

S. pneumoniae Antigen Rapid Test Cassette (Urine)

Package Insert

A rapid test for the qualitative detection of *S. pneumoniae* Antigens in human urine specimen.

For professional *in vitro* diagnostic use only.

[INTENDED USE]

The *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-hemolytic (under aerobic conditions) or beta-hemolytic (under anaerobic conditions), facultative anaerobic member of the genus *Streptococcus*.¹ As a significant human pathogenic bacterium *S. pneumoniae* was recognized 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 persons 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 *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-antigen 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 colored 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.

[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 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 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]

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

[SPECIMEN COLLECTION AND PREPARATION]

The *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.

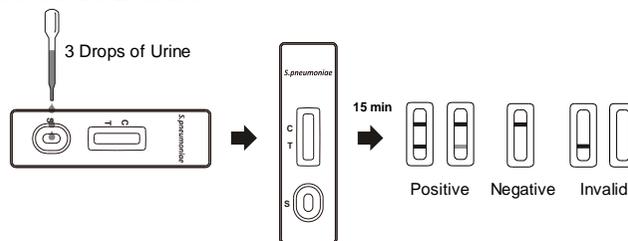
[MATERIALS]

- Materials Provided**
- Test Cassettes
 - Droppers
 - Package Insert
- Materials Required But Not Provided**
- Specimen collection containers
 - Timer

[DIRECTIONS FOR USE]

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

- Remove the test cassette from the foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the cassette on a clean and level surface.
- Absorb the urine specimen with a dropper, add **3 full drops** (approx.120ul) specimen into the sample well of test cassette vertically.
- Wait for the colored line(s) to appear. **Read results at 15 minutes.** Do not interpret the result after 20 minutes.



[INTERPRETATION OF RESULTS]

(Please refer to the illustration above)

POSITIVE: * Two lines appear. One colored line should be in the control line region (C) and the other colored line should be in the test line region (T). A positive result indicates that *S. pneumoniae* antigens are present in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of *S. pneumoniae* antigens 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 *S. pneumoniae* antigen is not present in the specimen, or is present below the detectable level of the test.

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 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 and correct procedural technique.

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.

[LIMITATIONS]

- The *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.

[EXPECTED VALUES]

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

[PERFORMANCE CHARACTERISTICS]

Clinical Sensitivity, Specificity and Accuracy

The performance of the *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%.

S. pneumoniae Antigen Rapid Test Cassette vs. Other Rapid Test

Method	Other Rapid Test			Total Results
	Results	Positive	Negative	
<i>S. pneumoniae</i> Antigen Rapid Test Cassette (Urine)	Positive	9	1	10
	Negative	1	92	93
Total Results		10	93	103

Relative Sensitivity: 90.0% (95%CI*: 55.5%–99.7%);

Relative Specificity: 98.9% (95%CI*: 94.2%–>99.9%);

Overall Accuracy: 98.1% (95%CI*: 93.2%–99.8%). *Confidence Intervals

Analytical Sensitivity (Detection Limit)

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

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

Precision

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.

[BIBLIOGRAPHY]

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