



Group A Streptococcus Test Kit



Instructions for use



For in vitro diagnostic use only.



A02167002, A02167F002



20 Tests, 25 Tests

【Product Name】

Group A Streptococcus Test Kit

【Intended Use】

The Anbio Group A Streptococcus Test Kit along with Anbio FIA Meter is a fluorescence immunoassay for qualitative measurement of Group A Streptococcus in human throat swab sample.



For professional use only.

【Summary】

Group A Streptococcus is one of the most common causes of acute upper respiratory tract infection. Group A streptococcus is spread through direct contact with nasal or throat secretions of an infected person or through contact with infected skin sores or drainage from wounds. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious complications.

【Test Principle】

The Anbio Group A Streptococcus Test Kit is based on fluorescence immunoassay technology. The Anbio Group A Streptococcus Test Kit uses a sandwich immuno detection method. When sample is added to the sample well of the test, the fluorescence-labeled detector Group A Streptococcus antibody binds to Group A Streptococcus antigen in the throat swab sample. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and Group A Streptococcus are captured to Group A Streptococcus antibody that has been immobilized on test strip. Thus the more Group A Streptococcus antigen is in the throat swab sample, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of Group A Streptococcus captured and Anbio FIA Meter shows Group A Streptococcus qualitative test results in the throat swab sample.

【Main Components】

The following components are included in the Group A Streptococcus Test Kit:

Supplied Materials:

Specification	20 Tests	25 Tests	Main Ingredients
Component			
Test Cartridge	20	25	1) T line: Rabbit anti-Group A Streptococcus antibody (coated) 2) C line: Goat anti-rabbit IgG polyclonal antibody 3) Binding pad: Fluorescent microsphere-labeled rabbit anti-Group A Streptococcus antibody (labeled) and fluorescent microsphere-labeled rabbit IgG polyclonal antibody
IC Card	1	1	/
Swab	20	25	/
Sample Diluent A	20	25	10mmol/L, NaNO ₂
Sample Diluent B	20	25	10mmol/L, CH ₃ COOH
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Materials required but not provided:

1. Timer
2. Anbio FIA Meter (model number: AF-100, AF-100s, AF-100C, AF-1200)

【Storage Conditions and Shelf Life】

Component	Storage- Temperature Limitation	Stability
Test Cartridge		The shelf life is up to 24 months. Please refer to use-by date on the label. Test Cartridge should be used within 1 hour after opening the pack.
IC Card		/
Swab		/
Sample Diluent A Sample Diluent B		The diluent is stable up to 24 months. Please refer to use-by date on the label.



【Warnings and Precautions】

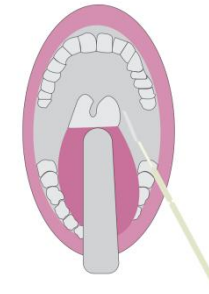
1. This kit is for in vitro diagnostic use only.
2. Do not mix components from different kit lots.
3. Do not use test kit beyond the expiration date.
4. Do not use Test Cartridge if its lot # does not match with IC Card # that is inserted onto the equipment.
5. The Anbio Group A Streptococcus Test Kit is only operational in the Anbio FIA Meter.
6. Do not use the Test Cartridge if the pouch is punctured or not well sealed.
7. The Test Cartridge and Meter should be used away from vibration and magnetic field. During normal usage, the Meter itself may cause vibration, which should be regarded as normal.
8. Use separate clean swab and detector diluent tubes for different samples.
9. Sample, used Test Cartridges and detector diluent tubes should be handled and disposed in accordance with standard procedures and relevant regulations of microbiological hazard materials.
10. The results should be interpreted by the physician along with clinical findings and other laboratory test results.

【Sample Collection and Preparation】

The test can be performed with human throat swab sample.

For Throat Swab Sample:

1. To collect samples, insert a sterile swab into the throat trying not to touch tongue, oral cavity and teeth. Let the swab touch the faucal or tonsil with inflammation and gently rotate it to collect sufficient amount of sample.



2. Test should be performed immediately after the sample have been collected. Do not leave the sample at room temperature for prolonged periods. Samples may be stored at 2°C ~8°C for up to 3 days. For long-term storage, samples should be kept below -20°C.

【Test Procedure】

Refer to Anbio FIA Meter Operation Manual (attached to Anbio FIA Meter) for the complete instructions on use of the Test. The test should be operated in room temperature.

Step1: Preparation

Check/ Swipe the IC Card information to the equipment.

Open sample diluent A purple cap, Add 4 drops of extraction sample diluent B into the extraction sample diluent A.

Step2: Sampling

Put the Throat swab into extraction buffer tube, and the incubate for about 1 minute to extract the sample from the swab.

Step3: Mixing

Swirl the swab at least 10 times while pressing the head against the bottom and side of the tube.

Clamp the throat swab tip and pull out the swab.

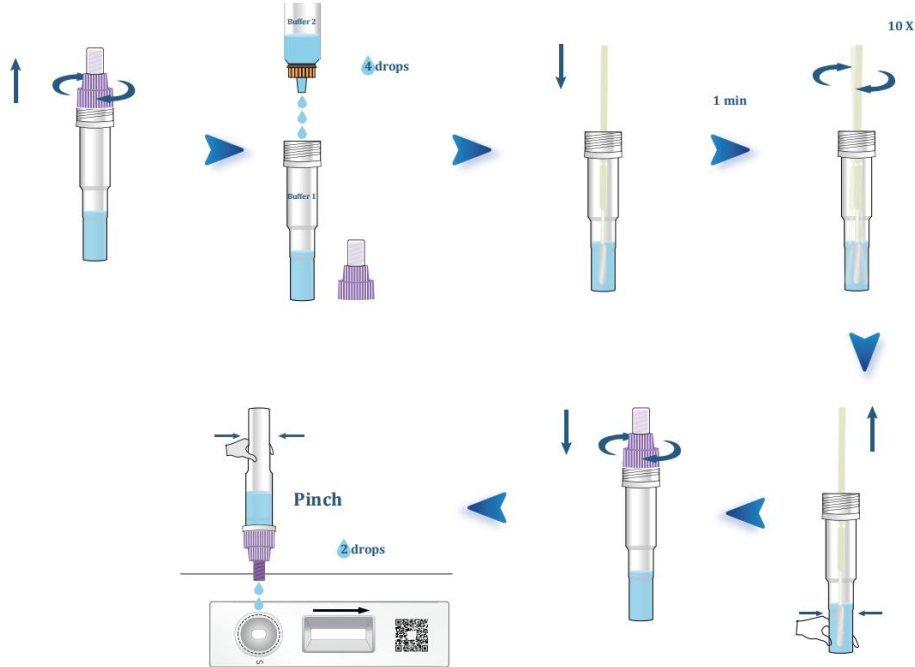
Step4: Loading

Screw on the purple cap, open the white cap and add two drops of the mixed sample into the sample well of the Test Cartridge.

Step5: Testing

Timing test: Insert the Test Cartridge onto the Test Cartridge Holder and click "Timing Test". 5 minutes later, the result will show in the display and print out when click "Print".

Quick test: Put the Test Cartridge on the operation platform. 5 minutes later, insert the Test Cartridge onto the Test Cartridge Holder and click "Quick Test". The result will show in the display and print out when click "Print".



【Limitations of Procedure】

1. This test has been developed for testing human throat swab sample.
2. The results of Anbio Group A Streptococcus Test Kit should be evaluated with all clinical and laboratory data available. If Group A Streptococcus test results do not agree with the clinical evaluation, additional tests should be performed.
3. Incorrect results can be caused by interference from some similar substance in the sample .
4. Other factors may interfere with Anbio Group A Streptococcus Test Kit and may cause erroneous results. These include technical or procedural errors, as well as additional substances in the throat swab sample.

【Quality Control】

Internal procedural controls are included in the test. When testing, the quality control line (C line) will show a certain luminescence intensity, which is an internal procedural control. It confirms that a sufficient volume of samples has been added and that the correct procedure has been performed.

【Interpretation of Results】

The Anbio FIA Meter automatically displays the test results

1. The reference value

Cut-off: 100 (RLU)

Measured value ≥ 100, Positive, Group A Streptococcus is detected in sample tested;

Measured value < 100, Negative, Group A Streptococcus is not detected or the concentration of Group A Streptococcus in sample been tested is lower than detection limit.

Note: Individual reference range is suggested to be established for each laboratory.

【Performance Characteristics】

1. Sensitivity and Specificity

The clinical performance of Group A Streptococcus Test Kit was evaluated in comparison to a reference test.

For Throat swabs:

The results show that, the clinical sensitivity of the Group A Streptococcus Test Kit is 98.47% and the clinical specificity is 98.68%.

Group A Streptococcus Test Kit	Reference test result		
	Positive	Negative	Total
Positive	193(a)	4(b)	197(a+b)
Negative	3(c)	300(d)	305(c+d)
Total	196(a+c)	304(b+d)	500(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.47%	95.59%~99.68%	
Clinical specificity	98.68%	96.67%~99.64%	
Total coincidence rate	98.60%	97.14%~99.44%	

2. Limitation of Detection (LoD)

The LoD of Group A Streptococcus Test Kit is 4×10^3 cfu/test.

3. Cross-reactivity

Group A Streptococcus Test Kit does not cross with the following common Potential Cross-Reactants.

S.N.	Potential cross-reactant	Concentration	S.N.	Potential cross-reactant	Concentration
1	Escherichia coli	1.9×10^6 cfu/test	9	Coxsackievirus A2	8.0×10^5 TCID ₅₀ /test
2	Haemophilus influenzae	1.0×10^7 cfu/test	10	Coxsackievirus A3	1.0×10^6 TCID ₅₀ /test
3	Klebsiella pneumoniae	1.0×10^7 cfu/test	11	Influenza A H1N1	1.8×10^4 TCID ₅₀ /test
4	Pseudomonas aeruginosa	1.4×10^6 cfu/test	12	Parainfluenza virus 1	1.0×10^4 TCID ₅₀ /test
5	Serratia marcescens	1.8×10^7 cfu/test	13	Parainfluenza virus 2	1.0×10^4 TCID ₅₀ /test
6	Staphylococcus aureus	2.0×10^6 cfu/test	14	Adenovirus Type 1	2.0×10^{10} TCID ₅₀ /test
7	Staphylococcus	1.4×10^6 cfu/test	15	Adenovirus Type 3	1.0×10^5 TCID ₅₀ /test
8	Streptococcus pneumoniae	1.0×10^6 cfu/test	16	Adenovirus Type 5	1.7×10^5 TCID ₅₀ /test

4. Interfering substances

















The following common potential interfering substances with the concentrations have no effect on the test results.

S.N.	Substances	Concentration	S.N.	Substances	Concentration
1	Nasal sprays drops	20%	8	Acetaminophen	10mg/ml
2	Nasal corticosteroids	20%	9	Ibuprofen	10mg/ml
3	Listerine cool mint	20%	10	Acetamidophenol	5mg/mL
4	Listerine natural green tea	25%	11	Halls honey lemon	20%
5	Ibuprofen	5mg/mL	12	Halls mentholiptus	20%
6	Acetylsalicylic acid	20mg/mL	13	Povidone-iodine	3.50%
7	Whole blood	10%	14	Throat candy (Lysozyme)	20mg/ml

【Bibliography of Suggested Reading】


1. Lauer, B.A., Reller, L.B., and Mirrett, S., Effect of Atmosphere and Duration of Incubation on Primary Isolat Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group
2. A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
3. ion of Group A Streptococci from Throat Cultures, J. Clin. Microb., 17: 338-340, 1983.
3. Chapin KC, Blake P, Wilson CD. Performance characteristics and utilization of rapid antigen test, DNA probe, and culture for detection of a streptococci in an acute care clinic. J Clin Microbiol. 2002;40(11):4207-4210.

【Index of Symbols】

	In vitro diagnostic medical device		Do not re-use
	Authorized representative in the European Community/ European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

For technical assistance, please contact:
 Anbio (Xiamen) Biotechnology Co.,Ltd.
 Tel: +86-592-6312399, Email: info@anbio.com

【Basic Information】

 Anbio (Xiamen) Biotechnology Co.,Ltd.
 Add: No.2016, Wengjiao West Road, Xinyang Street, Haicang District, 361026, Xiamen, Fujian,China.
 Tel: +86-592-6312399, Email: info@anbio.com

 Riomavix S.L.
 Add: Calle de Almansa 55,1D 28039-Madrid Spain.
 Email:leis@riomavix.com

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