



# Group A streptococcal Antigen Rapid Test Kit

Catalog No.: BG1501C

## NAME AND INTENDED USE

Bioneovan Group A Streptococcal Antigen Rapid Test Kit is an in vitro immunoassay for the qualitative determination of the detection of Group A Streptococcal in human throat swab specimens in one step. It is for diagnosis of early infection and epidemic survey. The kit is intended only for an initial screening test and reactive samples should be confirmed by a supplemental assay such as commercial enzyme immunoassay (ELISA) or RT-PCR.

## SUMMARY

Group A streptococcus (GAS) is the most pathogenic of Streptococcus, widely found in nature, human and animal feces, and in the nasopharynx of healthy people. It is especially acute respiratory infection. It is an important bacterial pathogen of upper respiratory tract infection, which can cause acute pharyngitis and tonsillitis in children and adults. It can also cause serious invasive infections such as necrotizing fasciitis and toxic shock syndrome. GAS is a common pathogen of upper respiratory tract infections, and often occurs in children aged 2 to 13 years. Repeated infections can cause secondary diseases such as rheumatic heart disease, rheumatoid arthritis, and acute glomerulonephritis. At present, relevant clinical and laboratory diagnostic methods include latex coagulation method, enzyme immunofilm method, colloidal gold immunochromatography, real-time fluorescent PCR technology and bacterial culture identification method. Among them, bacterial culture has been the traditional detection method of group A hemolytic streptococcus.

## PRINCIPLES OF THE ASSAY

The kit uses colloidal gold immunochromatography to qualitatively detect group A *S. pyogenes* antigen in throat swab specimens. A rabbit anti-A-type Streptococcus polyclonal antibody labeled with colloidal gold was coated on a gold-labeled mat, and a rabbit anti-A-type Streptococcus polyclonal antibody was coated on the nitrocellulose membrane. In the case of a positive specimen, the Group A Streptococcus antigen in the specimen can be combined with a colloidal gold-labeled rabbit anti-A-type Streptococcus polyclonal antibody to form an immune complex, due to the chromatographic complex and the sample flow forward within the nitrocellulose membrane. When the complex passes through the T line, it binds to the coated rabbit anti-A strain of Streptococcus polyclonal antibody to form an immune complex and agglutinate color. The remaining colloidal gold-labeled rabbit anti-rabbit A strain of Streptococcus polyclonal antibody binds to the C-line coated goat anti-rabbit IgG antibody to agglutinate color; if it is a negative specimen, the specimen does not contain group A beta-streptococcus antigen, which causes the formation of immune complexes, can only be developed at the C line.

## MATERIALS PROVIDED

### 20x1 tests (Cassette) Group A Streptococcal test Cassette

Each cassette contains a test strip with

1. T-line coated rabbit anti-A group B streptococcus polyclonal antibody. In the C line, a goat anti-rabbit IgG antibody was coated, and a buffer solution: 0.05 M PBS pH 7.4): 1 × 20 pieces
2. Extract A (2M sodium nitrite): 1 × 6 ml
3. Extract B (1 M acetic acid): 1 × 6 ml
4. Sample tube for extraction: 1.5ml × 20
5. Instructions: 1 copy

The components in different batches and different varieties of kits may not be mixed.

## SAMPLE COLLECTION AND PRESERVATION

Sample collection swab

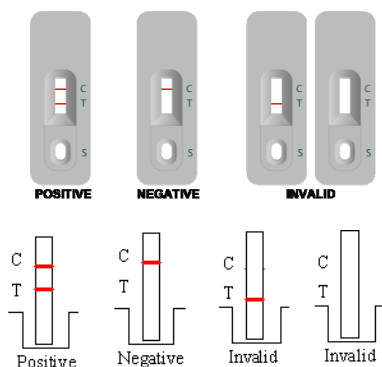
- 1) The main sample of group A Streptococcus is swabs or other parts of the cotton swabs with pathogens. It can also be obtained from the cultured bacterial colonies.
- 2) While sampling, use a cotton swab to gently wipe the tonsil and throat wall to avoid direct contact between the tongue and the swab. The collected samples should be sealed and refrigerated.
- 3) The bacteria to be identified should be pure culture with a bacterial age of no more than 48 hours. The number of colonies to be tested should not be less than 10<sup>5</sup> CFU/ml. The culture medium requires a blood plate medium.

## TEST PROCEDURE

1. Preparation before inspection: The specimens to be tested are taken out from the refrigerated environment and allowed to equilibrate for 30 minutes at room temperature.
2. Add 5 drops (about 250 μl) of extract A and extract B to the tube for extraction. Mix well.
3. Place the cotton swab containing bacteria into the test tube with the extract, let stand for 3 to 5 minutes at room temperature, shake the cotton swab for a few seconds, and repeatedly squeeze and rotate on the tube wall; discard the liquid on the cotton swab and discard it. Throat swabs, tube extracts can be used for testing (tested within 60 minutes).
4. Inspection process: Remove the test card from the foil pouch and place it on a dry horizontal work surface. Add 100 μl of extract finally formed in above Step 3 (about 2 drops, and then add a second drop after infiltration of the first drop) into the well and judge the results within 8 to 10 minutes.
5. Precautions during the inspection process: a. The test kit and the sample to be tested should be placed in a room temperature environment before being tested. b. The observation result is invalid after using the c.10 minutes within 30 minutes after the test card is opened.

## INTERPRETATION OF RESULTS

- Positive** Two pink lines appear in both C and T position  
**Negative** Only one pink line appears in C position  
**Invalid:** The control line next to the test line does not become visible within **10** minutes after the addition of the sample.



## LIMITATION

- The test results of this product are interpreted by human eyes and are subject to visual error or subjective judgment. Therefore, when the color of the strip is difficult to determine clearly, it is recommended to repeat the test.
- This test card is one of the auxiliary means of diagnosis. The test result is for reference only and should not be used as the sole basis for clinical diagnosis and treatment. The positive result should be further confirmed by other methods. The detection result is limited by the sensitivity of the test. The negative result may be due to the low antibody concentration. Due to the sensitivity of product analysis. Clinical diagnosis should be combined with clinical examination, medical history and other tests.
- Group A Streptococcal antigen detection kit (colloidal gold method) can not distinguish between dead and live bacteria. Due to the presence of group A streptococcal antigens, patients who have recently been treated with group A streptococci or similar infections will still have positive results for a period of effective treatment.
- This product does not distinguish between asymptomatic carriers and those with infection.
- Pharyngitis can also be caused by bacteria other than group A streptococci. When the laboratory diagnosis does not match the clinical performance, further diagnosis including bacterial culture is required.

## PRECAUTIONS

- The use of corporate standards for testing meets the following criteria: positive coincidence rate (+/+) = 10/10; negative coincidence rate (-/-) = 10/10; precision (n = 10) results are all positive. The color rendering is uniform; the minimum detection limit of the serial dilution is the internal control standard, and the positive end point should be no less than 1:8 dilution.
- Use this kit to detect samples of group B streptococcus (Strep B), group C streptococcus (Strep C), group D streptococcus (Strep D), and staphylococcus aureus (SA) at a concentration of 10<sup>8</sup> CFU/ml. Negative.
- Positive samples such as Mycoplasma pneumoniae IgM/IgG positive, Chlamydia pneumoniae IgM/IgG positive, and respiratory syncytial virus IgM positive will not be tested on this kit.
- Both plate and sample should be with room temperature 20-25°C











- Failure to detect Group A streptococcus may be a result of factors such as collection of specimen at an improper time in the disease when too few virions are present and improper sampling or handling of the specimen.
- Wrong result might be caused by expired kit or problematic samples.

## STORAGE AND STABILITY

Room Temperature.

## EXPIRATION

The shelf life is 24 months. Do not use the kit beyond its expiration date.

	<i>In vitro</i> diagnostic device		Lot code
	Consult instructions for use		Catalogue number
	Keep dry		Contains sufficient for <n> tests
	Temperature limitation		Manufacturer
	Use by		Do not use if package damaged