FRENOVO

Streptococcus pneumoniae Antigen Rapid Test Kit

Instructions For Use

PRODUCT NAME

Streptococcus pneumoniae Antigen Rapid Test Kit

PACKAGE SPECIFICATION

25 tests/kit

INTENDED USE

FRENOVO Streptococcus pneumoniae Antigen Rapid Test is a qualitative rapid assay which is intended to be used for the detection of Streptococcus pneumoniae antigen in urine without any dilution and as an aid in the diagnosis of pneumonia, meningitis and otitis media.

For professional use only.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Streptococcus pneumoniae (S. pneumoniae) is a gram-positive bacterium first isolated from the saliva of a patient with rabies by Pasteur in 1881. The chemical structure and antigenicity of the pneumococcal capsular polysaccharide and its association with virulence and its role in human disease were explained over the period of 1915 to 1945. The bacteria are lancet-shaped anaerobic organisms spreading by direct person-to-person contact via respiratory droplets and causing serious disease in humans: The 10 most common serotypes are estimated to account for about 62% of invasive disease worldwide. S. pneumoniae colonizes upper respiratory tract tissues causing severe pneumonia and mild/ acute earache/ otitis . Pneumococci cause 13% to 19% of all cases of bacterial meningitis in the United States . One-fourth of patients with pneumococcal meningitis also have pneumonia. Clinical symptoms are generally similar to those of other forms of purulent bacterial meningitis and include headache, lethargy, vomiting, irritability, fever, nuchal rigidity, cranial signs, seizures and coma. The case-fatality of pneumococcal meningitis is about 30% but can be as high as 80% among the elderly. Bacterial pneumonia accounts for 12-16% of invasive pneumococcal disease among children aged 2 years and younger whereas S. pneumoniae has become the leading cause of bacterial meningitis among children younger than 5 years of age in the United States. Antibiotic treatment is efficient even if more penicillin-resistant strains have been identified . Several vaccines are available with variable efficiency depending on patient age or whether patients are developing some chronic illness or immunodeficiency. Nevertheless, vaccines have been demonstrated to provide protection against pneumococcal pneumonia.

Streptococcus pneumoniae Antigen Rapid Test Kit is a qualitative rapid assay for the qualitative detection of Streptococcus pneumoniae antigen in human urine. In this test, the membrane is pre-coated with anti-Streptococcus pneumoniae antibodies on the test line region of the test. During testing,the specimen reacts with the particle coated with anti-Streptococcus pneumoniae antibodies.The mixture migrates upward on the membrane by capillary action to react with anti-Streptococcus pneumoniae antibodies on the membrane and generate a colored line.The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result.To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 25 pieces test devices individually pouched.
2. Droppers: 25 pieces droppers of 25 ul
3. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Specimen collection containers
- Disposable gloves and/or protective clothing
- Micropipette

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. FRENOVO Streptococcus pneumoniae Antigen Rapid Test Kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. FRENOVO Streptococcus pneumoniae Antigen Rapid Test is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The used test device should be discarded according to local regulations.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not use the kit past the expiration date (this date is printed on the kit box).
5. Adequate lighting is required to read the test results.

STORAGE INSTRUCTIONS

1. FRENOVO Streptococcus pneumoniae Antigen Rapid Test kit should be stored between 2-30°C and the shelf life is 24 months.
2. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
3. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

The urine specimen must be collected in a clean and dry container. For optimal detection, the first morning urine is preferred as this sample often has a higher bacteria concentration. If testing is not performed immediately, urine specimens may be stored at 2-8℃ for up to 24 hours. For prolonged storage, specimens may be frozen and stored below -20℃. Frozen specimens should be thawed and mixed well before testing.Avoid repeated freezing and thawing.

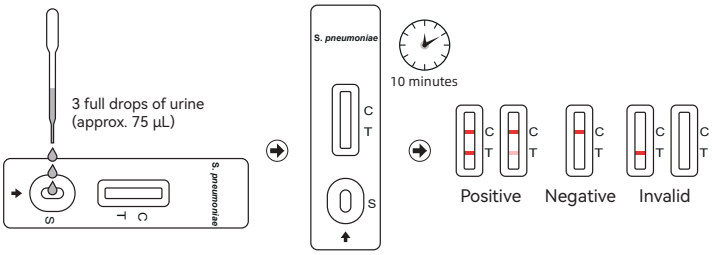
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

TEST PROCEDURE

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

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 75 µL) to the specimen well of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well. See the illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating a negative result for Streptococcus pneumoniae antigen.

Positive result: if both the quality control line C and the detection line T appear, indicating a positive result for Streptococcus pneumoniae antigen.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line, and the test shall be conducted again.

LIMITATIONS

1. Streptococcus pneumoniae Antigen Rapid Test Kit is a screening test for the presence of Steptococcus pneumoniae in urine samples.
2. A negative result does not exclude an S. pneumoniae infection. The result of this test as well as culture, serology or other antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.
3. S. pneumoniae vaccine may cause false positive results in urine up to 6 days after vaccination.
4. The test is not intended to replace PCR or culture.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

The Streptococcus pneumoniae Antigen Rapid Test Kit was compared to a leading commercial immunoassay. Results were as follows:

Clinical samples		commercial immunoassay		Total Results
Streptococcus pneumoniae Antigen Rapid Test Kit	Results	Positive	Negative	
	Positive	25	4	29
	Negative	2	98	100
Total Results		27	102	129

Clinical sensitivity=92.59% (75.71% ～ 99.09%)

Clinical specificity=96.08% (90.26% ～ 98.92%)

Accuracy=95.35% (90.15% ～ 98.27%)

CROSS-REACTIVITY

Different strains of bacteria were tested using the FRENOVO Streptococcus pneumoniae Antigen Rapid Test Kit.None cross reactivity was observed：Strep A, B, C, D, E, F, G, H；Staphylococcus Aureus；Bacillus subtitilis.

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use, Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2℃ 30℃	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don’t use the product when the package is damaged
	Biological risks		

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