STREP A

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.

What is the Test?

• 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 carbohydrate antigens in a throat swab specimen.

What is the Disease?

• Streptococcus pyogenes is an aerobic non-motile grampositive coccus, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.

• The bacterium is transmitted via respiratory droplets, hand contact and nasal discharge - patients suffering from streptococcal pharyngitis are infective during the acute phase of illness (7-10 days) and up to 1 week afterwards.

Symptoms

• Streptococcus pyogenes is responsible for a wide array of infections; perhaps the most common being a streptococcal sore throat. Characterised by fever and enlarged tonsils (amongst others), if untreated strep throat can last for 7-10 days. · Left untreated, these infections can lead to serious

complications, including rheumatic fever and peritonsillar abscess.



· Septicaemia, otitis media, mastitis, sepsis, cellulitis, erysipelas, myositis, osteomyelitis, septic arthritis, meningitis, endocarditis, pericarditis, and neonatal infections are less common infections due to S. pyogenes.

Mortality/Morbidity – Clinical Implications

• Clinical manifestations of S. pyogenes vary by geographical location - Streptococcal pharyngitis is predominant in areas with tepid or temperate climates, with infection numbers peaking in late winter and early spring.

· Humans are the primary reservoir for group A strep with transmission largely facilitated by crowded conditions (such as schools) contributing towards the >600 million cases of pharyngitis caused by S. pyogenes worldwide each year.

 There are at least 517,000 deaths globally each year due to severe S. pyogenes infections; rheumatic fever disease alone causes 233,000 deaths.

- Rapid detection for the presence of Strep A antigens, providing results from 5 minutes.
- In-built procedural control.
- Simple and easy to use test, to be used with throat swab samples.

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Why use PathFlow®

• 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.

• 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 from 5 minutes.



Performance vs. Culture

Sensitivity: 95.1%

Specificity: 97.8%

Accuracy: 97.1%

Ordering Information

Code: M597CE

Description – PathFlow® Strep A

Size: 20 Test Kits

Storage: 2°C-30°C

Procedure



Step 1. Bring the pouch to room temperature before opening it. Remove the test cassette from the foil pouch and use it within one hour. Hold the extraction reagent 1 bottle vertically and add 4 full drops of extraction reagent 1 to an extraction tube. Hold the extraction reagent 2 bottle vertically and add 4 full drops to the tube. Mix the solution by gently swirling the extraction tube. **Step 2.** 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.

Step 3. 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.

Step 4. 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 to the sample well and then start the timer. Read the result at 5 minutes. Do not interpret the result after 10 minutes.

Distributed by:





PathFlow[®] - Leading The Way to a Better Diagnosis

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Microgen Bioproducts Ltd, Unit 1, Watchmoor Point, Camberley, Surrey GU15 3AD, United Kingdom T: +44 (0)1276 600 081 F: +44 (0)1276 600 151 E: enquiries.microgen@novacyt.com www.microgenbioproducts.com

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