Strep.A Dipstick
(Streptococcus pyogenes)

for throat swab samples

For in vitro diagnostic use only

REF

Content

Z98230B* - 1 tests individually packed

Z98230BN* - 1 Extraction Reagent A: 2.0 M sodium nitrite per 20 tests
- 1 Extraction Reagent B: 0.2 M acetic acid per 20 tests
  safety data sheet available for professional users on request
- 1 package insert
- 1 extraction tube
- 1 swab (sterilized)
- 1 plastic rack per 20 tests
- 1 positive control (1 vial non-viable Strep.A; 0,09% NaN_3) per 20 tests
- 1 negative control (1 vial non-viable Strep.C; 0,09% NaN_3) per 20 tests

*minimum order: 20 tests or multiples thereof

INTENDED USE

The Strep.A Dipstick (throat swab) is an immunoassay for the rapid, qualitative detection of Group A Streptococcal antigen directly from throat swabs.

CLINICAL SIGNIFICANCE

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.[3,4]
The Strep.A Dipstick (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.

TEST PRINCIPLE

The Strep.A Dipstick (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. After the test is immersed into a specimen, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. This mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a coloured line in the test line region. The presence of this coloured line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred

STORAGE

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.

WARNINGS AND PRECAUTIONS

- Reagent A:
  H302: Harmful if swallowed
  H319: Causes serious eye irritation.
  P102: Keep out of reach of children.
  P280:Wear protective gloves/protective clothing/eye protection/face protection.
  P301 + P312: IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
  P305 + P351 + P338: 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.
- 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.
- 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 (NaN_3) as a preservative.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

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.[5]
- 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 Dipstick (throat swab).

ASSAY PROCEDURE

Allow the test strip, reagents, and/or controls to reach 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 test is performed immediately after opening the foil pouch.

2. Hold the Reagent A bottle upright and add 4 full drops (approximately 240 µL) to an extraction test tube. Reagent A is red in colour. Hold the Reagent B bottle upright and add 4 full drops (approximately 160 µL) to the tube. Reagent B is colourless. The addition of Reagent B to Reagent A changes the colour of the solution from red to pale yellow. Tap the bottom of the tube gently to mix the liquid.

3. Immediately add the throat swab into the tube of pale yellow solution. Rotate 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 while removing the swab so that most of the liquid stays in the tube. Discard the swab.

4. With arrows pointing down, place the test strip into the tube of solution and then start the timer. If the procedure is followed correctly, the liquid should be at or just below the maximum line (MAX) on the test strip.

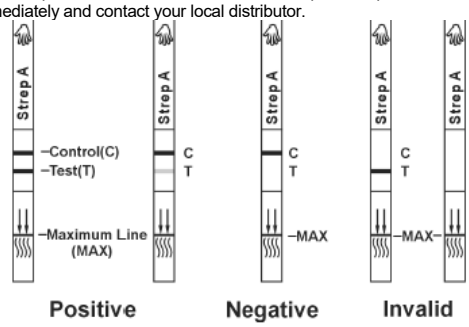
5. Leave the strip in the tube and read the result at 5 minutes. Note: Very low concentrations of Strep.A might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not read the result after 10 minutes.

INTERPRETATION OF TEST RESULTS

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

NEGATIVE: One coloured 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 coloured 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. Tap the bottom of the tube gently to mix the liquid.
2. Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
3. Place a clean swab into the tube. Rotate 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 while removing the swab so that most of the liquid stays in the tube. 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 Dipstick (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.

REAGENTS

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

EXPECTED VALUES

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta-haemolytic 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

Sensitivity and Specificity

Using three medical centres 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 Dipstick (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 grouping kit.

Method		Culture		Total
	Results	Positive	Negative	Results
Strep.A Dipstick	Positive	120	20	140
	Negative	4	355	359
Total Results		124	375	499

Sensitivity: 97% (91% to 99%)*
Specificity: 95% (92% to 97%)*
Accuracy: 95% (93% to 97%)*
*denotes a 95% confidence interval

Positive Culture Classification	Rapid Strip/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 Dipstick (throat swab). No mucoid-producing strains were tested.

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

POL Studies

Three physicians' offices were used to conduct an evaluation of the Strep.A Dipstick (throat swab). 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) specimens for three days. The results obtained had a 96% correlation with the expected results.

REFERENCES

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3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574-83.
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5. Shea, Y.R., Specimen Collection and Transport, 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. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
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.

Swabs:

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