status quo: 21.11.2007
ulti med Strep A
Dipstick Test 014A055
Polyester swab

RAPID SANDWICH IMMUNO ASSAY FOR QUALITATIVE DETECTION OF STREP A ANTIGEN IN THROAT SWAB SPECIMEN FOR IN-VITRO DIAGNOSTIC / PROFESSIONAL USE ONLY

INTENDED USE

The ulti med Strep A Dipstick Test 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

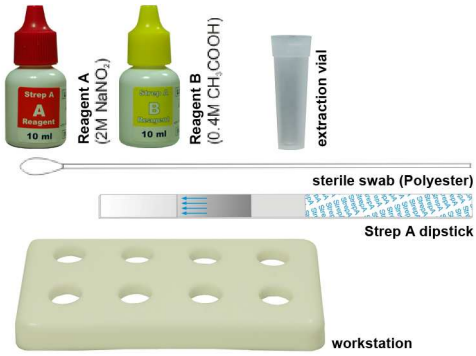
Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious 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]
The ulti med Strep A Dipstick Test 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 ulti med Strep A Dipstick Test 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 strip. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto coloured 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.

MATERIALS PROVIDED

- test strips
- Extraction vials
- Sterile swab (Polyester)
- Reagent A (2 M Sodium Nitrite)
- Reagent B (0.4 M Acetic Acid)
- Workstation
- Package insert
- available as a kit of 10 or 20



MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Positive control (Non-viable Strep A; 0.1% NaN_3, optional, on request)

SAFETY INFORMATION REAGENTS

Reagent A (2 M Sodium Nitrite)		**R8-25-50** Contact with combustible material may cause fire Toxic if swallowed Very Toxic to aquatic organisms **S1/2** Keep locked up and out of reach of children **S45** In case of accident or if you feel unwell, seek medical advice immediately (show label where possible) **S60** This material and/or its container must be disposed of as hazardous waste
Reagent B (0.4 M Acetic Acid)		Safety data sheet available for professional users on request

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- Do not use when pouch is damaged.
- The test device should remain in the sealed pouch until use.
- Read the instructions carefully before performing the test.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- Do not interchange reagent bottle caps.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent
- The used test device should be discarded according to federal state and local regulations.
- Do not inter mix reagents from different lots.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results

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STORAGE AND STABILITY

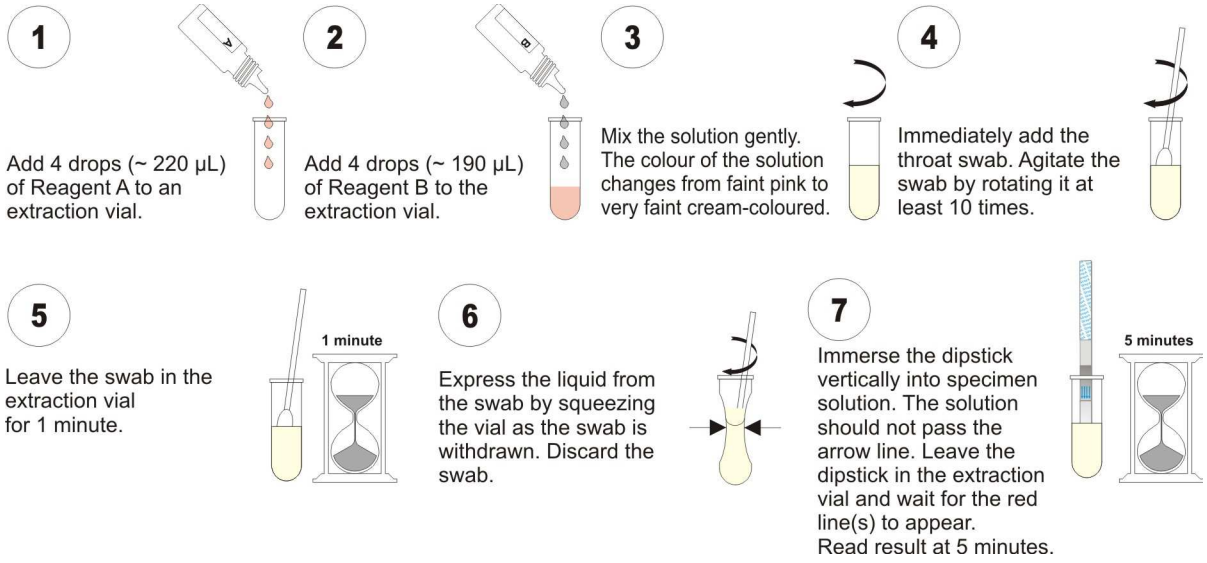
The kit can be stored at room temperature or refrigerated (2-30℃). The test strip must remain in the sealed pouch until use. The test strip and the reagents are stable through the expiration date printed on the box.

- Do not freeze.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

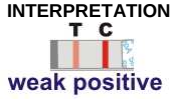
Only use reagents and sterile swabs provided in the kit. Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5] Testing should ideally be performed immediately after the specimens have been collected. Swab specimens may be stored at room temperature for up to four hours prior to testing.

TEST PROCEDURE



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**.**

INTERPRETATION OF 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). A positive result indicates that Strep A antigen was detected in the specimen.
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). 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 strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

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

External Quality Control

In addition to your laboratory's standard quality control procedures, it is recommended that a positive and negative external control be tested at least once within each 25-test kit and by each operator performing testing within a kit. This will verify that the reagents and test strips are working properly and the operator is able to correctly perform the test procedure. External positive control is supplied in the kit.

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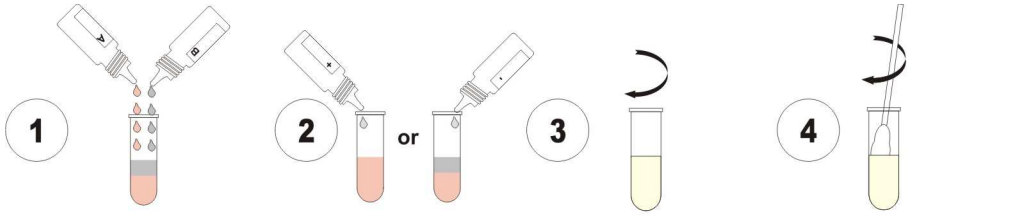
Procedure for External Quality Control Testing



Add 4 drops of Reagent A and B (~ 160 µL) to an extraction vial.

Add 1 drop of positive control or negative control (optional) to the extraction vial.

Mix the solution gently. The colour of the solution changes from faint pink to very faint cream-coloured.

Place a fresh swab in the extraction vial and proceed as described in TEST PROCEDURE.

LIMITATIONS

The ulti med Strep A Dipstick Test 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. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria. 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 is below the detectable level of the test. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test. 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. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

EXPECTED VALUES

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A β-hemolytic Streptococcus.[6] In school-aged children and adults, the incidence of Strep throat infection is about 40%.[7] This disease usually occurs in the winter and early spring in temperate climates.[3]

PERFORMANCE CHARACTERISTICS

Using three medical centers for evaluation, a total of 499 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 Strip. 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 499 total specimens, 375 were found to be negative by culture and 124 were found to be positive by culture. During this study, two Strep F specimens yielded positive results on the test. One of these specimens was re-cultured, 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.

		Culture	
		+	-
Strep A Test	+	120	20
	-	4	355

Sensitivity: 120/124 = 97% (91% to 99%)*
Specificity: 355/375 = 95% (92% to 97%)*
Accuracy: 475/499 = 95% (93% to 97%)*
PPV (+): 120/140 = 86% (79% to 91%)*
NPV (-): 355/359 = 99% (97% to 100%)*
Denotes a 95% Confidence Interval#

Positive Culture Classification	Strep A Rapid Test	Culture	% Correct
Rare	10	11	91%
1+	9	9	100%
2+	17	19	89%
3+	36	37	97%
4+	48	48	100%

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 Strip. No mucoid-producing strains were tested.

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

POL Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Strip. Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results obtained had a 96% correlation with the expected results.

BIBLIOGRAPHY

1. Manual of Clinical Microbiology, 6. Auflage, ASM Press, Seiten 299-307.
2. Webb, KH. *Pediatrics* (Februar 1998), 101:2,2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH, *Clinical Infections Diseases* (1997), 25, 574-83.
4. Needham CA, McPherson KA, Webb KH, *Journal of Clinical Microbiology* (Dezember 1998), 3468-3473.
5. Shea, Y.R., Secimen 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.
6. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. *Clinical Pediatrics* (Juni 1999), 357-360.
7. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA, *Southern Medical Journal* (Mai 1999), 491-492.

	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Use by
	Read instructions for use		Store at

ulti med Products (Deutschland) GmbH
Reeshoop 1 • 22926 Ahrensburg
Telefon: 04102 - 80090
Fax: 04102 - 50082
e-mail: info@ultimed.de

Distributor:
ulti med Products (Belgium) BVBA
Honzebroekstraat 137 • 8800 Roeselare • Belgium
Phone: +32 +51 200 425
Fax: +32 +51 200 449
e-mail: belgium@ultimed.org

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