STREP PNEUMONIAE

For *in Vitro* diagnostic use

Immunochromatographic rapid test for the qualitative detection of *Streptococcus pneumoniae* antigen in human urine

I. INTENDED USE

Strep Pneumoniae Mascia Brunelli is a lateral flow, immunochromatographic rapid test for the qualitative detection of *Streptococcus pneumoniae* antigen in human urine of patient with symptoms of pneumoniae. The test provides a simple and rapid diagnostic method to aid in the diagnosis of pneumococcal pneumonia, with the culture and other methods.

II. INTRODUCTION

Infection with *Streptococcus pneumoniae* is one of the leading bacterial causes of morbidity and mortality worldwide and is the principal causative agent of community-acquired pneumonia, the sixth most common cause of overall mortality in Western countries. The incidence of pneumococcal disease is highest in infants under 2 years of age and in people over 60 years of age. Recent estimates of child deaths caused by *S. pneumoniae* range from 700000 to 1 million every year worldwide. On the basis of differences in capsular polysaccharide structure *S. pneumoniae* can be divided into more than 80 serotypes that can lead to varying clinical and epidemiologic profiles.

III. PRINCIPLE

The Strep Pneumoniae test kit is a qualitative lateral flow immunoassay for the detection of *Streptococcus pneumoniae* in human urine samples.
The test band (T) and the control band (C) consist respectively of a monoclonal antibody anti S. pneumoniae, and other monoclonal antibodies adsorbed on the nitrocellulose membrane. The anti-S.Pneumoniae antibodies are conjugated to the colored particles which are dried on an inert absorbent support (conjugated antibody-colored particles). The sample, added in the circular window, migrates along the membrane and the possible presence of the antigen determines a link with the antibodies of the colored conjugate. This complex reacts with the pre-adsorbed antibodies on the membrane at the "T" zone, producing a red-purple band. In the absence of the specific antigen, no band will appear in the "T" zone. The sample continues to migrate along the filter membrane to zone "C", where a generic substrate capable of binding the second labeled antibody is also bound, giving rise to a red-purple band that serves as verification that a sufficient volume has been added, which the correct flow was obtained and as an internal control for the reagents.

IV. REAGENTS AND MATERIALS Each kit contains everything needed to perform 25 tests.
25 devices for immunochromatographic reaction containing a desiccant
Positive Control: (1 x 0.5 mL) vial with dropper containing non-infectious components, sodium azide (NaN_3) as preservative.
Plastic pipettes: 25 items
1 Instructions for use
MATERIALS REQUIRED BUT NO PROVIDED
Sample collection container, disposable gloves, timer; negative control: use saline solution.

V. STORAGE

Storage the kit at room temperature (between 2°C and 30°C). Do not freeze the test kit. The kit is stable until the expiry date stated on the package label.

VI. PRECAUTIONS

- This test is designed for *in vitro* diagnostic use and professional use only.
- Read carefully instructions leaflet before using this test.
- Do not use beyond the expiry date stated on the package label.
- All reagents and materials coming in contact with potential infectious specimens must be treated with appropriate disinfectants or autoclaved at 121°C for at least one hour.
- Wear protective clothing such as laboratory coats and disposable gloves while assaying samples. Do not eat, drink or smoke in the area where specimens and kit reagents are handled. Avoid any contact between hands and eyes or nose during specimen collection and testing.
- Do not use a test from a damaged protective wrapper.

VII. SPECIMEN COLLECTION AND PREPARATION

Urine samples (for pneumonia diagnosis)

Take the middle section of urine. Note: When taking a urinary sample, first remove the previous urination and leave the middle section. The last urination should not be retained. Collect urine in a standard container. After collection, if measured within 24 hours, store at room temperature (15-30 ℃). In addition, the urine is stored at 2-8℃ or stored frozen for 14 days. Boric acid can be used as a preservative. If necessary, urine samples can be transported in leakproof containers at 2-8 ℃ or in frozen conditions.

Note on sample processing :

1. Since removing the cellular components will reduce the sensitivity, do not centrifuge before performing this test.
2. All samples are at risk of infection, please be careful when handling.

VIII. ASSAY PROCEDURE

Do not remove device test from pouch until test sample has reached room temperature. Bring tests, urine samples, reagent and controls to room temperature (15-30°C).

1. Remove the test from its pouch just before use. Place the test on a flat surface.
2. Mix the samples first. Use a disposable pipette to drop 3 drops (about 100 µL) of sample and drop it onto the circular window of the device. Start the timer.
3. Wait and read the result at 15 minutes.

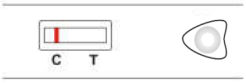
Procedure for the controls

Add the requested volume, 3 drops (100 µL), of Positive/Negative Controls into the sample well of the cassette and read the test results after 15 minutes.

IX. INTERPRETATION OF RESULTS

Positive test: In addition to the red-purple control band across the central window in the site marked with the letter C (control line), another red-purple band (test line) also appears in the site marked with the letter T (result region).

Negative test: Only one red-purple control band appears across the central window in the site marked with the letter C (control line).



Invalid: A total absence of the control coloured band. Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are likely the reasons for control line failure. Review the procedure and repeat the tests using a new test.

X. QUALITY CONTROL

Internal procedural controls are included in the test:
Red-purple line appearing in the control lines regions (C). It confirms sufficient specimen volume and correct procedural technique.

XI. PERFORMANCES CHARACTERISTICS

Minimum detection limit

This kit shows positive results when the tests are performed following the specified procedures with positive quality standard solution containing extract of Streptococcus pneumoniae, CICC10913 ($2x10^4$CFU/mL).

Cross-reactivity

The exception of Streptococcus pneumoniae No cross reactivity was observed with the following bacteria and fungi : Aspergillus niger, Acinetobacter baumannii, Bacillus cereus, Bacillus subtilis, Bacteroides fragilis, Bordetella bronchiseptica, Campylobacter jejuni, Candida albicans, Candida glabrata, Candida tropicalis, Citrobacter freundii, Clostridium difficile, Enterobacter cloacae, Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Gardnerella vaginalis, Haemophilus influenzae, Parainfluenza Haemophilus, Helicobacter pylori, Klebsiella oxytoca, Klebsiella pneumoniae, Lactobacillus casei, Legionella pneumophila, Listeria monocytogenes, Moraxella catarrhalis, Mycoplasma, Neisseria gonorrhoeae, Neisseria meningitidis, Nocardia asteroides, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Salmonella enteritidis, Serratia marcescens, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus (B, C, F, G), Streptococcus mutans, Streptococcus pyogenes.

Clinical Studies

The performance of the Strep pneumoniae MB test was compared to another immunochromatographic assay method ("Another product") at one clinical site. A total of 50 clinical specimens from suspect Strep pneumoniae patients were evaluated with the two tests.

		Another product	
		positive	negative
Strep pneumoniae MB	Positive	22	0
	Negative	0	28

Overall percent agreement: 100%

Interfering substances

Use the influences of glucose (4000 mg/dL), sodium ascorbate (1000 mg/dL), serum albumin (1000 mg/dL), urea (3000 mg/dL), calcium chloride (110 mg/dL), which showed no influence on the assessment results. If the whole blood content in the hematuria sample is ≧ 0.1%, the reagent strip will not flow or affect the interpretation, resulting in incorrect results.

XII. LIMITATIONS

- Strep pneumoniae test kit is a qualitative test and cannot determine the amount of antigen in the sample.
- A negative antigen result does not exclude infection with *Streptococcus pneumoniae*. Culture or other methods are recommended for suspected pneumoniae to detect causative agents other than *S. pneumoniae* and to recover *S. pneumoniae* when antigen is not detected in the sample.
- The diagnosis of Streptococcus pneumoniae's disease cannot be based on clinical or radiological evidence alone. There is no single satisfactory laboratory test for Streptococcus pneumoniae's disease. Therefore, culture results, serology and antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.
- Excretion of Streptococcus pneumoniae antigen in urine may vary depending on the individual patient. A positive Streptococcus pneumoniae device result can occur due to current or past infection and therefore is not definitive for infection without other supporting evidence.
- In order to prevent the quality from affecting, please keep it at 2-30°C to avoid high temperature, humidity and direct sunlight.

XIII. BIBLIOGRAPHY

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IVD	In Vitro Diagnostic Medical Device		Temperature limitation	LOT	Batch code (EXXX)		Manufacturer		Keep dry	NON STERILE	Non-sterile
	Consult Instructions for use		Use by (year/month)	REF	Catalogue number		Do not reuse		Fragile, handle with care		Keep away from heat

CONTENT (25 tests) **Ref. VQ84070P**

Devices for immunochromatographic reaction	25 items
Plastic dropper	25 items
Positive Control	1 x 0,5 mL
Instructions leaflet	1 item

EDMA CODE 15.01.11.01 CE IVD