

Strep.A Cassette (Streptococcus pyogenes)

for throat swab samples

For in vitro diagnostic use only

REF

Z98223B*
Z98223BN*

Content

- 1 cassettes individually packed
- 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 dropper caps
- 1 swab (sterilized)
- 1 plastic rack per 20 tests
- 1 positive control (1 vial non-viable Strep.A; 0,09% NaN₃) per 20 tests
- 1 negative control (1 vial non-viable Strep.C; 0,09% NaN₃) per 20 tests

*minimum order: 20 tests or multiples thereof

INTENDED USE

The Strep.A Cassette (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.

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 Cassette (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 Cassette (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.

STORAGE

Store as packaged in the sealed pouch either 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 beyond 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 the 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 (NaN₃) as a preservative.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

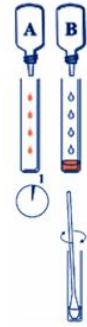
SPECIMEN COLLECTION AND PREPARATION

- 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 in the Strep.A Cassette (throat swab).

ASSAY PROCEDURE

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

- Remove the test cassette 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.
- Hold the Reagent A bottle upright and add 4 full drops (approximately 240µL) to an extraction test tube. Reagent A is red in colour. Hold the Reagent B bottle upright and add 4 full drops (approximately 160µL) to the tube. Reagent B is colourless. Mix the solution by gently swirling the extraction test tube. 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.
- Immediately add the throat swab into the test tube (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.
- Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. Add 3 full drops of the solution (approx. 100µl) to the specimen well (S) of the cassette and then start the timer.
- Wait for the coloured lines to line(s) to appear. Read the result at 5 minutes. Some positive results may appear sooner. Do not read the results after more than 10 minutes.



3 drops

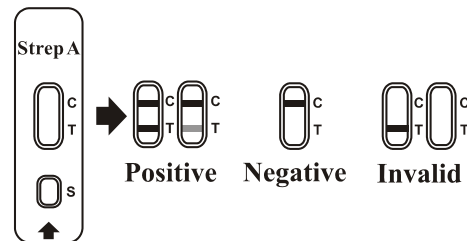
INTERPRETATION OF TEST RESULTS

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 was 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 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 kit 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 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

- 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.
- Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
- 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.
- 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 Cassette (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 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 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 Cassette (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.A 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.A strains were cultured and tested for cross-reactivity and also yielded negative results.

Method	Results	Culture		Total Results
		Positive	Negative	
Strep.A Cassette	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 10⁷ organisms per test and were all found to be negative when tested with the Strep.A Cassette (throat swab). No mucoid producing strains were tested.

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

POL Studies


Three physicians' offices were used to conduct an evaluation of the Strep.A Cassette (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) for three days. The results obtained had a 100% 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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6. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. *Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months 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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