TROD'ANGINE

Rapid Diagnostic Referral Test
for the screening of group A strep throat

Ref: TR-ANG-002, TR-ANG-008

Instructions for use

USAGE

The TROD'ANGINE test is a rapid immunochromatographic test designed for the qualitative detection of streptococcal A antigen on oropharyngeal specimens to aid in the diagnosis of group A streptococcal infections.

INTRODUCTION

Streptococcus A is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of streptococcal A pharyngitis can reduce the severity of symptoms and the risk of additional complications, such as rheumatic fever or glomerulonephritis. The TROD'ANGINE test detects viable or non-viable organisms directly from an oropharyngeal swab and provides a result within 5 minutes.

PRINCIPLE

The TROD'ANGINE assay is an immunochromatographic assay in which antibodies specific to the carbohydrate antigen of streptococci A are attached to a nitrocellulose membrane. The pharyngeal swab undergoes chemical treatment to extract streptococcal A specific carbohydrate antigen, if present. The extract migrates over the membrane and if the specific antigen of streptococcus A is present in the sample, it forms a complex with the colored particles associated with the anti-streptococcal A antibodies. The resulting complex then binds to the anti-streptococcus A capture antibodies and reveals a coloured band indicating that the test is positive.

WHAT'S IN THE BOX

- 25 hermetically sealed pouches, each containing a strip and a moisture absorber,
- 25 sterile swabs (applicators),
- 25 extraction tubes,
- 25 tongue depressors,
- 1 reagent A (sodium nitrite 2 M): 10 mL,
- 1 reagent B (0.2M acetic acid): 10 mL,
- 1 tube holder,
- 1 instruction manual.

MATERIALS REQUIRED BUT NOT PROVIDED

A timer or watch.

WARNINGS AND PRECAUTIONS

For professional use in In Vitro Diagnostics. Do not use after expiration date.
Do not eat, drink or smoke in the area where the sample is taken and the test is performed.
Follow current safety guidelines for the collection, handling, storage, and disposal of patient specimens and all components that have been in contact with these specimens.
Wear appropriate clothing, disposable gloves, and eye protection during procedures.
Poor humidity and temperature conditions can affect the results.
Do not use if protective pouches are damaged.
Reagent A contains sodium nitrite which needs to be handled with care. If swallowed, rinse your mouth thoroughly and call a poison control center or doctor immediately.
Reagent B contains an acidic solution, if in contact with skin or eyes, wash thoroughly under running water.
Do not exchange or mix items from different batches.

CONSERVATION AND STABILITY

Store properly closed reagents between 2°C and 30°C. **Do not freeze**.
Keep strips in airtight packaging until ready to use.
Reagents A and B are stable after opening until the expiry date indicated on the kit.

SAMPLE COLLECTION AND PREPARATION

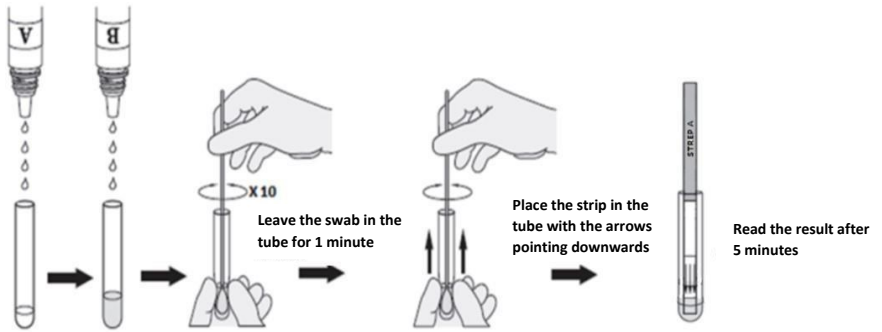
Use only the components contained in the enclosure. Wait until all components are at room temperature.

1. Collect samples using the sterile swab from the tonsils and/or the inflamed part of the throat using the tongue depressor to avoid the surface of the teeth, gums, tongue or cheeks.
2. Process the swab immediately after collection. If the test is not performed immediately, store the swabs in a clean, dry plastic tube for up to 8 hours at room temperature or for 72 hours at 2-8°C.

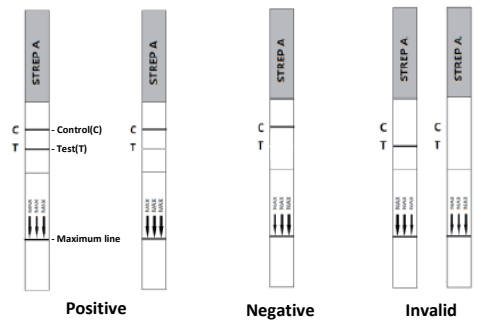
TEST PROCEDURE

Wait until all reagents are at room temperature.

1. Hold the A (pink) reagent vial vertically and place **4** drops in an extraction tube. Add **4** drops of reagent B to the tube. Mix, gently twisting the tube. The solution should turn pale yellow.
2. Immediately dip the swab into the tube. Swivel the swab 10 times in the tube. Let the swab rest in the tube for 1 minute. Then press the swab against the sides of the tube and discard the swab.
3. Remove the strip from the airtight bag.
4. Dip the strip, with the arrows pointing downwards, into the extraction tube. Then start the timer. Do not handle or move the strip until the test is complete and ready to be read.
5. Wait for the colored line(s) to appear. Read the result in 5 minutes. Do not read after 10 minutes.



INTERPRETATION OF RESULTS



Positive : Two colored lines appear. One should be in the Control (C) row region and the other colored line should be in the Test (T) row region.
Negative: A line appears in the region of the Control line (C). No line in the region of the Test line (T).
Invalid: The Control line does not appear.

Note: Insufficient sample volume, incorrect execution of the procedure, or use of expired reagents are the most common causes of no control strip.

QUALITY CONTROL

Internal Quality Control:
Control Line (C) is a positive internal procedural control. It confirms that a sufficient volume of sample has been used, that the nitrocellulose membrane on which the sample was migrated is not damaged, and that the test procedure has been properly followed.

BOUNDS

TROD'ANGINE is intended for in vitro diagnostic use only. The test is intended for the detection of streptococcal A antigen on throat swabs. No quantitative notion or concentration of streptococcal antigen can be obtained with this test, which is only qualitative.
TROD'ANGINE indicates the presence of streptococcal antigens from live or dead bacteria.
The sterile swabs provided with this test should be used for the collection of oropharyngeal specimens. The test has not been validated with other swabs.
Excess blood or mucus can interfere and give false positives, hence the importance of using tongue depressors so as not to touch the tongue, teeth, the inside of the cheeks or any area with blood present during the collection. As with any diagnostic test, the results should be interpreted in conjunction with other available clinical information.

PERFORMANCE

TROD'ANGINE was evaluated with specimens obtained from patients with culture-confirmed symptoms of streptococcal A pharyngitis and from asymptomatic patients (without pharyngitis symptoms) tested by a reference streptococcal A screening test.

The results obtained show that the TROD'ANGINE test has a high degree of reliability:

Table 1: TROD'ANGINE versus Culture

	Culture		Total
	+	-	
TROD'ANGINA +	60	0	60
TROD'ANGINA -	5	0	5
Total	65	0	65

Relative Sensitivity：92.3% (82.2%-97.1%)* *95% (CI)

Table 2: TROD'ANGINE versus Reference Test

	Benchmark test		Total
	+	-	
TROD'ANGINA +	0	4	4
TROD'ANGINA -	0	108	108
Total	0	112	112

Relative specificity：96.4% (90.6%-98.8%)* *95 % (CI)

The detection limit of the test is approximately 2.5x105 bacteria/test.

Cross-reactivity
During the analysis with TROD'ANGINE, the tests performed with the organisms mentioned below, concentrated at approximately 107 organisms/test, were all negative.

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

Studies in doctors' surgeries
Studies were conducted in 3 doctors' offices. The people who took the tests had different levels of education. Each site tested a panel of 20 negatives, 20 weak positives, and 20 medium positives. The results obtained showed a 96% correlation with the expected results.

BIBLIOGRAPHY

- Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C. pp. 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.
- Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
- Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
- Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
- 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.

SYMBOL LEGEND

	Read the user manual		Number of tests per kit		Manufacturer
IVD	For in vitro *diagnostic use* only		Expiry date		Do not reuse
	Store between 2 and 30°C	LOT	Batch number	REF	Reference
CE	CE marking		Careful		

AAZ-LMB
43 rue de Bellevue
92100 Boulogne-Billancourt – France