QuickStripe™ Streptococcus pneumoniae

A rapid test for the qualitative detection of *Streptococcus pneumoniae* Antigens in human urine. For professional in vitro use only.

Instruction Manual

Test kit for 20 determinations
(Catalog No. 41224)

For professional in vitro diagnostic use only
Store at 2-30°C. **Do Not Freeze**

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INTENDED USE

The QuickStripe™ Streptococcus pneumoniae is a rapid chromatographic immunoassay for the qualitative detection of *Streptococcus pneumoniae* antigens in human urine specimen.

For professional in vitro use only.

SUMMARY AND EXPLANATION

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 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. 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 OF THE PROCEDURE

The QuickStripe™ Streptococcus pneumoniae test is a qualitative, membrane based immunoassay for the detection of *Streptococcus pneumoniae* in urine specimen. During testing, *Sreptococcus pneumoiae (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 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 the T line region and no line would form in the 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 the Control region should appear in all correctly performed cases. Absence of a C line indicates an invalid test result.

REAGENTS

The QuickStripe™ Streptococcus pneumoniae test contains anti-*S. pneumoniae* antibody conjugated gold particles and anti-*S. pneumoniae* antibody coated on the membrane.

WARNING AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. 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.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at either refrigerated or room temperature (2-30ºC).
2. The test is stable through the expiration date printed on the sealed pouch.
3. The test must remain in the sealed pouch until use.
4. **DO NOT FREEZE.**

MATERIALS PROVIDED

20 pouches: Each containing
- 1 Test Cassette
- 1 Dropper

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection containers
- Timer

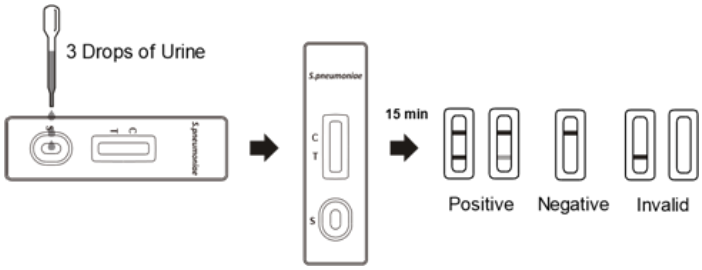
SPECIMEN COLLECTION AND HANDLING

The QuickStripe™ Streptococcus pneumoniae test 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.

PROCEDURE

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

1. Remove the test cassette from the pouch and use it within 1 hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Place the cassette on a clean and level surface.
3. Absorb the urine specimen with a dropper, add 3 full drops (approx.120ul) specimen into the sample well of test cassette vertically.
4. 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 RESULT*: 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 RESULT: 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 OF THE PROCEDURE

1. The QuickStripe™ Streptococcus pneumoniae 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.
2. This test will only indicate the presence of S. pneumoniae antigens in the specimen from both viable and non-viable *S. pneumoniae* bacteria.
3. 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.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

EXPECTED VALUES

The QuickStripe™ Streptococcus pneumoniae has been compared with other rapid tests, demonstrating an overall accuracy of 98.1%.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy
The performance of the QuickStripe™ Streptococcus pneumoniae has been evaluated with 103 clinical specimens collected from the patient symptomatic and asymptomatic in comparison with a commercial CE approved rapid test. The results show that the relative sensitivity of the *QuickStripe™ Streptococcus pneumoniae* is 90.0% and the relative specificity is 98.9%.

Method		**S. pneumoniae Rapid Kit**		**Results**
QuickStripe Streptococcus pneumoniae	**Results**	**Positive**	**Negative**	
	Positive	9	1	10
	Negative	1	92	93
Total Results			10	93

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)
QuickStripe™ Streptococcus pneumoniae 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 $1x10^7$ pathogens was tested and found to be negative for the following pathogens.

- *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 QuickStripe™ Streptococcus pneumoniae have been tested using these specimens. The specimens were correctly identified >99% of the time.

REFERENCES

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Symbols for IVD components and reagents

	Manufacturer	IVD	For *in vitro* diagnostic use only	Control +	Positive control swab
EC REP	Authorized representative		Consult instructions for use	Control -	Negative control swab
Σ n	Contains sufficient for <n> tests		Keep dry	DIL	Reagent
REF	Catalogue Code		Temperature limitation		
LOT	Lot Number		Use by		