Strep A Rapid Test for Throat Swabs Package Insert

REF ISTA-RC81 English

Rapid test for the qualitative detection of Strep A antigens in throat swabs.
For professional in vitro diagnostic use only.

INTENDED USE

This Strep A test cassette is a chromatographic immunoassay-based rapid test for the qualitative detection of Strep A antigens in throat swabs to support the diagnosis of a Group A streptococcal infection.

SUMMARY

Streptococcus pyogenes belongs to the group of immobile, gram-positive cocci, which contain the Lancefiled Group A antigens and can cause serious illnesses like pharyngitis, respiratory infections, impetigo, endocarditis, mengingitis, childbed fever and arthritis. If left untreated, these infections may lead to serious complications, such as rheumatic fever or pertonsillar abscesses. Conventional detection of Group A streptococcal infections involved the identification of living organisms, which could take 24-48 hours longer.
This Strep A test cassette is a rapid test that provides qualitative detection of Strep A antigens in throat swabs within 5 minutes. The test makes use of special Lancefield Group A streptococcus-specific antibodies to selectively detect Strep A antigens in throat swabs.

PRINCIPLE

This Strep A rapid test is an immunoassay-based membrane test for the qualitative detection of Strep A carbohydrate antigens in throat swabs. For this purpose, the test line was coated with Strep A antigen-specific antibodies. During testing, the sample material migrates across the membrane and reacts with the antibodies in the test line region. If there are Strep A antigens present in the specimen, a red line appears. A red test line indicates a positive result, while its absence indicates a negative result. A control line serves as an integrated procedural control and appears if sufficient sample material has been applied and membrane wicking has occurred.

REAGENTS

This test contains Strep A antibody-coated particles as well as a coated membrane.

PRECAUTIONS

1. For in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for the proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when the specimens are assayed.
5. The used materials should be discarded according to local regulations regarding infectious agents.
6. Humidity and temperature can adversely affect the results.
7. Do not use the test if the foil pouch is damaged.
8. The reagent B contains an acidic solution. If it comes into contact with the skin or eye, immediately rinse the affected area with water.
9. The positive and negative control solutions contain NaN3 as a preservative.
10. Do not mix the caps of the different reagents.

STORAGE AND STABILITY

The test in the sealed pouch can either be refrigerated or stored at room temperature (2-30°C). The test is stable through the expiration date printed on the sealed pouch and must remain in the sealed pouch until use. Do not use the test/ test materials after the expiration date and do not freeze them!

SPECIMEN COLLECTION AND PREPARATION

1. Collect the specimen with the sterile, supplied swab. You may also use Amies medium swabs or Stuart medium swabs for shipping. Collect the specimen from the mucous membrane in the throat, the tonsils and other inflamed areas. Prevent the swab from coming into contact with the tongue, teeth or cheeks.
2. It is recommended to perform the test immediately after specimen collection, even though it is possible to store collected specimens in clean, dry plastic tubes at room temperature (up to 8 hours) or at 2-8°C (up to 72 hours).
3. Should a culture be needed, roll the end of the swab over a Strep A-specific blood agar plate prior to testing.

TEST MATERIALS

Provided materials

Test cassettes, extraction tubes, sterile swabs, workstation, dropper caps, extraction reagent 1 (2M NaNO3), extraction reagent 2 (0.027M citric acid), positive control (immobile Strep A: 0.09% NaN3), negative control (immobile Strep C: 0.09% NaN3)

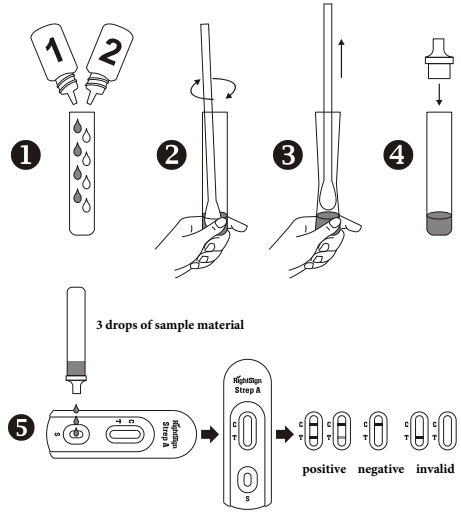
Materials required but not provided

Timer

TEST PERFORMANCE

Bring the test cassette, specimen and/or the control solution to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the foil pouch and perform the test within one hour. The most reliable results are achieved immediately after opening the package.
2. Hold the bottle with the extraction reagent 1 vertically and add 4 drops (approx 240µl) to an extraction tube. The extraction reagent is red. Hold the extraction reagent 2 over the extraction tube and add 4 drops (approx 160µl). The extraction solution 2 is clear. When the reagents are mixed, the solution in the tube turns yellow.
3. Place the swab in the tube, twist it 15x and leave the mixture alone for 1 minute.
4. Press the swab against the tube wall and squeeze the lower end of the extraction tube together when removing the swab to retain as much solution as possible.
5. Place the dropper cap on the extraction tube. Place the test cassette on a clean and level surface. Add 3 drops (approx 100µl) of the sample material to the specimen well and start the timer. Read the results after 5 minutes. Test results read after more than 10 minutes are invalid.



INTERPRETATION OF RESULTS

Please refer to the illustration above!

POSITIVE: 2 visible lines. 1 line should appear in the test line region (T) and the 2. should appear in the control line region (C). A positive result means that Strep A antigens have been detected in the specimen.

NOTE: The colour intensity varies depending on the antigen concentration present in the specimen. Therefore, any shade of colour in the test line region should be considered positive.

NEGATIVE: 1 visible line in the control line region (C). One line appears in the control line region (C) and no line appears in the test line region (T). A negative result means that the specimen contains no Strep A antigens or that the concentration is below minimum detection levels. If the clinical presentation still hints to a streptococcal infection, collect another sample to prepare a culture.

INVALID: no control line. In most cases this is due to insufficient specimen application or incorrect procedural techniques. Review the procedure and repeat the test with a new cassette. If the problem persists, discontinue using the test immediately and contact your local distributor.

QUALITY CONTROL

Internal Quality Control

This test is equipped with an internal procedural control. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen application and adequate membrane wicking.

External Quality Control

It is recommended to perform a positive and negative control for every 25th test or whenever your lab requires it. External positive and negative controls are supplied with this test. Alternatively, other Strep A or non-Strep A strains may be used for verification. The use of standard control solutions is not recommended as some standard control solutions may contain interfering preservatives.

Performing an external quality control

1. Add 4 drops of the extraction solutions 1 and 2 to an extraction tube. Carefully tap the bottom of the tube to mix the solution.
2. Hold the tube vertically and add one drop of positive or negative control solution.
3. Place a unused swab in the extraction tube, twist it 15x and leave it for 1 minute. Press the swab against the tube wall and squeeze the lower end of the extraction tube when removing the swab to retain as much solution as possible. Discard the swab.
4. Proceed as mentioned in 5) of "Test Performance". Should the obtained results not match the expected results, perform a new quality control or contact your distributor.

LIMITATIONS

1. This Strep A rapid test is only intended for in vitro diagnostic use. It should only be used for the detection of Strep A antigens in throat swabs. It delivers no quantitative results and should not be used to estimate the increase or decrease of antigen concentrations.
2. This test only detects the presence of viable and non-viable Strep A antigens.
3. A negative result should be confirmed with a culture, as the result may be due to an insufficient Strep A antigen concentration or a concentration below minimum detection levels.
4. A high blood or mucus content in the specimen may lead to false positive results. Avoid touching the teeth, gums, tongue, cheeks and bleeding areas in the mouth.
5. As with all diagnostic tests, the results must be interpreted together with other clinical information available to the medical professional.

EXPECTED RESULTS

Sensitivity and Specificity

525 throat swabs showing symptoms of respiratory tract infections were collected from patients. Each swab was rolled over an agar plate with ovine blood before being tested with the RightSign Strep A rapid test. The plates were cultivated for 18-24 hours at 37°C with 5-10% CO2. Possible GAS colonies were subcultured and confirmed with a standard latex agglutination grouping assay. Of the 525 specimens, 401 were confirmed negative, while 124 were confirmed positive. Over the course of the study, a Strep F positive specimen was confirmed positive with the RightSign Strep A rapid test. This specimen was recultured and tested again, presenting a negative result. 3 other Strep F strains were tested for cross-reactivity and gave negative results.

Method		Culture		Total Results
	Result	Positive	Negative	
Strep A Rapid Test	Positive	117	11	128
	Negative	7	390	397
Total Results		124	401	525

Relative sensitivity: 94.4% (88.7%-97.7%)*
Relative specificity: 97.3% (95.1%-98.6%)*
Accuracy: 96.6% (94.6%-98.0%)*

* 95% Vertrauensbereich

Positive Culture Classification	Strep A Rapid Test/ Culture	% Conformity
Rare	10/12	83.3%
1+	20/22	90.9%
2+	18/20	90.0%
3+	31/32	96.9%
4+	38/38	100.0%

Cross-Reactivity

The following organisms (O) were tested at a concentration of 1.0 x 10^7O/ test. No cross-reactivity was detected. Mucus-producing strains were not tested.

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

BIBLIOGRAPHY

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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.
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Index of Symbols

	Consult Instructions for use	Σ	Tests per kit	EC REP	Authorised Representative
IVD	For in vitro diagnostic use only		Use by	2	Do not reuse
2°C 30°C	Store at 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if the package is damaged				

Manufacturer
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CE

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