Strep A Strips

Rapid Test Group A Strep

DIAGNOSTIK NORD
IHR PARTNER FÜR IN VITRO DIAGNOSTIKA

» INTENDED USE

Strep A Dipstick-Test is a lateral flow, one-step immunoassay for the rapid, qualitative detection of Group A Streptococcal antigen directly from throat swabs.

» SUMMARY AND EXPLANATION

Beta-hemolytic Group A Streptococcus is a major cause of upper respiratory infections such as tonsillitis, pharyngitis and scarlet fever. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications, such as rheumatic fever and glomerulonephritis (1).
Conventional methods used for the detection of the disease depend on the isolation and subsequent identification of the organism (1, 2). These methods often require 24-48 hours to complete. Recent developments of immunological techniques (3, 4) which can detect Group A Streptococcal antigen directly from throat swabs allow physicians to diagnose and administer therapy immediately.
The kit identifies growing isolated colonies, where the concentration is above the detection limit. The test doesn't identify the different strains.

» TEST PRINCIPLE

The DIAGNOSTIK NORD Strep A Test utilizes two site sandwich immunoassay technology for the detection of Group A Streptococcal antigen. The test consists of a membrane strip which was precoated with rabbit anti-Strep A antibody on the test line region and goat anti-rabbit antibody on the control line region. A pad containing a colored conjugate is placed at the end of the membrane. This conjugate consists of polyclonal rabbit anti-Strep A antibody and colloid gold. During testing, the Strep A antigen is extracted from the throat swab using Extraction Reagents 1 and 2. The dipstick is them added into the solutions in the tube. The Strep A antigen reacts with colored antibody-colloid conjugate to form Strep A antigen-antibody complexes. The mixture then moves chromatographically on the membrane to the immobilized rabbit anti-Strep A antibody at the test line region.
If Strep A antigen is present in the specimen, a colored sandwich complex of solid phase-anti-StrepA antibody/StrepA-antigen/anti-StrepA-gold-conjugate is formed on the test line region. Absence of the colored line at the test line region indicates a negative result.
Regardless of the presence of Strep A antigen, as the extract mixture continues to move laterally across the membrane to the immobilized goat anti-rabbit antibody test line region, a colored line at the control region will always appear. The presence of this colored line serves as: 1) verification that sufficient volume has been added, 2) verification that proper flow is obtained, and 3) reagent control.

» REAGENTS AND MATERIALS SUPPLIED

- Extraction Reagent 1: 1.0 M Sodium Nitrite (7 ml)

T Toxic
R25: Toxic if swallowed

- Extraction Reagent 2: 0.4 M Acetic Acid (7 ml)
- 20 Test strips (single pouched): dipsticks containing rabbit anti-Strep A antibody coated membrane and colloid gold conjugate.
- 20 Extraction Tubes with dropping cap
- 20 Sterile Throat Swabs:

Copan Diagnostics Inc. 26055 Jefferson Avenue Murrieta, CA 92562 USA
(CE Representant: CopanItalia S.p.a., Via Perotti 10, 25125 Brescia Italy)
(Zusätzliches Material ist in Übereinstimmung mit Richtlinie 93/42/EWG.)

CE 0123

- 1 Workstation
- Positive control: Heat-killed Group A Streptococcus in solution (1×10^8 organism/ml) with 0.05% sodium azide as preservative. (2 ml)

» MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

» STORAGE

All reagents included in the Strep A test can be stored at room temperature or refrigerated (2–30 °C).

» PRECAUTIONS

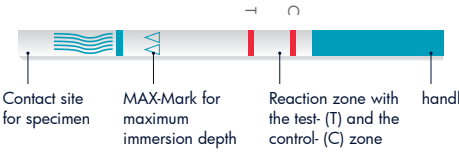
- For professional IN VITRO DIAGNOSTIC use only!
- For single use only!
- Do not use after stated expiration date.
- Do not use swabs if pouch is damaged.
- The test should remain in the sealed pouch until use, because it is humidity-sensitive!
- Therefore do not use the test if the pouch has been damaged!
- Do not mix reagents from different lots!
- Do not mix reagent bottle caps.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15–30°C) before use.
- Do not dip the dipstick above the MAX-mark!
- Do not spill the samples into the reaction zone.
- Do not touch the reaction zone of the dipstick to avoid contamination.
- Evaluate the test result after 5 minutes.
- Store and transport the test always at 2–30°C (36°–86°F).
- Humidity and high temperature can adversely affect results.
- Use only Dacron or Rayon tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped, or wooden shafted swabs.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Extraction Reagent 1 is toxic at swallowing.
- Extraction Reagents 1&2 are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- Positive and negative controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions always flush with copious amounts of water to prevent azide buildup.
- Standard guidelines for handling infectious agents and chemical reagents should be observed throughout all procedures. All contaminated waste such as swabs, Strep A Test strips and extracts should be properly disposed.

» SPECIMEN COLLECTION AND STORAGE

- If a bacteria culture is desired, lightly roll the swab on a 5% sheep blood agar plate before using it in the test. The extraction reagents in the test will kill bacteria on the swabs and make them impossible to culture.
- Collect throat swab specimens by standard clinical methods. Swab the posterior pharynx, tonsil and other inflamed areas. Avoid touching the tongue, cheeks or teeth with the swab.
- It is recommended that swab specimens be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed in a sterile, dry, tightly capped tube or bottle and refrigerated. Do not freeze. Swabs can be stored at room temperature (15–30°C) up to 4 hours, or refrigerated (2–8°C) up to 24 hours. All specimens should be allowed to reach room temperature (15–30°C) before testing.

» SET-UP OF THE TEST STRIPS

At the left ending the test strip or dipstick has got the contact site for the extracted specimen with a mark, which indicates the maximum immersion depth. Right next to it there is the reaction zone with the test- (T) and control- (C) zone. At the right ending there is the green handle to hold the strip with your fingers



» ASSAY PROCEDURE

Procedural Notes

- Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) before use.
- To avoid cross contamination, do not allow the tips of the reagent bottles to come in contact with sample swabs and Extraction Tubes.

Prepare swab specimens

- Place a clean extraction tube in the designated area of the workstation. Add 4 drops of reagent 1 to the extraction tube, then add 4 drops of reagent 2. Mix the solution by gently swirling the extraction tube.
- Immediately immerse the swab into the extraction tube. Use a circular motion to roll the swab against the side of the extraction tube so that the liquid is squeezed from the swab and can reabsorb.
- Let stand for 1-15 minutes at room temperature, then squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Cap the extraction tube with the attached drop per tip. Discard the swab following guidelines for handling infectious agents.

Test Procedure

1. Open the pouch and put the strip inside the tube and let the strip remain inside. Alternatively, put the strip after 1 minute on a dry surface.
2. Read result within 5 minutes for positive results. Depending on the number of the organisms on the swab, positive result may be visible as soon as 1 minute. However, to confirm a negative result the complete reaction time of 5 minutes is required (the maximum sensitivity is reached at 5 minutes). Do not read result after 10 minutes.

» INTERPRETATION OF TEST RESULTS

POSITIVE

In addition to the control line (C), a distinct colored line also appears on the test (T) region. The color intensity of the test line may be weaker or stronger than that of the control line. This test result shows a specimen containing Strep A.

NEGATIVE

Only one colored line appears in the control (C) region. No line is visible in the test region (T). Therefore no Strep A was detected.

INVALID

No line appears in the control region. This indicates possible error in performing the test, the test is invalid. A new test should be performed. If the problem persists, call DIAGNOSTIK NORD GmbH for assistance.

Strep A Strips

Rapid Test Group A Strep

DIAGNOSTIK NORD
IHR PARTNER FÜR IN VITRO DIAGNOSTIKA

» QUALITY CONTROL

- Internal procedural controls are included in the test. A colored line appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- Good laboratory practice recommends the use of control materials to ensure proper kit performance. A positive control containing heat-killed Group A Streptococcus is provided with each kit.

Operating Procedure for External Quality Control Testing

1. Add 4 drops of reagent 1 and 4 drops of reagent 2 to an extraction tube.
2. Thoroughly mix the control by shaking the bottle vigorously. Add 1 drop of positive control to the tube.
3. Place a clean sterile swab into the tube and swirl. Leave the swab in the extraction tube for 1 minute. Then squeeze 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 as described from Step 2 of the Procedure section, above.

- If controls do not yield expected results, do not use the test. Repeat the test or contact your distributor.

» LIMITATIONS

- The Strep A Rapid Test Dipstick Test (Swab) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of Group A Streptococcus. No meaning should be inferred from the color intensity or width of any apparent bands.
- The accuracy of the test depends on the quality of the swab specimen. False negatives may result from improper specimen collection or storage. A negative result may also be obtained from patients at the onset of the disease due to low antigen.
- The test does not differentiate asymptomatic carriers of Group A Streptococcus from those with symptomatic infection. If clinical signs and symptoms are not consistent with laboratory test results, a follow-up throat culture is recommended.
- In rare cases, test specimens heavily colonized with Staphylococcus aureus can yield false positive results. If clinical signs and symptoms are not consistent with clinical test results, a follow-up culture and grouping procedure should be performed.
- Respiratory infections, including pharyngitis, can be caused by streptococci from serogroups other than Group A, as well as other pathogens.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

» EXPECTED RESULTS

It is believed that approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci (6). Infection is most prevalent in winter and early spring, with most cases arising in patients living in highly populated areas.

» PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
To determine the analytical sensitivity of the Diagnostik Nord Strep A Test, Group A Streptococcus bacteria organisms were grown in broth culture. The detection limit of the Diagnostik Nord Strep A Test was determined to be 1.5×10^5 organisms per test.

Specificity Study
To determine the specificity of the Diagnostik Nord Strep A Test to Group A Streptococcal bacteria, the following Group A Streptococcal Strains at different levels of organisms per test were examined. Positive results obtained at level of 1.5×10^5 organisms/test for all strains indicate that DIMA Strep A Test is sensitive to Group A Streptococcal bacteria.

Group A Streptococcal Strains:

SS-091	SS-410	SS-492	SS-496	SS-633
SS-634	SS-635	SS-721	SS-754	SS-799
ATCC-19615				

Cross-reactivity studies with organisms likely to be found in the respiratory trace were also performed using the Diagnostik Nord Strep A Test. The following organisms were tested at 1×10^8 organisms/test. Diagnostik Nord Strep A Test gave negative results in all cases.

Bordetella pertussis
Candida albicans
Corynebacterium diphtheriae
Escherichia coli
Haemophilus parahaemolyticus
Moraxella catarrhalis
Neisseria gororrhoeae
Neisseria lactima
Neisseria meningitidis
Neisseria sicca
Neisseria subflava
Proteus vulgaris
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus saprophyticus
Streptococcus bovis
Streptococcus faecalis
Streptococcus faecium
Streptococcus Group B
Streptococcus Group C
Streptococcus Group D
Streptococcus Group F
Streptococcus Group G
Streptococcus mitis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus salivarius
Streptococcus sanguis

Correlation Study
A correlation study between Diagnostik Nord Strep A Test and the conventional culture tests has been determined in multi-center clinical evaluations. Throat swab specimens were taken from children and adults exhibiting symptoms of pharyngitis. The swabs were then used to inoculate blood agar plates prior to testing with the Diagnostik Nord Strep A Test. Beta-hemolytic colonies from the blood agar plates were confirmed as Group A Streptococcus using serologic streptococcal grouping methods. Strep A was reported as present or not present. Semiquantitation was not performed during testing of clinical specimens. The results are summarized as follows:

The results are summarized as follows:

		Strep A dipstick		
		+	-	Total
Culture	+	76	8	84
	-	4	156	160
Total		80	164	244

Diagnostic Sensitivity: 97.6 % (95 % CI, 93.8 % bis 99.4 %)
Specificity: 97.5 % (95 % CI, 93.7 % bis 99.3 %)

» LITERATURE

1. *Facklam,R. R. and Carey, R. B., Streptococci and Aerococci, Manual of Clinical Microbiology, 4 th ed., Lennette, E. H., Balows, A., Hausler, W. J. and Shadomy, H. J. (eds), American Society for Microbiology, 1985, PP154-175.*
2. *Levinson, M. L. and Frank, P. F., Differentiation of Group A from other Beta Hemolytic Streptococci with Bacitracin, J. Bacteriol., 69,284-287(1995).*
3. *Edwards, E. A., Phlillips, I. A., and Suiter, W. C., Diagnosis of Group A Streptococcal Infections Directly from throat secretions, J. Clin. Micro. 15, 481-483 (1982).*
4. *Gupta, R., Talwar, G. P. And Gupta, S. K., Rapid Antibody Capture Assay for Detection of Group A Streptococci Using Monoclonal Antibody and Colloidal Gold-Monospecific Polyvalent Antibody Conjugate, J. Immunoassay, 13, 441-445(1992)*
5. *Ross, P.W., Throat Swabs and Swabbing Technique, The Practitioner, 207,791-796(1971).*
6. *Lauer, B. A., Rellar, L. B. and Mirrett, S., Effect of Atmosphere and Duration of Incubation on Primary Isolation of Group A Streptococci from Throat Cultures, J. Clin. Micro.,17,338-340(1983).*

» SYMBOLERLÄUTERUNGEN

CE		Σ n	Content
IVD	For in-vitro diagnostic use only	LOT	Lot number
	For single use only		Expiry date
	Carefully read package insert		Store at room temperature

Rev.: 12.06.2014 (JM)

» HERSTELLER

Diagnostik Nord GmbH
Mecklenburgstraße 97
19053 Schwerin
Germany

Telefon: +49 (0) 385 208 409-0
Telefax: +49 (0) 385 208 409-29
E-Mail: info@diagnostik-nord.de
Internet: **www.diagnostik-nord.de**