S. pneumoniae Antigen Rapid Test Cassette (Urine)

English

CITEST DIAGNOSTICS INC.
170-422 Richards Street
Vancouver BC, V6B 2Z4, Canada

EC REP
CMC MEDICAL DEVICES & DRUGS, S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga-Spain

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 *Streptococcuspneumoniae* 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 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, septicarthritis, endocarditis, peritonitis,pericarditis, cellulitis, and brain abscess.[5]

PRINCIPLE

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

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

The kit can be stored at room temperature or refrigerated (2-30 ℃). 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 ℃) if assayed within 24 hours of collection. Alternatively, specimens may be stored at 2-8 ℃ for up to 14 days or at -10 ℃ to -20 ℃ for longer periods before testing. When necessary, urine specimens should be shipped in leak-proof containers at 2-8 ℃ or frozen. Allow all specimens to equilibrate to room temperature before testing.

MATERIALS

Materials Provided

- Test Cassettes
- Droppers
- Package Insert

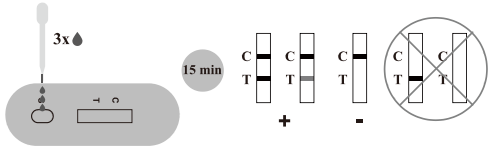
Materials Required But Not Provided

- Specimen Collection Containers
- Timer

DIRECTIONS FOR USE

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

1. 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.
2. Place the cassette on a clean and level surface.
3. Absorb the urine specimen with a dropper, **add 3 full drops** (approx.120μL) of 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: * 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

1. 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.
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.

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
***S. pneumoniae* Antigen Rapid Test Cassette (Urine)**	Results	Positive	Negative	
	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 following1.0 x 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

1. Ryan KJ, Ray CG, eds. (2004). Sherris Medical Microbiology. McGraw Hill. ISBN 0-8385-8529-9.
2. "Transmission". cdc.org. Retrieved 24 Oct 2017.
3. Baucells, B.J.; MercadalHally, M.; Álvarez Sánchez, A.T.; FiguerasAloy, J. (2015). "Asociaciones de probióticos para la prevención de la enterocolitis necrosante y la reducción de la sepsis tardía y la mortalidad neonatal enrecién nacidospretérmino de menos de 1.500g: unarevisión sistemática". Anales de Pediatría.doi:10.1016/j.anpedi.2015.07.038.ISSN 1695-4033.
4. van de Beek, Diederik; de Gans, Jan; Tunkel, Allan R.; Wijdicks, Eelco F.M. (5 January 2006). "Community-Acquired Bacterial Meningitis in Adults". New England Journal of Medicine. 354 (1): 44–53.doi:10.1056/NEJMra052116.ISSN 0028-4793.PMID 16394301.Retrieved 15 February 2017.
5. Siemieniuk, Reed A.C.; Gregson, Dan B.; Gill, M. John (Nov 2011). "The persisting burden of invasive pneumococcal disease in HIV patients: an observational cohort study". BMC Infectious.Diseases.11:314.doi:10.1186/1471-2334-11: 314. PMC3226630. PMID22078162.

INDEX OF SYMBOLS

IVD	*In vitro* diagnostic medical device
2°C 30°C	Temperature limit
	Do not use if package is damaged and consult instructions for use
REF	Catalogue number
Σ	Contains sufficient for <n> tests
	Use-by date
LOT	Batch code
	Manufacturer
	Do not re-use
	Consult instructions for use or consult electronic instructions for use
	Caution
EC REP	Authorized representative in the European Community

REF: ISP-102
Number: 145791201
Date: 2023-07-04

Digitally signed by Dolgopol Iulian
Date: 2026.05.20 13:43:51 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ