot distinguish between dead and viable bacteria.
4. This product cannot distinguish *Group A streptococcus* carriers from acute infected persons. Pharyngitis may be caused by microorganisms other than *Group A streptococcus*.
5. This product is only used for the initial diagnosis of Group A streptococcal infection, and its final confirmation should be made after integrating all clinical and laboratory results.

AVAILABILITY

Product	Cat. No.	Contents
EZER™ Strep A Antigen Rapid Test	P211116	20 tests

REFERENCES

- 1.K. Todar, Online Textbook of Bacteriology; See textbookofbacteriology.net.
2. WalkerMJ, BarnettTC, McArthurJD , et al.Disease manifestations and pathogenic mechanisms of Group A Streptococcus[J] . Clin Microbiol Rev , 2014 , 27(2):264-301.DOI : 10.1128/CMR.00101-13.

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog #

 **CMC Medical Devices & Drugs S.L.**
C/ Horacio Lengo no 18, CP 29006,
Málaga, Spain



Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.

ADD : NO.139, St.10th (East), Hangzhou Economic &
Technological Development Zone. Hangzhou,
Zhejiang Province, China, 310018

TEL : +86-571-87818163

FAX : +86-571-8782-4695

Web : www.genesis-ivd.com

Nasal Swab Manufacturers



Jiangsu HanHeng Medical Technology Co., Ltd. 
16-B4, #1 North Qingyang Road, Tianning District, Changzhou,
213017 Jiangsu P.R. China



Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany



Jiangsu Rongye Technology Co., Ltd. 
Touqiao Town, Yangzhou City 225109 Jiangsu P.R. China



Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain