

PathFlow™ *S. pneumoniae* antigen Rapid Test Cassette (urine) (EN)

Instructions for Use

INTENDED USE

The PathFlow™ *S. pneumoniae* Antigen Rapid Test Cassette (urine) is a rapid chromatographic immunoassay for the qualitative detection of *Streptococcus pneumoniae* antigens in human urine specimen.

SUMMARY

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*.^[1] 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. *S. pneumoniae* resides asymptotically 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. It spreads by direct person-to-person contact via respiratory droplets and by autoinoculation in people carrying the bacteria in their upper respiratory tract.^[2] It can be a cause of neonatal infections.^[3] *S. pneumoniae* is the main cause of community acquired pneumonia and meningitis in children and the elderly,^[4] and of septicemia 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.^[5]

PRINCIPLE

The PathFlow™ *S. pneumoniae* Antigen Rapid Test Cassette (urine) is a qualitative, membrane-based immunoassay for the detection of *Streptococcus pneumoniae* in urine specimen. During testing, *Streptococcus pneumoniae* (*S. pneumoniae*) antigens, if present in the specimen react with *S. pneumoniae* antibody-conjugate in the reagent area. The conjugate-antigens complex thus formed will bind with Anti-*S. pneumoniae* antibodies coated on the membrane in case of a positive result. This would result in a dark red coloured line in T line region in case of a positive result. In case of negative result, no conjugates would bind at Anti-*S. pneumoniae* coated in T line region and no line would form in T line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. A line in Control region should appear in all correctly performed cases. Absence of C line indicates an invalid test result.

REAGENTS

The *S. pneumoniae* antigen Rapid Test Cassette (Urine) contains anti-*S. pneumoniae* antibody conjugated gold particles and anti-*S. pneumoniae* antibody coated on the membrane.

MATERIALS

Provided: Test cassettes, Package insert, Droppers.

Not Provided but required: Timer, Specimen collection containers.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test cassette should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.

- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures 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 materials should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.

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.

SPECIMENS

It is advised the test is to be used in conjunction with freshly collected samples to provide optimal results. Inadequate sample collection or improper sample handling could potentially yield a false-negative result. Ensure that the specimen(s) are not treated with cleaning solutions containing formaldehyde or its derivatives.

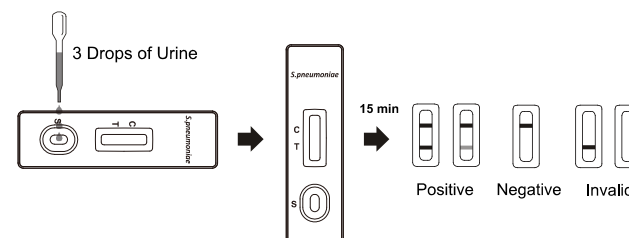
The PathFlow™ *S. pneumoniae* Antigen Rapid Test Cassette (urine) can be performed using urine. Urine specimens should be collected in standard containers. The sample can be stored at room temperature (15-30°C) if assayed within 24 hours of collection. Alternatively, specimens may be stored at 2-8°C for up to 14 days or at -10°C to -20°C for longer periods before testing. When necessary, urine specimens should be shipped in leak-proof containers at 2-8°C or frozen. Allow all specimens to equilibrate to room temperature before testing.

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.

- Swirl the urine sample gently to mix before testing. Place the cassette on a clean & level surface.
- Add 3 drops of homologised urine sample (approximately 120 µL) to the sample well.
- Wait for the colour line to appear. Read the results at 15 minutes, do not interpret the results after 20 minutes.



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.

QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal valid procedural control. It confirms that sufficient specimen volume has been used and correct procedural technique has been followed.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

EXPECTED VALUE

The *S. pneumoniae* antigen rapid Test Cassette (urine) has been compared with other rapid test, demonstrating an overall accuracy of 98.1%.

LIMITATIONS

- The PathFlow™ *S. pneumoniae* antigen Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of *S. pneumoniae* antigens in urine specimens only. Neither the quantitative value nor the rate of increase in *S. pneumoniae* antigen concentration can be determined by this qualitative test.
- This test will only indicate the presence of *S. pneumoniae* antigens in the specimen from both viable and non-viable *S. pneumoniae* bacteria.
- A negative result should be confirmed by culture. A negative result may be obtained, if the concentration of the *S. pneumoniae* antigens present in the urine is not adequate or is below the detectable level of the test.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

The performance of the PathFlow™ *S. pneumoniae* Antigen Rapid Test Cassette (urine) has been evaluated with 103 clinical specimens collected from the patient symptomatic and asymptomatic in comparison with other rapid test method. The results show that the relative sensitivity of the *S. pneumoniae* Antigen Rapid Test Cassette (Urine) is 90.0% and the relative specificity is 98.9%.

Method		Other Rapid Test		Total Result
PathFlow™	Results	Positive	Negative	
<i>S. pneumoniae</i> antigen	Positive	9	1	10
	Negative	1	92	93
Total Result		10	93	103

Relative sensitivity: 90.0% (95%CI*: 55.5%~99.7%);

Relative specificity: 98.9% (95%CI*: 94.2%~99.9%);

Accuracy: 98.1% (95%CI*: 93.2%~99.8%).

*Confidence Intervals

LIMIT OF DETECTION

S. pneumoniae antigen Rapid Test Cassette (Urine) can detect *S. pneumoniae* antigen as low as 0.25ng/ml CWPS (Cell Wall Polysaccharides).

INTERFERING SUBSTANCES

The following analytes were tested as interfering substances spiked with negative and positive (1ng/ml) samples: Acetaminophen (20mg/dl), Acetoacetic Acid (2000mg/dl), Ascorbic Acid (20mg/dl), Acetylsalicylic Acid (20mg/dl), Albumin (2000mg/dl), Bilirubin (2mg/dl), Caffeine (20mg/dl), Codeine (10mg/dl), Ephedrine (20mg/dl), EDTA (20mg/dl), Ethanol (1%), Gentic Acid (20mg/dl), Glucose (2000mg/dl) haemoglobin (1mg/dl), Methadone (10mg/dl), Methanol (10%), Phenylpropanolamine (20mg/dl), Phenothiazine (20mg/dl), Salicylic Acid (20mg/dl). No substances showed any interference with the test.

REPEATABILITY AND REPRODUCIBILITY

INTRA-ASSAY

Within-run precision has been determined by using 3 replicates of these specimens: negative, 0.25ng/ml, 1ng/ml and 5ng/ml positive specimens. The specimens were correctly identified >99% of the time.

INTER-ASSAY

Between-run precision has been determined by 3 independent assays on the same specimens: negative, 0.25ng/ml, 1ng/ml and 5ng/ml positive specimens. Three different lots of the *S. pneumoniae* Rapid Test Cassette (Urine) have been tested using these specimens. The specimens were correctly identified >99% of the time.

CROSS REACTIVITY

Cross-reactivity to urines spiked with the following 1.0×10^7 pathogens was tested and found to be negative.

Legionella pneumophila

Chlamydia

Neisseria gonococcus

Candida albicans













Helicobacter pylori

Clostridium difficile

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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:
M594CE

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