MICROGEN BIOPRODUCTS

STREPTOCOCCUS PNEUMONIAE

The PathFlow[®] Streptococcus pneumoniae is an easy-to-use lateral flow immunoassay for the rapid qualitative detection of *S. pneumoniae* antigens in human urine specimens.

What is the Test?

• The PathFlow[®] *S. pneumoniae* Antigen Rapid Test Cassette is a qualitative, membrane-based immunoassay for the detection of Streptococcus pneumoniae in human urine specimen.

What is the Disease?

- *Streptococcus pneumoniae,* or pneumococcus, is a Gram-positive, alpha-haemolytic (under aerobic conditions) or beta-haemolytic (under anaerobic conditions), facultative anaerobic member of the genus *Streptococcus.*
- As a significant human pathogenic bacterium
- *S. pneumoniae* was recognised as a major cause of pneumonia in the late 19th century and is the subject of many humoral immunity studies.

Symptoms

• *S. pneumoniae* resides asymptomatically in healthy carriers, typically colonizing the respiratory tract, sinuses, and nasal cavity.

• However, in susceptible individuals with weaker immune systems, such as the elderly and young children, the bacterium may become pathogenic and spread to other locations to cause disease.

• *S. pneumoniae* is the most common etiological agent of community acquired pneumonia and meningitis in children and the elderly, and of septicaemia in those infected with HIV.



• The organism also causes many types of pneumococcal infections other than pneumonia. These invasive pneumococcal diseases include bronchitis, rhinitis, otitis media, conjunctivitis, meningitis, sepsis, osteomyelitis, septic arthritis, endocarditis, peritonitis, pericarditis, cellulitis, and brain abscess.

Mortality/Morbidity – Clinical Implications

• *S. pneumoniae* is disseminated by direct personto-person contact via respiratory droplets and by autoinoculation in people carrying the bacteria in their upper respiratory tract.

- Transmission is common; however, infection is infrequent as healthy individuals carry the bacteria asymptomatically.
- The organism has a strong presence worldwide and infection rates are highest in people <2 or >60 years of age however afflictions will occur outside of these two age groups, particularly amongst those who are immunosuppressed.

• Globally, it causes approximately 1.6 million deaths annually; of which up to 1.2 million are infants. Its prevalence is especially high in regions of widespread HIV-1 infection.

- Simple and easy-to-use single step test.
- Results available from 15 minutes considerably faster than traditional culture based diagnostic methods.
- In-built procedural control.
- Complete system, no additional reagents required.

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Why use PathFlow®

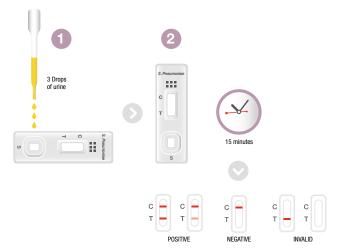
• Typically, bacterial cultivation remains the main diagnostic technique to identify invasive *Streptococcus pneumoniae* – through the growth of bacterium from sterile body fluids (such as blood/spinal fluid).

• Cultivation allows for a very accurate diagnosis and can be used to inform appropriate antimicrobial susceptibility however, the process takes time (12-48 hours).

• PathFlow[®] Streptococcus pneumoniae rapid test cassette allows for accurate diagnosis to be derived from 15 minutes – providing fast, actionable results.



Procedure



Step 1. 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.

Step 2. Swirl the urine sample gently to mix before testing. **Step 3.** Add 3 drops of homologised urine sample to the sample well.

Step 4. Wait for the colour line to appear. Read the results at 15 minutes, do not interpret the results after 20 minutes.

Performance vs. Competitor Rapid Test

Sensitivity: 90.0%

Specificity: 98.9%

Accuracy: 98.1%

Ordering Information

Code: M594CE

Description – PathFlow® Streptococcus pneumoniae

Size: 10 Test Kits

Storage: 2°C-30°C

Distributed by:		



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

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