TROD'ANGINE® +

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

Ref: TR-ANG-009

Instructions for use

USAGE

TROD'ANGINE® + 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.

TEST PRINCIPLE

TROD'ANGINE® + is an immunochromatographic assay in which antibodies specific to streptococcus A carbohydrate antigen 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.

EQUIPMENT PROVIDED

- 25 sealed pouches, each containing a strip and a moisture absorber
- 25 sterile (oropharyngeal) swabs
- 25 pre-filled tubes of reagent A (2M sodium nitrite): 250µl
- 25 single doses of reagent B (0.2M acetic acid): 150µl
- 25 Tongue depressors
- 1 cardboard stand
- 1 instruction manual

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

STORAGE & STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). Do not freeze kit components. The kit is stable until the expiry date indicated on the kit. The strip must remain in the sealed pouch until it is used.

WARNINGS AND PRECAUTIONS

- For professional use in Vitro Diagnostics.
- Do not use the kit after the expiry date
- Do not eat, drink or smoke in the area where the sample is taken and the test is performed.
- Wear appropriate clothing, disposable gloves, and eye protection during procedures.
- Do not use if sealed pouch or single dose reagent is damaged
- The single-dose reagent contains sodium nitrite and an acidic solution that needs to be handled with care. If contact occurs with skin or eyes, wash thoroughly under running water. If swallowed, rinse your mouth thoroughly and call a poison control center or doctor immediately.
- Do not exchange or mix items from different batches.
- Humidity and temperature can affect results.
- The equipment used must be disposed of in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

Use only the components contained in the kit. 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.

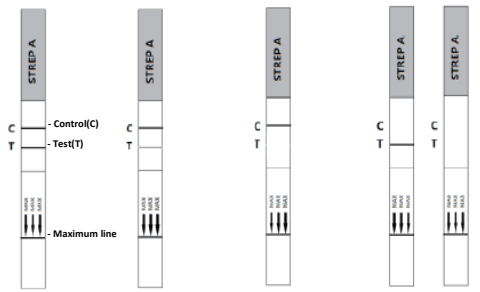
TEST PROCEDURE

Ensure that the sample and kit components are at room temperature (15-30°C) before testing. Remove the strip from the sealed pouch just before performing the test.

1. Carefully remove the seal from the tube pre-filled with reagent A to prevent liquid splashes.
2. Insert the pre-filled tube of reagent A into the cardboard holder provided and make sure it is stable.
3. Take a single dose of reagent B, open it and pour its entire contents into the pre-filled tube of reagent A.
4. Take the pre-filled tube and knead it gently between two fingers, making slight rotations to mix reagents A and B.
5. Immediately dip the swab into the tube. Rotate the swab 10 times in the single dose. Let the swab rest for 1 minute in the single dose. Then press the swab against the walls of the single dose and discard the swab.
6. Remove the strip from the sealed bag.
7. Dip the strip, with the arrows pointing downwards, into the single dose of reagent and start the timer. Do not handle or move the strip until the test is complete and ready to be read.
8. Wait for the colored line(s) to appear. Read the result in 5 minutes. Do not read after 10 minutes.

(see the procedure illustrated inside the box)

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 the test execution procedure has been followed correctly.

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

Clinical Performance

TROD'ANGINE® + was evaluated on 368 oropharyngeal specimens from patients with pharyngitis symptoms in 3 medical centers.
Of the 368 samples, 162 were confirmed negative and 206 were confirmed positive by culture.
The sensitivity and specificity results obtained are summarized in the table below:

TROD'ANGINE®+ performance compared to culture

Method		Culture		Total
		Positive	Negative	
TROD'ANGINE® +	Positive	200	1	201
	Negative	6	161	167
Total		206	162	368

Relative Sensitivity:97.1% (93.7%-98.8%)*
Relative Specificity:99.4% (96.2%-100.0%)*
*95% CI

Limit of Detection (LOD)
The detection limit of the test is 2.5x105 bacteria/test.

Interference
The substances listed below have been tested at different concentrations: blood, triglycerides, mouthwashes (of different brands).
The results showed no interference.

Precision
Intra-batch: 4 samples (one negative, one weak positive, one medium positive and one strong positive) were tested 10 times each, on 3 different batches. The results were all correct.
Inter-batch: 4 samples (one negative, one weak positive, one medium positive and one strong positive) were tested 5 times, at different times of the day, on 3 different batches. The results were all correct.

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.
No mucoid-producing strains were tested.

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

BIBLIOGRAPHY

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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		

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