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PROFESSIONAL MEDICAL PRODUCTS

CARD PER TEST STREP A RAPID TEST (TAMPONE FARINGEO)
STREP A RAPID TEST DEVICE (THROAT SWAB)
CASSETTE TEST RAPIDE STREP A (PRÉLÈVEMENT DE GORGE)
STREP A SCHNELLTEST-KASSETTE (HALS-/RACHENABSTRICH)
PRUEBA RÁPIDA DE STREP A EN PLACA (FROTIS DE GARGANTA)
DISPOSITIVO PARA TESTE RÁPIDO DE ESTREPTOCOCOS A (COTONETE DE GARGANTA)
ΣΥΣΤΗΜΑ ΤΑΧΕΙΑΣ ΕΞΕΤΑΣΗΣ STREP A (ΛΑΡΥΓΓΙΚΟΥ ΕΚΚΡΙΜΑΤΟΣ)

Manuale d'uso - User manual
Manuel de l'utilisateur - Gebrauchsanweisung
Guía de Uso - Guia para utilização - Οδηγίες χρήσης

PER USO PROFESSIONALE
FOR PROFESSIONAL USE
FÜR DEN PROFESSIONELLEN GEBRAUCH
PARA USO PROFESIONAL
PARA USO PROFISSIONAL
ΓΙΑ ΕΠΑΓΓΕΛΜΑΤΙΚΗ ΧΡΗΣΗ

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*
AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*
ACHTUNG*: Die Bediener müssen vorher dieses Handbuch gelesen und verstanden haben, bevor sie das Produkt benutzen.*
ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*
ATENÇÃO: *Os operadores devem ler e entender completamente este manual antes de usar o produto*
ΠΡΟΣΟΧΗ*: Οι χειριστές αυτού του προϊόντος πρέπει να διαβάσουν και να καταλάβουν πλήρως τις οδηγίες του εγχειριδίου πριν από την χρήση του.*

REF **24522**

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Made in P.R.C.

STERILE EO

30°C
2°C

IVD

Σ 20

M24522-M-Rev.4-11.19

Strep A Rapid Test Device (Throat Swab) Package Insert

A rapid test for the qualitative detection of Strep A antigen in throat swab specimens.For professional in vitro diagnostic use only.

INTENDED USE

The Strep A Rapid Test Device (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

SUMMARY

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. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess. 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.

The Strep A Rapid Test Device (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.

PRINCIPLE

The Strep A Rapid Test Device (Throat Swab) is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. 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 color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains Strep A antibody coated particles and Strep A antibody coated on the membrane.

PRECAUTIONS

- 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 againstmicrobiological 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.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Do not use test if pouch is damaged.
- Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- The positive and negative controls contain sodium azide (NaN3) as a preservative.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
- Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.
- If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab with the Strep A Rapid Test Device (Throat Swab).

MATERIALS

Materials Provided

- Test devices
- Sterile swabs
- Workstation
- Package insert
- Dropper tips
- Strep A Reagent A (2M Sodium Nitrite)
- Strep A Reagent B (0.2M Acetic Acid)
- Test tubes
- Strep A Positive control (Non-viable Strep A; 0.09% NaN3)
- Strep A Negative control (Non-viable Strep C; 0.09% NaN3)

Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

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

1) Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.

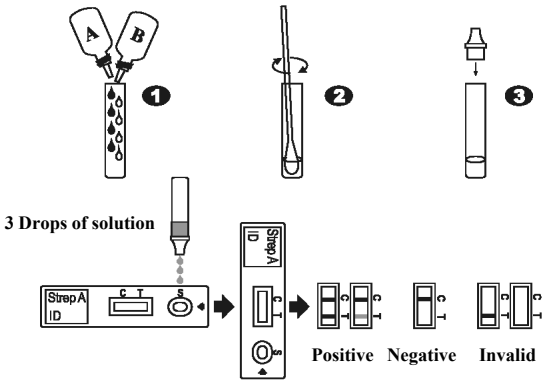
2) Hold the Reagent A bottle vertically and **add 4 full drops** (approximately 240 μL) of Reagent A to an extraction test tube. Reagent A is red in color. Hold the Reagent B bottle vertically and **add** 4 **full drops** (approximately 160 μL) to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction test tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow. See illustration 1.

3) **Immediately add the throat swab to the extraction test tube of yellow solution.** Agitate the swab **10 times** in the tube. Leave the swab in the tube for **1 minute**. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab. See illustration 2.

4) Fit the dropper tip on top of the extraction test tube. Place the test device on a clean and level surface. **Add 3 full drops of solution** (approx. 100 μL) to the specimen well (S) and then start the timer. See illustration 3.

5) Wait for the colored line(s) to appear. **Read the result at 5 minutes.** Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS



POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that Strep A antigen is detected in the specimen.

***NOTE:** The intensity of the 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 color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture.

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. If the problem persists, discontinue using the test immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control

It is recommended that a positive and negative external control be run every 25 tests, and as deemed necessary by internal laboratory procedures. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A Streptococcus reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

Procedure for External Quality Control Testing

1) Add 4 full drops of Reagent A and 4 full drops of Reagent B into an extraction test tube. Mix the solution by gently swirling the extraction tube.
2) Add 1 full drop of positive or negative control solution into the extraction tube, holding the bottle vertically.
3) Place a clean swab into this extraction tube and agitate the swab in the solution by rotating it at least 10 times. Leave the swab in the extraction tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
4) Continue with Step 4 of Directions For Use.
If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATIONS

1) The Strep A Rapid Test Device (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 should 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 is below the detectable level of the test.
4) Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth[5] and any bleeding areas of the mouth with the swab when collecting specimens.
5) As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS - Sensitivity and Specificity

Using three medical centers for evaluation, a total of 492 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 Strep A Rapid Test Device (Throat Swab). The plates were further streaked for isolation, and then incubated at 37° C with 5-10% CO2 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 grouping kit.
Of the 492 total specimens, 384 were confirmed to be negative and 108 were confirmed to be positive by culture. During this study, two Strep F specimens yielded positive results with the Test. One of these specimens was re-cultured, then re-tested and yielded a negative result. Three additional different Strep F strains were cultured and tested for cross-reactivity and also yielded negative results.

Method		Culture		Total Results
Strep A Rapid Test	**Results**	Positive	Negative	
	Positive	102	7	109
	Negative	6	377	383
Total Results		108	384	492

Relative Sensitivity: 94% (88%-98%)*
Relative Specificity: 98% (96%-99%)*
Accuracy: 97% (96%-98%)*
* 95% Confidence Intervals

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 Strep A Rapid Test Device (Throat Swab). No mucoid-producing strains were tested.

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

Simbologia / Index of symbols - TEST

	Leggere le istruzioni per l'uso Consult instructions for use
IVD	Dispositivo medico-diagnostico in vitro In vitro diagnostic medical device
2°C 30°C	Conservare tra 2 e 30°C Store between 2 and 30°C
	Conservare in luogo fresco ed asciutto Keep away from sunlight
	Conservare in luogo fresco ed asciutto Keep in a cool, dry place
Σ	Contiene <n> di test Contains sufficient for "n" tests
	Dispositivo monouso, non riutilizzare Disposable device, do not re-use

	Data di scadenza Expiration date
LOT	Numero di lotto Lot number
	Attenzione: Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso Caution: read instructions (warnings) carefully
EC REP	Rappresentante autorizzato nella Comunità europea Authorized representative in the European community
STERILE EO	Sterilizzato con ossido di etilene Sterilized using ethylene oxide
CE	Dispositivo medico conforme alla Direttiva 93/42/CEE Medical Device complies with Directive 93/42/EEC

REF	Codice prodotto Product code
	Fabbricante Manufacturer
!	Tossicità acuta di grado 4" Tenere fuori dalla portata dei bambini. Indossare guanti e indumenti protettivi, protezione per gli occhi e viso. In caso di ingerimento consultare un medico o rivolgersi ad un centro ospedaliero. In caso di contatto con gli occhi, lavare immediatamente ed abbondantemente con acqua per diversi minuti. Rimuovere le lenti a contatto, nel caso siano presenti, e continuare a sciacquare gli occhi. Se l'irritazione dovesse persistere consultare un medico. Acute toxicity category 4 Keep out of the reach of children. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.

Tamponi sterili / Sterile swabs:

Puritan Medical Products Company LLC
31 School Street
Guilford, ME 04443-0149, U.S.A.

EC REP Emergo Europe
Prinsessegracht 20
2514 AP, The Hague,
The Netherlands

CE 0086 STERILE EO

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7. 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.