Group A Streptococcus Assay Kit (Fluorescence Immunochromatography) User Manual

（For Medical Professional Use Only）

1.Product Name

Group A Streptococcus Assay kit (Fluorescence Immunochromatography)

2.Package Specification

20 T/box

3.Intended Use

This kit is used for the in vitro qualitative detection of group A streptococcal antigens in oropharyngeal swab samples.

4.Summary

Group A streptococci can cause a variety of health problems including group A streptococcal infections. Group A streptococcal infections can range from minor skin infections or sore throats to serious life-threatening illnesses such as toxic shock syndrome (multiple organ failure) and necrotizing fasciitis (soft tissue disease), commonly known as flesh-eating bacterial disease. The well-known septic pharyngitis complicated by minor skin infections is the most common form of morbidity. Health experts estimate that more than 10 million people have such minor infections (throat and skin) each year. Traditional methods of identifying group A streptococci from throat swabs include isolation and culture and in vivo identification, which takes 24-48 hours or more

5.Test Principle

The Group A Strep Assay Kit (Fluorescence Immunochromatography) uses a double antibody sandwich fluorescence immunochromatography method. The NC membrane detection line (T line) on the test card is coated with anti-StrepA antibody and the quality control line (C line) is coated with anti-DNP antibody. During the test, StrepA in the sample binds to the fluorescent microsphere-labeled anti-StrepA antibody to form a reaction complex [fluorescent microsphere-(anti-StrepA antibody)-(StrepA)], which moves forward along the nitrocellulose membrane by chromatography and moves to the detection line (T line), where the reaction complex is captured by the detection line-coated anti-StrepA antibody to form the final The reaction complex is captured by the anti-StrepA antibody encapsulated in the detection line, forming the final reaction complex. The fluorescent microspheres emit a fluorescent signal upon excitation with excitation light, and the concentration of StrepA in the sample is positively correlated with the fluorescent signal. The concentration of StrepA in the sample is calculated from the relative fluorescence signal intensity of the sample by a fluorescence immunoassay analyzer.

6.Components

This test kit consist of :

① Individually Packaged Test Cassette

a. One kit device

b. One desiccant

② Reagent A: 0.75mL/bottle　Reagent B: 15mL/bottle

③ ID Card

④ Quick Reference Instructions

7.Materials Required but not Provided

(1)Timer or watch

(2)Fluorescent Immunoanalyzer

(Model type: GTF2600, GTF3000B. Manufactured for International Biomedical Supplies INC.)

8.Storage and Expiration Date

It is stored at 2~30℃, and its validity period is 24 months. After the aluminum foil bag is opened, the test card should be used within 60 minutes. See the product label for the production date and expiration date.

9.Specimen Requirements

1. Use a sterilized swab to collect samples from the tonsils or the posterior wall of the throat, avoiding touching the teeth, gums, tongue and inner surface of the cheeks. The swab should be processed as soon as possible after collection. If culture results need to be obtained, the swab can be used to line the culture plate before performing this test, as the extraction reagents can cause the organism to die.

2. Swabs can be stored at room temperature or 2-4° C for 24 hours. The swab and kit should be brought back to room temperature before testing.

10.Testing Procedures

Open the test bag after the test is ready. It is recommended to conduct a one-time test at low ambient humidity (RH ≤ 70%) within 1 hour. Before the test, the room temperature is required to reach 18 ° C~26 ° C. Remove the test card from the aluminum foil bag and place it on a clean and dry surface.

- Machine operate

1.Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.

2.Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.

3. Put the test card in the card warehouse.

4. Take off the bottle cap, remove 750ul of solution B into solution A, and shake well.

5. Place the swab sample in buffer, roll the swab 3 to 5 times and stand for 2 minutes.

6. Remove the swab, shake the collection tube well, place it on the test tube rack, and test it by machine.

7. Select the sample type on the machine, establish the test task, and give the results after 15 min.

- Manual operate

1.Before the experiment, take out the samples and test reagents to be tested from the storage conditions and balance them to room temperature.

2.Take out the kit ID card and store the kit data in the fluorescence immunoassay analyzer.

3. Remove the detection card from the aluminum foil bag and place it on a horizontal, dry surface.

4. Take off the bottle cap, remove 750ul of solution B into solution A, and shake well.

5. Place the swab sample in buffer, roll the swab 3 to 5 times and stand for 2 minutes.

6. Remove the swab, shake the collection tube well, take 100ul of sample mixture and add it to the reagent card filling hole.

7. React for 15 minutes at room temperature, test by fluorescence immunoassay analyzer, read or print the test results.

*For the operation of the instrument, please strictly refer to the corresponding fluorescence immunoassay analyzer manual.

11.Expected Value

Positive judgment value: ≥$1.9*10^4$CFU/mL

The test results of this reagent are only for reference, and the patient's diagnosis results need to be judged in combination with clinical diagnosis.

12.Interpretation of Test Result

1. Use fluorescent immunoanalyzer to analyze the test card and issue quantitative test results. Professional personnel are responsible for the review and analysis of test results, which are usually considered normal within the reference range and are influenced by age, sex, diet and region.

2. The test results of this reagent are for clinical reference only, and the clinical diagnosis and treatment of patients should be considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.

13.Limitation of Test Method

1. This kit is suitable for testing oropharyngeal swabs. Testing with other samples or solutions, operational errors, and the presence of interfering substances in the sample may lead to incorrect results.

2. The test results of this kit can only be used as an auxiliary reference for clinical diagnosis. If the test results are not consistent with clinical assessment, further examination is required.

14.Warnings and Precautions

For *in Vitro* Diagnostic Use

1. This kit is only for in vitro diagnosis, any form of in vivo use is prohibited, do not use expired products.

2. The kit should be completed as soon as possible after 15 minutes of sample addition, otherwise the accuracy of the test results will be affected.

3. Collected, transported and discarded test specimens, used reagents and other wastes should be disposed of according to medical waste regulations.

4. Each test card is for single use, please do not reuse.

5. The operation should be carried out strictly according to the instructions, and the components of the kit of different batches should not be mixed.

6. This kit is for qualitative detection of group A streptococcal antigen content in oropharyngeal swab samples, and the test results of the reagent must be analyzed in conjunction with the clinical information of the patient.

7. Do not insert the test card whose surface is wet with blood or other liquids into the instrument, otherwise it will contaminate or damage the instrument.

8. Avoid vibration and electromagnetic environment when the test card and the instrument are performing the test. It is normal for the instrument itself to shake during normal use.

15.Reference

1. Dos Santos, Ana Gabriele P., Berezin, Fitan N.; Comparative analysis of clinical and laboratory methods for diagnosing Streptococcal sore throat. J. Pediatr. (Rio J.) 2005; 81 (1): 23-8

2. Borbeau, Paul P. and Heither, Barbara J.; Use of swab without Transport media for the Gen-Probe Group A Strep Direct Test. Journal of Clinical Microbiology, July 2004, p. 3207-3211

3. Petts, D.N.; Evaluation of a modified nitrous acid extraction latex agglutination kit for grouping beta-hemolytic Streptococci and Enterococci. Journal of Clinical Microbiology, Apr. 1995, p.1016-1018.

4. Sheeler, Robert P. et al., Accuracy of Rapid Strep testing in patients who have had recent Streptococcal Pharyngitis. JABFP, July-August 2002, Vol 15 No 4, p. 261-265.