

Strep A Rapid Test Dipstick (Throat Swab)
Package Insert

A rapid test for the qualitative detection of Strep A antigens in human throat swab specimens. For professional in vitro diagnostic use only.

【INTENDED USE】

The Strep A Rapid Test Dipstick is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens from human 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 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.

【PRINCIPLE】
 The Strep A Rapid Test Dipstick 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.

【REAGENT】

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

【PRECAUTIONS】

- 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 2 contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- The positive and negative controls contain Proclin300 as a preservative.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

【STORAGE AND STABILITY】

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 beyond the expiration date.

【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.³
- 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 Rapid Test Dipstick.

【MATERIALS】

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| <ul style="list-style-type: none"> Test dipsticks Extraction reagent 1 (2M Sodium Nitrite) Extraction reagent 2 (0.027M Citric acid) Sterile swabs Package insert | Materials Provided <ul style="list-style-type: none"> Extraction tube Positive control (Non-viable Strep A; 0.01% Proclin 300) Negative control (Non-viable Strep C; 0.01% Proclin 300) Workstation |
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Materials Required But Not Provided

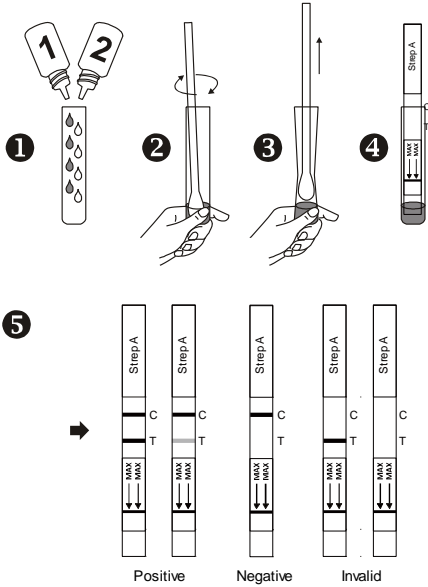
- Timer

【DIRECTIONS FOR USE】

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

- Remove the test dipstick 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 Extraction Reagent 1 bottle vertically and add **4 full drops** (approximately 240 µL) of Extraction Reagent 1 to an extraction tube. Extraction Reagent 1 is red in color. Hold the Extraction Reagent 2 bottle vertically and add **4 full drops** (approximately 160 µL) to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow. See illustration 1.
- Immediately add the swab into the extraction tube, agitate the swab vigorously 15 times, Leave the swab in the extraction test tube for 1 minute. See illustration 2.
- 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. See illustration 3.
- With arrows pointing down, place the dipstick 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 dipstick. See the illustration 4.

- Wait for the colored line(s) to appear. **Read the result at 5 minutes.** Do not interpret the result after 10 minutes. See illustration 5.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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

NEGATIVE: **One colored 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 colored line appearing in the control region (C) is an internal 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 Extraction Reagent 1 and 4 full drops of Extraction Reagent 2 into an extraction 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 15 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 5 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】

- The Strep A Rapid Test Dipstick 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 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.
- 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 teeth⁴ 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.

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

Using three medical centers for evaluation, a total of 526 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 Dipstick (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 526 total specimens, 404 were confirmed to be negative and 122 were confirmed to be positive by culture. During this study, one Strep F 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 F strains were cultured and tested for cross-reactivity and also yielded negative results.

Strep A Rapid Test Dipstick	Method	Culture		Total Results
	Results	Positive	Negative	
	Positive	116	9	125
	Negative	6	395	401
	Total Results	122	404	526

Relative Sensitivity: 95.1% (95%CI*: 89.6%-98.2%)

Relative Specificity: 97.8% (95%CI*: 95.8%-99%)

Accuracy: 97.1% (95%CI*: 95.3%-98.4%)

*Confidence Interval

Positive Culture Classification	Strep A Rapid Test/Culture	% Agreement
Rare	8/10	80.0%
1+	18/20	90.0%
2+	19/20	95.0%
3+	33/34	97.1%
4+	38/38	100.0%

Cross Reactivity

The following organisms were tested at 1.0 x 10⁷ CFU/mL per test and were all found to be negative when tested with the Strep A Rapid Test Dipstick. No mucoid-producing strains were tested.

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

【BIBLIOGRAPHY】

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