NOTICE D'UTILISATION

STREPTOP A

Ref: 5443

INSTRUCTIONS FOR USE

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Liste des Symboles

	Attention, voir notice d'utilisation		Tests par coffret		Fabricant
	Pour diagnostic in vitro uniquement		Péremption		Usage unique
	Conserver entre 2-30°C		No. de lot	REF	Code produit

Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number	REF	Catalog #

Directive 98/79/CE

Version 9 – Mise à jour le 21/06/2007

Fabriquant /
Manufacturer

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Streptop A® CE

The Streptop A test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen in throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

Réf. : 5443
For professional in vitro diagnostic use only.

1- INTRODUCTION

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3] Rapid diagnosis and early antibiotic therapy of Group A Streptococcal infection appear to be the best means of preventing medical complications and reducing the spread of the disease.[4] The Streptop A test (Throat Swab) is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

2- PRINCIPLE

The Streptop A test (Throat Swab) is a qualitative, lateral flow immunoassay for the detection of Strep A antigen in a throat swab. In this test, antibody specific to Strep A antigen is coated on the test line region of the strip. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a red line in the test region. The presence of this red line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a red line will always appear in the control region if the test has been performed properly. If a red control line does not appear, the test result is not valid. The test strip contains an antibody against Strep A antigen that is coated onto particles and another antibody against Strep A antigen that is immobilized onto the membrane.

3- MATERIAL PROVIDED

- Test strips
- Disposable extraction test tubes
- Swabs
- Reagent A (2M Sodium Nitrite)
- Reagent B (0.4M Acetic Acid)
- Inactivated positive control (Strep A: $1X10^9$ bacteria/mL), 1ml
- Inactivated negative control (Strep C) , 1ml
- Procedure card
- Package insert

4- MATERIAL NON PROVIDED

- Timer
- Tongue depressor

5- STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

6- PROCEDURE

- Only use reagents and sterile swabs provided in the kit.
- Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5]
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for more than one hour. Specimens may be stored at 2-8°C for up to 24 hours.

Allow the test strip, throat swab specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test strip from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Hold the Reagent A bottle vertically and add 4 full drops (approximately 240 µL) to an extraction test tube. Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops (approximately 160 µL) of Reagent B. Reagent B is colorless. Mix the solution by gently swirling the extraction test tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
3. Immediately add the throat swab into the extraction test tube of yellow solution. Agitate the swab by rotating it at least 10 times. Leave the swab in the extraction test tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the tube and squeezing the tube as the swab is withdrawn. Discard the swab.
4. With arrows pointing toward the specimen, immerse the test strip vertically into the extracted specimen solution and then start the timer.

If the procedure is followed correctly, the extraction solution should not pass the maximum line (MAX) on the test strip when the strip is immersed. See the illustration below.

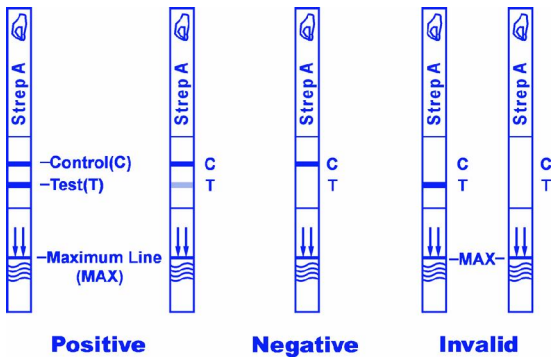
5. Leave the strip in the extraction tube and wait for the red line(s) to appear. Read the result at 5 minutes.

7- RESULTS

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
* NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of Strep A antigen present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Note: Very low concentrations of Strep A antigen might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

8- QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region © is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background that provides a distinct result functions as an internal negative procedural control.

Control standards are supplied with this kit; it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

1. Add 4 drops of reagents A and 4 drops of reagents B in a tube of extraction. Mix by light agitation.
2. Deposit a drop of positive control or negative control in the tube.
3. Mix by light agitation and immerse the strip in the tube. Leave the strip in the tube. Read the result at the end of 5 minutes

9- PRECAUTIONS

Regarding the potential risks of false handling with the A and B buffer in our Streptop A kit we add a safety data sheet (MSDS) to this instruction for use. Please read this MSDS before the first handling and keep this instruction for use in order to facilitate the first-aid organizations action. Cork the bottle of extraction after use and do not to leave the bottle within reach of the patient.

- For professional in vitro diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- Humidity and temperature can adversely affect results.
- Do not interchange reagent bottle caps.

10- LIMITATIONS

1. The Streptop A test (Throat Swab) is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
3. A negative result obtained from this kit must be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or below the detectable limit of the test.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.

11- EXPECTED VALUES

10 à 20% des angines de l'adulte et 20 à 40% des angines de l'enfant sont dues à des streptocoques bêta hémolytiques du groupe A. L'infection prévaut surtout en hiver et au début du printemps principalement au niveau des zones à forte concentration urbaine.
The Streptop A test (Throat Swab) has been compared with traditional culture method. The correlation between these two systems is 95%.

12- PERFORMANCE CHARACTERISTICS

A total of 525 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, and then tested by the Streptop A test (Throat Swab). The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO_2 and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were subcultured and confirmed with a commercially available latex agglutination testing kit.

	STREPTOP® A POSITIF	STREPTOP® A NEGATIF	TOTAL
CULTURE POSITIVE	120	4	124
CULTURE NEGATIVE	20	355	375
TOTAL	140	359	499

Sensitivity: 96.8% (91% à 99%)*
Specificity: 94.7% (92% à 97%) *
Accuracy: 95.2% (93% à 97%)*

Positive Predictive Value (PPV): 85.7% (79% à 91%)*
Negative Predictive Value (NPV): 98.9% (97% à 100%)*
*95% of Confidence Interval.

Sensitivity
Of the 124 found to be positive by culture, 120 were tested positive by the Streptop A test (Throat Swab), yielding a sensitivity of 96.8%.

Specificity
Of the 375 found to be negative by culture, 355 were tested negative by the Streptop A test (Throat Swab), yielding a specificity of 95.1%. The overall accuracy of the Streptop A test (Throat Swab) is 94.7%.

Precision

1. **Intra-Assay**

Within-run precision has been determined by using 15 replicates of three specimens: a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified >99% of the time.

2. **Inter-Assay**

Between-run precision has been determined by 15 independent assays on the same three specimens: a negative, a low positive and a high positive. Three different lots of the Streptop A test (Throat Swab) has been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time.

Cross Reactivity
The following organisms were tested at 1.0 x 10^7 organisms per test and were all found to be negative when tested with the Streptop A Rapid Test Strip (Throat Swab).

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

13- BIBLIOGRAPHY

1. Manual of Clinical Microbiology, 6th Edition, ASM Press, p. 299-307.
2. Webb, KH. Pediatrics (Feb 1998), 101:2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Clinical Infectious Diseases (1997), 25, 574-83.
4. Needham CA, McPherson KA, Webb KH. Journal of Clnical Microbiology (Dec 1998), 3468-3473.
5. Shea, Y.R., Specimen Collection and Transport, in Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington, D.C., 1.1.1-1.1.30, 1992.

Fiche de Sécurité : Acide Acétique Page 1/2

Version 1 – Mai 2007

*Identification:***Acide Acétique**
Acide Acétique glacial ; Acide éthanoïque $C_2H_4O_2$ /CH_3COOH
N° ICSC : 0363 ; N° CAS : 64-19-7 ; N° ONU : 2789 ; N°CE : 607-002-00-6

Utilisations :

- **Produit entrant dans la composition de la solution permettant l'extraction de l'antigène spécifique des streptocoques du groupe A dans le cadre de la réalisation du test de diagnostic rapide de l'angine (Réactif B)**
- Fabrication de nombreux solvants
- Fabrication de l'anhydride acétique, de matières plastiques, d'acétates métalliques
- Opérations de teinture et d'impression en industrie textile
- Tannerie, parfumerie, photographie, imprimerie…

Identification de la société assurant la mise sur le marché :
ALL.DIAG 10 rue Ettore Bugatti 67201 Eckbolsheim - Tel : 03 88 78 80 88 Fax: 03 88 78 76 78
E-mail: info@alldiag.com – Hot Line Tel: + 33 (03) 88 77 57 27

*Classification :*C, R10, R35, S23, S25, S45
Identification des dangers/Risques et Symptômes/Prévention/Premiers Secours

Dangers	*Risques*	*Prévention*	*Premiers secours*
Incendie	Inflammable	Pas de Flamme ni étincelle. Défense de fumer	Poudre, mousse résistante aux alcools, eau pulvérisée, dioxyde de carbone.
Explosion	Si T°>39°c risque de formation de vapeurs explosives	Si T°>39°c en vase clos, ventiler et protéger les appareils électriques des risques d'explosions	En cas d'incendie maintenir les contenants à basse température en les arrosant d'eau.

Contact	*Symptomes*	*Prévention*	*Premiers secours*
Inhalation	Maux de gorge, Toux, Sensation de brulures, Maux de têtes, vertiges, essoufflements, respiration difficile.	Ventilation, aspiration locale ou protection respiratoire.	Air frais, repos, position semi assise, consulter un médecin.
Peau	Douleur, Rougeur, ampoules, Brulures cutanées	Gants de protection, Vêtements de protection	Retirer les vêtements contaminés, rincer et laver la peau abondamment à l'eau savonneuse, consulter un médecin.
Yeux	Douleur, Rougeur, Brulures profondes graves, perte de la vue.	Ecran facial ou protection oculaire associée à une protection respiratoire.	Rincer abondamment à l'eau pendant plusieurs minutes, retirer les lentilles de contact, consulter un médecin.
Ingestion	Douleurs abdominales, sensations de brulures, diarrhée, choc ou collapsus, maux de gorge, vomissements.	Ne pas manger, ne pas boire ni fumer durant la manipulation.	Rincer la bouche, ne pas faire vomir, donner abondamment à boire, consulter un médecin.

Déversements & Fuites	*Stockage*	*Conditionnement, Etiquetage, Transport*
Recueillir le liquide répandu dans un récipient hermétique. Neutraliser le liquide répandu avec du carbonate de sodium. Laver abondamment à l'eau les résidus.	A l'épreuve du feu. Séparer des aliments et des produits alimentaires. Stocker dans un local bien ventilé.	Ne pas transporter avec des aliments ni des produits alimentaires. Note :B Symbole :C R : 10-35 S : 23-26-45 Classe de danger ONU :8 Classe de danger subsidiaire ONU :3 Classe d'emballage ONU :II 

Physico-chemical Properties / Stability and Reactivity / Toxicology / Ecological Data

- **Appearance**: Colourless liquid, pungent odour
- **Physical dangers**:
- **Chemical dangers:** Weak acid, reacts violently with oxidants and bases.
  Attacks a large number of metals by forming hydrogen,
  Flammable/explosive gas
  Attacks certain types of plastic, rubber and surface coatings.
- **Occupational exposure limits (LEP)**: TLV (TWA): 10 ppm; 25mg/m^3 ,as
  STEL: 15 ppm; 37 mg/m^3
- **Routes of exposure:** May be absorbed by inhaling vapour or by ingestion.
- **Inhalation risk:** Hazardous contamination of air rapidly reached on evaporation at 20 °C.
- **Short-term exposure:** Substance and vapour are corrosive to eyes, skin, respiratory tracts and by ingestion. Inhalation of vapour may cause lung oedema. Effects may be delayed. Medical observation is recommended.
- **Long-term or repeated exposure: S**kin: may cause dermatitis
  Gastrointestinal tract: pyrosis, constipation …
- **Physical properties:**

Boiling point: 118 °C
Melting point: 16.7 °C
Relative density (water=1): 1.05
Solubility in water: soluble
Vapour pressure at 20 °C: 1.5 kPa
Relative vapour density (air=1): 2.1
Relative density of the vapour/air mixture at 20 °C (air=1): 1.02
Flash point: 39 °C
Auto-ignition temperature: 427 °C
Explosive limits, vol % in air: 5.4-16
Octanol/water partition coefficient as log Pow: -0.31

- **Environmental data**: Substance is toxic to aquatic organisms

Material Safety Data Sheet: SODIUM NITRITE Page 1/2

Version 1 – May 2007

Identification: **SODIUM NITRITE**
NaNO2
No. ICSC: 1120; No. CAS: 7632-00-0; No. UN: 1500; No. EC: 231-555-9

Uses:

- **Product is an ingredient in the solution for extracting specific streptococcal antigen in Group A as part of the rapid diagnostic test for angina (Reagent A)**
- Manufacture of azo dyes and nitro compounds…
- Bleaching of natural fibres
- Rubber vulcanisation
- Preservation, dying and smoking of meats and fish
- Corrosion inhibitor and compound in heat treatment baths for metals

Name of company:
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Classification: R8, R25, R50, S45, S61

Hazards Identification/Risks & Symptoms/Prevention/Emergency Aid

HAZARDS	RISKS	PREVENTION	FIRST AID
Fire	Not combustible but facilitates combustion of other substances. Several reactions may cause fire or explosion. Gives off irritating or toxic fumes (or gases)	No contact with combustible substances	In case of fire in the surrounding area: use appropriate extinguishing devices.
Explosion			

CONTACT	SYMPTOMS	PREVENTION	FIRST AID
Inhalation	Blue lips or fingernails, blue skin, confusion, convulsions, dizziness, headaches, nausea, unconsciousness	Prevent dispersion of dust! Local exhaust or breathing protection	Fresh air, rest, artificial respiration if necessary, seek medical attention
Skin		Protective gloves,	First rinse thoroughly with water, then remove contaminated clothing and rinse again
Eyes	Redness, pain	Safety goggles	First rinse thoroughly with water for several minutes, (remove contact lenses if possible), seek medical attention
Ingestion	Rapid pulse. (See Inhalation)	Do not eat, drink or smoke during work. Wash hands before eating.	Induce vomiting (**only in conscious persons**), give large quantities of water, seek medical attention

SPILLAGE DISPOSAL	HANDLING & STORAGE	PACKAGING, LABELLING & TRANSPORT
Sweep up spilled substance and collect in containers. Carefully collect residue, then remove to safe place. Do NOT let this chemical enter the environment. Use personal protection equipment: P3 filter respirator (for toxic particles)	Keep away from combustible and reducing agents, and acids. Keep dry. Close securely.	Symbol: O Symbol: T Symbol: N R: 8-25-50 S: ½-45-61 UN Hazard Class: 5.1 UN Subsidiary Risks: 6.1 UN Packaging Group: III 

Physico-chemical Properties / Stability and Reactivity / Toxicology / Ecological Data

- **Appearance**: Hygroscopic white to yellow solid in various forms, odourless, salty taste
- **Physical dangers**:
- **Chemical dangers:** May explode on heating above 530°C.
  The substance decomposes on contact with acids, producing toxic fumes including nitrogen oxides.
  The substance is a strong oxidant and reacts with combustible and reducing agents causing fire and explosion hazards. The solution in water is a weak base, which reacts with aluminium, aluminium ammonium compounds and amines
- **Occupational exposure limits (LEP)**: TLV not established
- **Routes of exposure:** May be absorbed by inhaling vapour or by ingestion.
- **Inhalation risk:** Evaporation at 20 ºC is negligible; a hazardous concentration of airborne particles can, however, be reached rapidly.
- **Short-term exposure:** The substance is irritating to the eyes. The substance may affect the cardiovascular and blood system, resulting in lower blood pressure and the formation of methaemoglobin. Exposure may result in death. The effects may be delayed. Medical observation is recommended.
- **Long-term or repeated exposure:**

- **Physical properties:**
  - Decomposes below boiling point: 320 ºC
  - Melting point (decomposition): 280 ºC
  - Density: 2.2 g/cm3
  - Molar mass: 69
  - Solubility in water at 20 ºC: 82g/100 ml
  - Octanol/water partition coefficient as log Pow: -3.7

- **Environmental data**: Substance is toxic to aquatic organisms