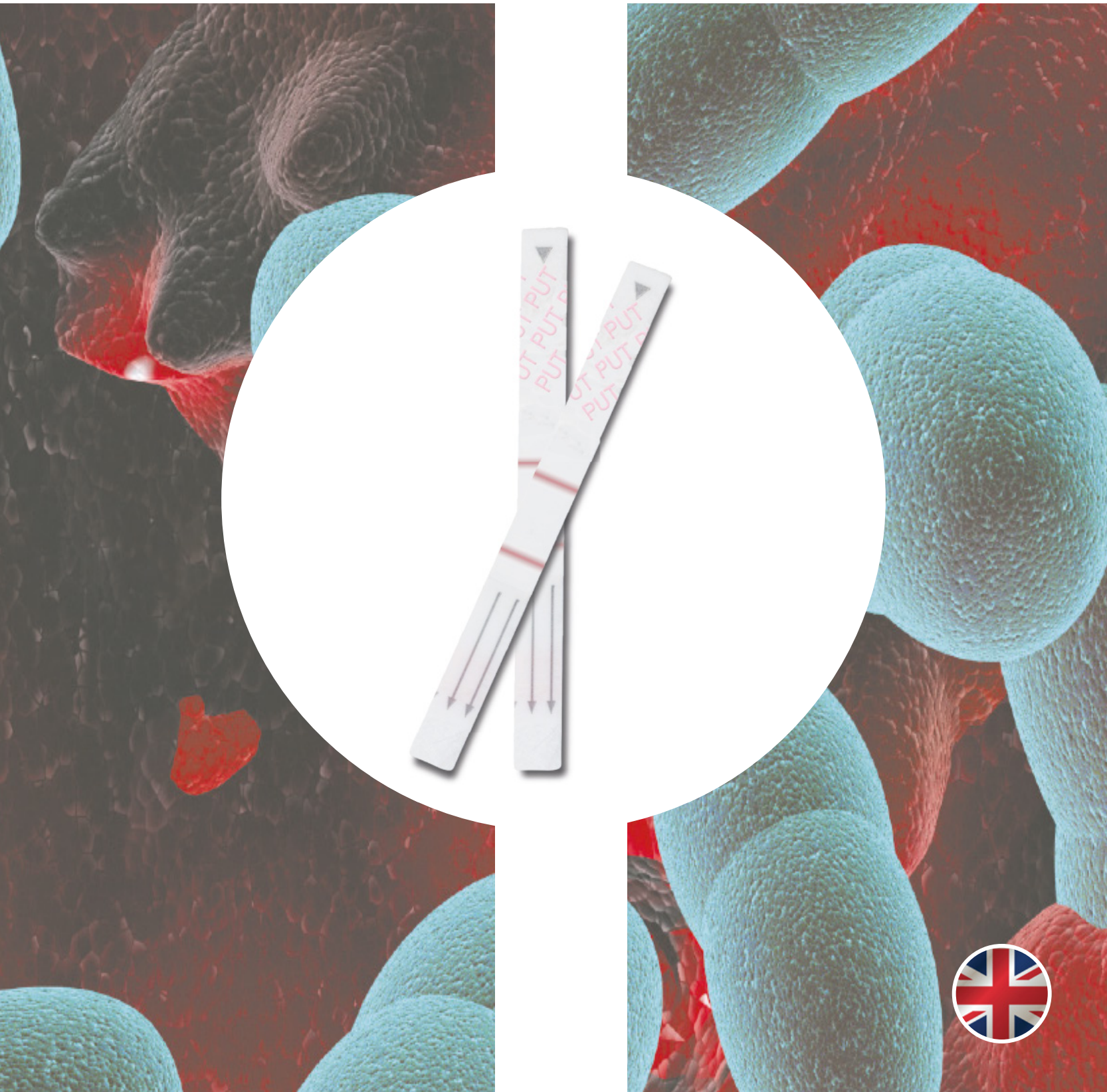
IMMUVIEW®
S. PNEUMONIAE ANTIGEN TEST

Lateral flow test for qualitative detection of
S. pneumoniae in urine and cerebrospinal fluid.

SSI DIAGNOSTICA



IMMUVIEW® S. PNEUMONIAE ANTIGEN TEST

For *in vitro* diagnostic use

Application

The ImmuView® *S. pneumoniae* Antigen Test is intended for diagnosis of *Streptococcus pneumoniae* infections by detection of urinary antigens or antigens in cerebrospinal fluid (CSF). The test is a lateral flow test also known as a lateral flow immuno-chromatographic assay.

Description

ImmuView® *S. pneumoniae* Antigen Test is a rapid lateral flow test for qualitative detection of *S. pneumoniae* antigens in human urine and CSF samples.

The test is effective in presumptive diagnosis of pneumonia and meningitis caused by *S. pneumoniae*, in conjunction with culture and other methods. Correct and early treatment is vital for the prognosis and therefore quick methods to confirm the cause of diseases in the initial phase are very important in order to initiate the proper antibiotic treatment as soon as possible.

Principle

ImmuView® *S. pneumoniae* Antigen Test is a rapid lateral flow test for detection of *S. pneumoniae*.

Limitations

- ImmuView® *S. pneumoniae* Antigen Test has not been validated to use with urine samples from children under 8 years.

- ImmuView® *S. pneumoniae* Antigen Test has been validated using urine and CSF specimens only. Other specimens (e.g. serum or other body fluids) that may contain antigen have not been validated.

- The diagnosis of an *S. pneumoniae* infection cannot be based on clinical or radiological evidence alone.

- 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.

- *S. pneumoniae* vaccine may cause false positive results in urine in ImmuView® *S. pneumoniae* Antigen test up to 6 days after vaccination.

- Reading test results before or after 15 minutes may give incorrect results.

- The test is not intended to replace PCR or culture.

Materials Provided

- 1 tube with 22 test strips
- 0.5 mL positive control for *S. pneumoniae*
- 0.5 mL negative control for *S. pneumoniae*
- 2.5 mL running buffer
- 1 tweezer
- 22 transfer pipettes
- 22 test tubes
- 1 cardboard test tube holder

Quick guide can be found on the inside of the box and on page 7.

Materials Required but not Provided

Timer. Sterile standard urine collection containers/transport tubes

Sample Collection

Collect urine sample or CSF in sterile standard sample container (urine with or without boric acid as preservatives).

If the urine sample is run within 24 hours it can be stored at room temperature. Alternatively, the sample can be stored at 2-8°C for 1 week or frozen (-20°) for 2 weeks.

CSF samples should be tested as soon as possible after sampling or be stored frozen until testing is possible.

Make sure that samples always reach room temperature before testing.

Procedure

The positive and negative controls should follow the same procedure as if it was a urine sample or CSF sample. The positive control should be visible at the control test line and the *S. pneumoniae* test line. The negative control should only be visible at the control line.

1. Bring the patient urine or CSF sample to room temperature. Whirl thoroughly prior to testing.

2. Apply a test tube in the cardboard holder.

3. Fill the transfer pipette with urine or CSF and add **3 drops** (120 µL) of sample to the test tube (hold the pipette vertically). *, **

4. Add **2 drops** (90 µL) of running buffer to the test tube (hold the buffer bottle vertically).

5. Whirl the test tube gently.

6. Take the "Test" container, open it and take out the number of test strips needed, and close it firmly afterwards.

7. Insert the test strip into the test tube.

8. Wait 15 minutes.

9. Lift the test strip out of the test tube. Read the result within **5 minutes**. ***

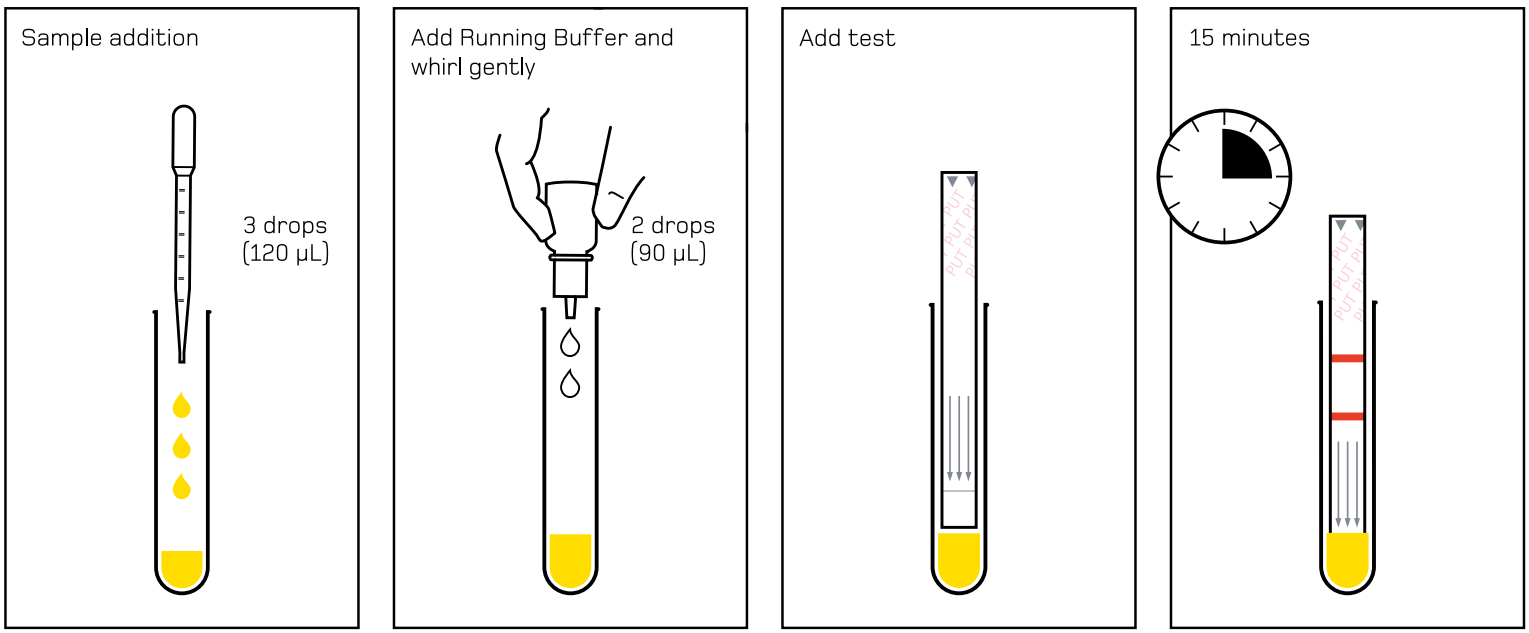
10. Discard the test strip after interpretation of the result.

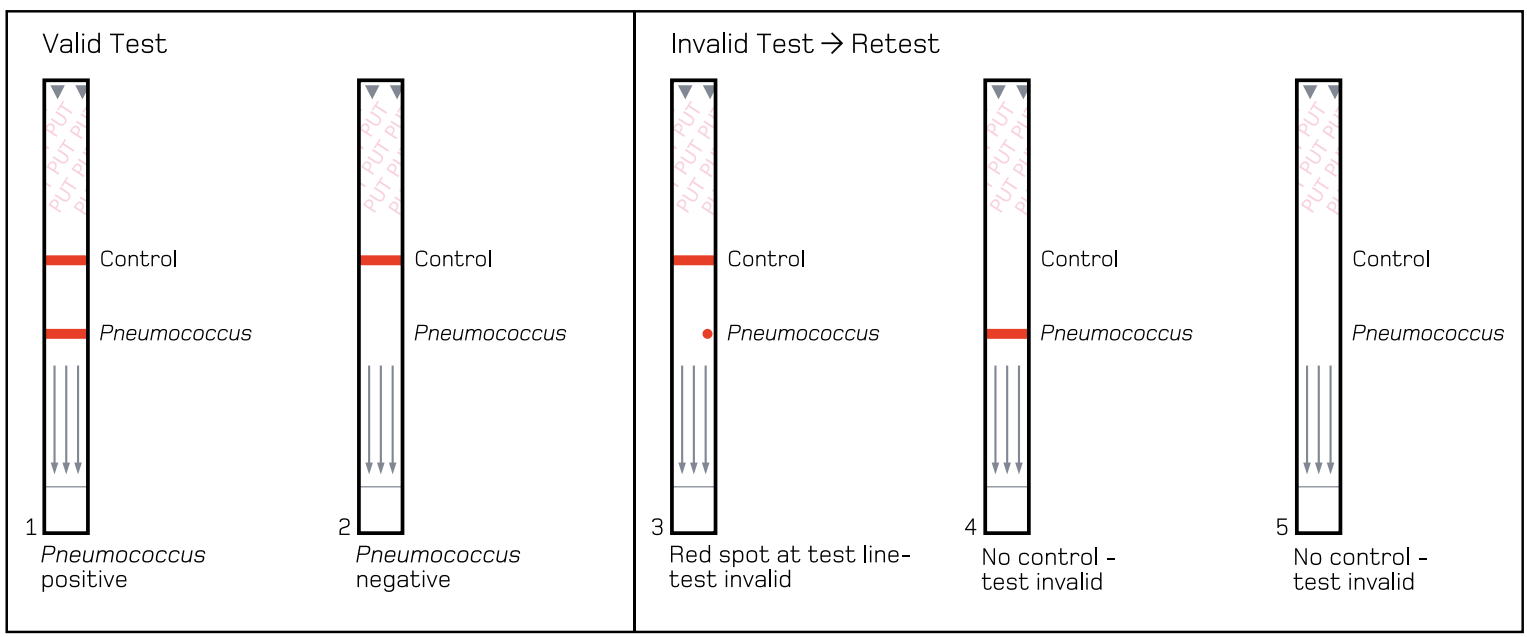
* If the urine sample contains visible blood, please confirm a positive result by boiling the sample for 10 minutes.

** The test has also been validated for using only 10µL CSF adding 200µL running buffer.

*** Otherwise the test result may be inaccurate.

Quick guide


Sample addition
3 drops
(120 µL)
Add Running Buffer and
whirl gently
2 drops
(90 µL)
Add test
15 minutes


Valid Test
Control
Pneumococcus
1
Pneumococcus
positive
Control
Pneumococcus
2
Pneumococcus
negative
Invalid Test → Retest
Control
Pneumococcus
3
Red spot at test line-
test invalid
Control
Pneumococcus
4
No control -
test invalid
Control
Pneumococcus
5
No control -
test invalid

Interpretation of results

S. pneumoniae positive will appear as a red test line in the bottom of the test. The Control test line in the top will appear red. Only a full line indicates a positive result - dots do not indicate a positive result.

A **positive sample for Pneumococcus** will show a red line for Pneumococcus positive, and at the top of the test a red Control test line will appear (see test number 1).
A **negative sample** will show a single red Control line in the top of the test (see test number 2). If a red spot is seen at *S. pneumoniae* test line the test is **invalid** and the sample should be retested (see test number 3). If no Control line is observed the test is **invalid** and the sample should be retested (see test number 4 and 5).

Clinical Sensitivity and Specificity for urine

The clinical sensitivity of the *S. pneumoniae* test line was obtained by testing retrospective urine samples from patients with a blood culture positive sample for *S. pneumoniae*.
The clinical sensitivity of the *S. pneumoniae* test line was 93% (28/30).

The clinical specificity of the *S. pneumoniae* test line was obtained by testing urine samples from patients with urinary tract infections and blood culture negative samples. The clinical specificity of *S. pneumoniae* test line was 98% (119/121).

S. pneumoniae urine

	ImmuView® *S. pneumoniae* Antigen Test
Sensitivity (n=30)	93%
Specificity (n=121)	98%

Analytical Sensitivity and Specificity for urine

To determine the analytical sensitivity and specificity of the ImmuView® *S. pneumoniae* Antigen Test a panel of the 92 known *S. pneumoniae* serotypes were tested. A panel of 116 potential cross-reactants was spiked in negative urine at a concentration of 10^7 CFU/mL. No cross-reactions were detected.

Acinetobacter (4)	*Lacto. catenaforme*	*S. mutans*
Bacillus subtilis	*Lacto. rhamnosus*	*S. parasanquis*
Bordetella pertussis	*Listeria monocytogenes*	*S. sanquis*
Branhamella catarrhalis	*M. morganii*	*S. saprophyticus*
Candida albicans (4)	*Moraxella olsoensis*	*S. thomson*
C. aquaticum (2)	*N. cineria*	*S. typhimurium*
Corynebacterium sp.	*N. gonorrhoeae (3)*	*Serratia marcescens*
E. cloacea (4)	*N. lactamica*	*Staph. aureus (6)*
E. coli (10)	*N. meningitidis*	*Staph. epidermidis (5)*
E. faecalis (5)	*N. polysak*	*Staph. saprophyticus*
E. faecium	*P. mirabilis (2)*	*Steno. maltophilia*
Enterococcus durans	*P. vulgaris (2)*	*Streptococcus group A (2)*
G. vaginalis	*Pseudomonas (2)*	*Streptococcus group B (10)*

H. influenzae (11)	*Ps. aeruginosa (4)*	*Streptococcus group C*
H. parainfluenzae	*Ps. stutzeri*	*Streptococcus group F*
K. oxytoca (2)	*S. bredeney*	*Streptococcus group G*
K. pneumoniae (3)	*S. epidermidis*	*Streptococcus group L*
Lactobacillus	*S. glostrup*	

The analytical test performance is:
Sensitivity (n = 92) 100 %
Specificity (n = 116) 100 %

Clinical Sensitivity and Specificity for CSF

The clinical sensitivity of the *S. pneumoniae* test line was obtained by testing 11 CSF samples which were culture positive *S. pneumoniae*. The specificity of the *S. pneumoniae* test line was obtained by testing 163 negative CSF samples from negative donors.

S. pneumoniae CSF

	ImmuView® *S. pneumoniae* Antigen Test
Sensitivity (n=11)	100%
Specificity (n=163)	98%*

* It was not possible to culture any bacteria from the samples which can be caused by too many times of freezing and thawing of the sample.

Storage and Shelf Life

Store at room temperature. Expiry date is printed on the package.

Quality Certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 9001 and ISO 13485.

Presafe Denmark A/S

Quality System DS/EN ISO 9001

Quality System DS/EN ISO 13485

CE

REF 98748

References

1. Jørgensen, Uldum, Sørensen, Skovsted, Otte, Elverdal. (2015) "Evaluation of a new lateral flow test for detection of *Streptococcus pneumoniae* and *Legionella pneumophila* urinary antigen." J Microbiol Methods. 116 (2015): 33-36.

Information and Ordering

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