

# PathFlow™ Strep A Rapid Test Cassette (EN)

## Instructions for Use

### INTENDED USE

The PathFlow™ Strep A Rapid Test Cassette is a chromatographic immunoassay for the qualitative detection of Strep A antigens from 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 antigens 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 PathFlow™ Strep A Rapid Test Cassette is a rapid test to qualitatively detect the presence of Strep A antigens 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 antigens in a throat swab specimen.

### PRINCIPLE

The PathFlow™ Strep A Rapid Test Cassette a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigens in a throat swab. In this test, antibodies specific to Strep A carbohydrate antigens are 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 generates 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

### REAGENTS

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

### MATERIALS

**Provided:** Test cassettes, Extraction Tubes, Sterile Swabs, Workstation, Dropper Tips, Package Insert, Extraction reagent 1 (2M NaNO<sub>2</sub>), Extraction reagent 2 (0.027M Citric Acid), Positive Control (Non-viable Strep A; 0.01% Proclin 300), Negative Control (Non-viable Strep C; 0.01% Proclin 300).

**Not Provided but required:** Timer.

### WARNINGS AND 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 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 (Proclin 300) as a preservative.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

### STORAGE AND STABILITY

- Store as packaged at room temperature or refrigerated (2-30°C).
- The test is stable until the expiration date printed on cassette pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE**
- Do not use beyond the expiration date.

### SPECIMEN COLLECTION & 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 a Strep A Rapid Test Cassette.

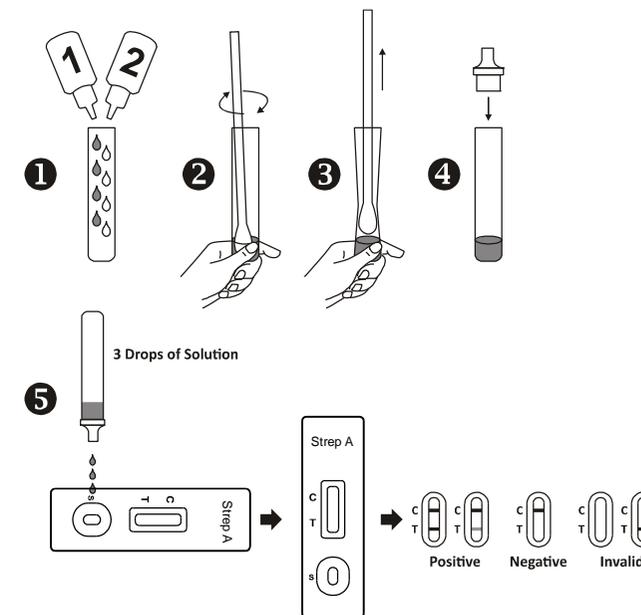
### DIRECTIONS FOR USE

**Allow the test, specimen, buffer 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 assay 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 colour. Hold the extraction reagent 2 bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Extraction reagent 2 is colourless. Mix the solution by gently swirling the extraction tube. The addition of extraction reagent 2 to extraction reagent 1 changes the colour of the solution from red to yellow.
- 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.
- 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 three drops of the solution (approx. 100ul) to the sample well and then start the timer. Read the result at 5 minutes. Do not interpret the result after 10 minutes.

MICROGEN  
BIOPRODUCTS



### INTERPRETATION OF RESULTS

**POSITIVE:** \*Two distinct coloured lines appear. One coloured line should be present in the control line region (C) and another in the test region (T).

\*NOTE: The intensity of the colour in the test line region (T) will vary depending on the concentration of test antigens present in the specimen. Any shade of colour in the test line region should be considered positive.

**NEGATIVE:** One coloured line appears in the control line region (C). No line appears in the test line region (T).

**INVALID:** Colour line (C) fails to appear. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for control line failure.

Review the procedure and repeat the test with a new cassette.

If the problem persists, discontinue using the cassette immediately and contact your local distributor.

### 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

1. 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.
2. Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
3. 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.
4. 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

1. The PathFlow™ Strep A Rapid Test Cassette 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 bacterium.
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.

### EXPECTED VALUE

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

Using three medical centres 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 Cassette (Throat Swab). The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO<sub>2</sub> and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were sub-cultured 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 specimen yielded positive results with the Test. This specimen was re-cultured, then re-tested and yielded a negative result – indicating potential initial cross contamination. To further investigate this false positive, three additional Strep F strains were cultured and tested for cross-reactivity and also yielded negative results.

Method	Culture		Total Result
PathFlow™ Strep A	Results	Positive	Negative
	Positive	116	9
	Negative	6	395
<b>Total Result</b>	<b>122</b>	<b>404</b>	<b>526</b>

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 Intervals

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 10<sup>7</sup> organisms per test and were all found to be negative when tested with the Strep A Rapid Test Cassette. No mucoid-producing strains were 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 gonorrhoea
Staphylococcus aureus	Group G Streptococcus	Neisseria subflava
Corynebacterium diphtheria	Streptococcus sanguis	Hemophilus influenza
Candida albicans	Staphylococcus epidermidis	Pseudomonas aeruginosa
Enterococcus faecalis		

### LIMIT OF DETECTION

The detection level of the PathFlow™ Strep A Rapid Test is 1E+07org/ml for Strep A antigen.

### INTERFERING SUBSTANCES

The following analytes were tested as interfering substances (swabs spiked with 100µl): Cherry Halls cough drops, Menthol Halls cough drops, Robitussin cough syrup, Dimetapp cough syrup, Vicks Chloraseptic spray, Cepacol Chloraseptic spray, Listerine mouthwash, Scope mouthwash. No substances showed any interference with the test.

### BIBLIOGRAPHY

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C., 1995, p. 299-307.
2. Webb, KH. Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Paediatrics (Feb 1998), 101:2, 2.
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.
4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
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-haemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Paediatrics (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.

### TABLE OF SYMBOLS

SYMBOL	DEFINITION
	Batch Code/Lot Number
	In Vitro Diagnostic Medical Device
	Catalogue Reference
	Upper and Lower Temperature Limits
	Expiry Date
	Manufacturer and Address Details
	Date of Manufacture
	Please consult IFU
	Sufficient for
	Do not use if package is damaged
	CE Mark
	Caution

This document applies to the following product codes:

**M597CE**

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