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CE

IVD

Rapid-VIDITEST
Streptococcus pneumoniae

One step Card test for *in vitro* detection of *Streptococcus pneumoniae* in urine.

Instruction manual

INTENDED USE:

Rapid-VIDITEST Streptococcus pneumoniae 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 laboratory use only.

INTRODUCTION:

Streptococcus pneumoniae (S. pneumoniae) is a gram-positive bacterium (1) 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 (2). *S. pneumoniae* colonizes upper respiratory tract tissues causing severe pneumonia and mild/ acute earache/ otitis (3). Pneumococci cause 13% to 19% of all cases of bacterial meningitis in the United States (4). 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 (5). 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 (6).

PRINCIPLE:

Rapid-VIDITEST Streptococcus pneumoniae test is a qualitative rapid assay for the detection of *Streptococcus pneumoniae* antigen in urine without any dilution. The method employs a unique combination of monoclonal antibody-dye conjugate and monoclonal solid phase antibodies directed to different epitopes to selectively identify *Streptococcus pneumoniae* with a high degree of sensitivity. As the test sample is added, the labelled antibody-dye conjugate binds to the *S. pneumoniae* antigen forming an antibody-antigen complex. This complex binds to immobilized *S. pneumoniae* antibody in the test line region (T) producing a rose-pink-coloured line. In absence of *S. pneumoniae* in the sample, there will be no line present in the test line region (T). The reaction mixture continues flowing along the membrane.
Unbound conjugate binds to reagents in the control line region (C) producing a rose-pink-coloured line, indicating correct functioning of the test reagents and correct procedural technique.

MATERALS PROVIDED:

- Streptococcus Pneumoniae test cassettes
- Disposable pipettes
- Instructions for use

MATERIALS REQUIRED BUT NO PROVIDED:

- Urine collection container

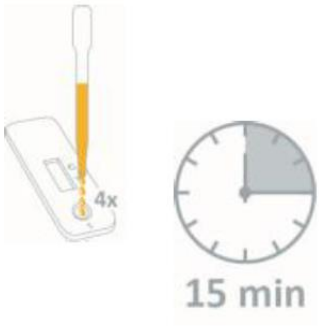
SPECIMEN COLLECTION AND PREPARATION:

Collect the urine specimen in a clean container free from detergent.
For optimal detection, the first morning urine is preferred as this sample often has a higher bacteria concentration.
If testing is not performed immediately, the specimen should be refrigerated (2-8°C) for up to 24 hours. In such case bring the specimen to room temperature prior to testing. If testing is delayed for more than 24 hours, the specimen should be frozen. The frozen specimen must be completely thawed, thoroughly mixed and brought to room temperature prior to testing. Avoid repeated freezing and thawing.

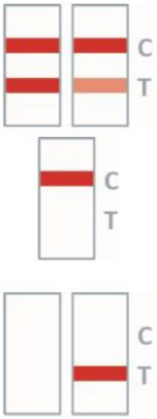
TEST PROCEDURE:

Bring samples and test cassettes to room temperature prior to testing.

1. Remove the test cassette from the foil pouch.
2. Label the test cassette with a patient's name or control number.
3. Holding a pipette vertically, fill it with urine sample and dispense 4 drops (150 µL) into the sample well (S) of the test cassette.
4. **Read the test result after 15 minutes.** Do not interpret the result after more than 15 minutes.



RESULT INTERPRETATION:



POSITIVE: In addition to the coloured line in the control line region (C) a clearly distinguishable coloured line appears in the test line region (T).

NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).

INVALID: If there is no distinct coloured line in the control line region (C), the test is invalid. It is recommended in this case that the test be repeated or a fresh urine specimen be obtained and tested later.

QUALITY CONTROL:

An internal procedural control is included in the test cassette:
A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS:

1. Rapid-VIDITEST Streptococcus pneumoniae is a screening test for the presence of *Steptococcus pneumoniae* in urine samples.
2. As with any diagnostic procedure, the physician should evaluate the data obtained with the test in the light of other clinical information, including cell culture, if the results are inconsistent with the clinical presentation.
3. The test does not differentiate between colonized and infected individuals.

   Rapid-VIDITEST Streptococcus pneumoniae cannot distinguish different pneumococcal infections potentially induced by *Streptococcus pneumoniae*.

PERFORMANCE CHARACTERISTICS:

Sensitivity and specificity

Diagnostic sensitivity and specificity
A comparative study between the BinaxNOW® Streptococcus pneumoniae rapid test and the Rapid-VIDITEST Streptococcus Pneumoniae was performed using a panel of 16 fresh urine samples and 42 stored urine samples.
The Streptococcus Pneumoniae Test vs. the BinaxNOW® pneumoniae rapid test:

Rapid-VIDITEST Streptococcus pneumoniae vs BinaxNOW® test:

		BinaxNOW® Streptococcus pneumoniae (reference method)		
		+	-	Suma
Rapid-VIDITEST Streptococcus pneumoniae	+	26	4	30
	-	7	21	28
	Total	33	25	58

From the above table, the diagnostic sensitivity of the Rapid-VIDITEST Streptococcus Pneumoniae test is 79% (26/33) and the specificity is 84% (21/25) when compared to the reference method. The overall agreement is 81% (47/58) and is satisfactory despite the fact that long storage of the 42 samples (33 positive and 9 negative) might have caused a degradation of *Streptococcus pneumoniae* antigens.

Analytical sensitivity
Serial dilutions of *Streptococcus pneumoniae* culture were performed in negative-tested urine. Dilutions were further tested with both the BinaxNOW® Streptococcus pneumoniae rapid test and the Rapid-VIDITEST Streptococcus Pneumoniae test. The results are presented in the following table and show that both tests have the same analytical sensitivity.

Streptococcus pneumoniae dilutions	Results	
	Rapid-VIDITEST Streptococcus pneumoniae	BinaxNOW® Streptococcus pneumoniae
1/50000	-	-
1/20000	+	+
1/10000	+	+
1/1000	+	+
1/100	+	+
1/10	+	+

Cross-reactivity
Different strains of bacteria were tested using the Rapid-VIDITEST Streptococcus Pneumoniae test in order to determine whether they caused non-specific reactions (cross-reactions). The results are shown in the table.

Group	Result
Streptococcus pneumoniae capsular types (8)	Positive
Strep A, B, C, D, E, F, G, H	Negative
Staphylococcus Aureus	Negative
Bacillus subtitilis	negative

Intra-assay reproducibility
The intra-assay reproducibility was evaluated by running 10 replicates of 5 samples dilution having different *Streptococcus pneumonia* concentrations. All the series showed converging results in conformance with the expected results.
Intra-lot reproducibility performance of the Rapid-VIDITEST Streptococcus Pneumoniae test is 100%.

STORAGE AND STABILITY:
Test kit components should be stored in the sealed foil pouch at room temperature (4-30°C). Do not freeze the test kit. The test is stable up to the expiry date stated on the foil pouch.

WARNINGS AND PRECAUTIONS:

- The test is for professional *in-vitro* diagnostic use only.
- Read the Instruction manual carefully before performing the test.
- Do not use the test after the expiration date stated on the foil pouch.
- Do not use the test if the foil pouch is damaged.
- Do not eat, drink or smoke in the area where specimens and test kits are handled.
- Handle all specimens as if they contained infectious agents.
- Observe established precautions for microbiological risks throughout all procedures and standard guidelines for appropriate disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being assayed.
- Humidity and temperature can adversely affect test results.

REFERENCE:

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4. Robinson, K.A., Baughman, W., Rothrock, G. Epidemiology of invasive Streptococcus pneumoniae infections in the United States, 1995-1998. Opportunities for prevention in the conjugate vaccine era. JAMA, 285 : 1729-1735, 2001.
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6. Tsai, C.J., Griffin, M.R., Nuorti, J.P. et al. Changing epidemiology of pneumococcal meningitis after the introduction of pneumococcal conjugate vaccine in the United States. Clin. Infect. Dis., 46 : 1664-1672, 2008.

POUŽITÉ SYMBOLY:

IVD	*In vitro* diagnostic device	LOT	Batch code
	Use by		Manufacturer
+2 +30	Store at 2-30°C		Do not reuse
Σ 1	Number of tests		Read instruction manual

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