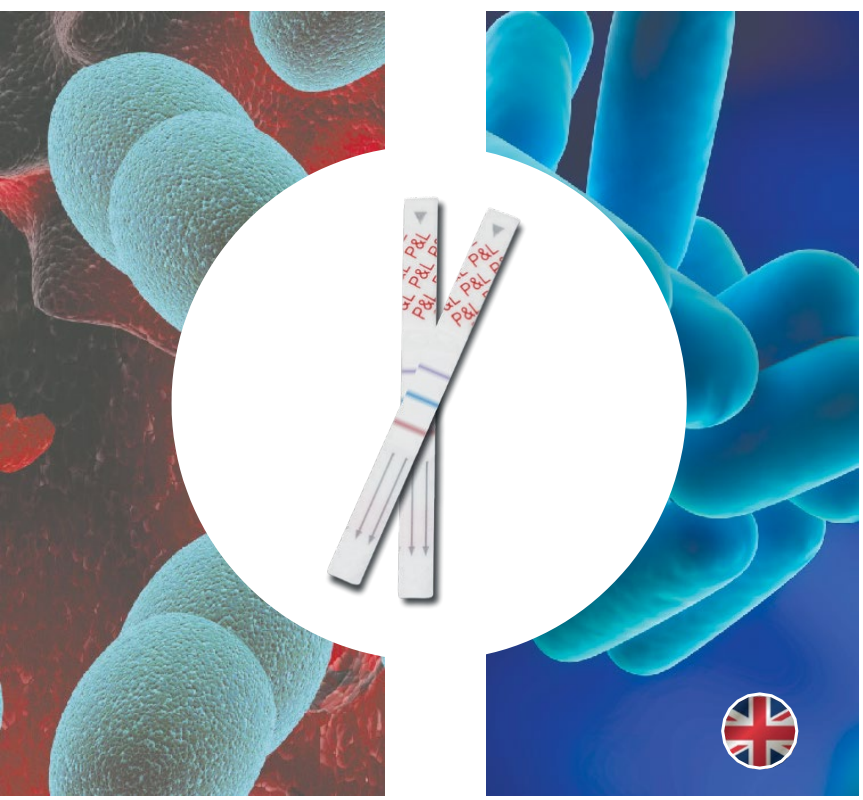
SSI Diagnostica

IMMUVIEW®

S. PNEUMONIAE AND L. PNEUMOPHILA URINARY ANTIGEN TEST

Combined lateral flow test for qualitative detection of *S. pneumoniae* and *L. pneumophila* in urine and cerebrospinal fluid.

ENGLISH



IMMUVIEW® S. PNEUMONIAE AND L. PNEUMOPHILA URINARY ANTIGEN TEST

For *in vitro* diagnostic use

Application

The ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is intended for diagnosis of *Streptococcus (S.) pneumoniae* and *Legionella (L.) pneumophila* infections by detection of urinary antigens for either or both *S. pneumoniae* and *L. pneumophila* serogroup 1. The assay is furthermore intended for diagnosis of *S. pneumoniae* infections by detection of *S. pneumoniae* antigen in cerebrospinal fluid (CSF). The test is a lateral flow test also known as a lateral flow immunochromatographic assay.

Description

ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is a rapid lateral flow test for qualitative detection of *S. pneumoniae* in human urine and CSF samples and *L. pneumophila* serogroup 1 antigens in human urine samples.

The test is effective in presumptive diagnosis of pneumococcal pneumonia caused by *S. pneumoniae* or *Legionella* pneumonia (Legionnaires' Disease) caused by *L. pneumophila* serogroup 1, in conjunction with culture and other methods. Correct and early treatment is vital for the prognosis of both diseases and therefore quick methods to confirm both diseases in the initial phase are very important in order to initiate the proper anti- biotic treatment as soon as possible.

Principle

ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test is a rapid lateral flow test for detection of *S. pneumoniae* and *L. pneumophila* using the same test.

Limitations

- ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test has not been validated to use with urine samples from children under 8 years.
- ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary 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 sensitivity of ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test when testing CSF samples has only been validated for *S. pneumoniae*.
- The diagnosis of an *S. pneumoniae* or *L. pneumophila* infection cannot be based on clinical or radiological evidence alone.

A negative result does not exclude a *Legionella* infection, as it can be caused by other serogroups and *Legionella* species. There is no single satisfactory laboratory test for Legionnaires' Disease. Therefore, culture results, PCR, serology and/or antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis

- 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* and *L. pneumophila* Urinary 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 combined positive control for *S. pneumoniae* and *L. pneumophila*
- 0.5 mL combined negative control for *S. pneumoniae* and *L. pneumophila*
- 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 9.

Materials Required but not Provided

Timer. Sterile standard urine and CSF collection containers/ transport tubes.

Sample Collection

Collect urine sample in sterile standard container (with or without boric acid as preservatives). If the 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 at least 2 weeks. Make sure that samples always reach room temperature before testing. CSF samples should be tested as soon as possible after sampling or be store frozen until testing is possible.

Procedure

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

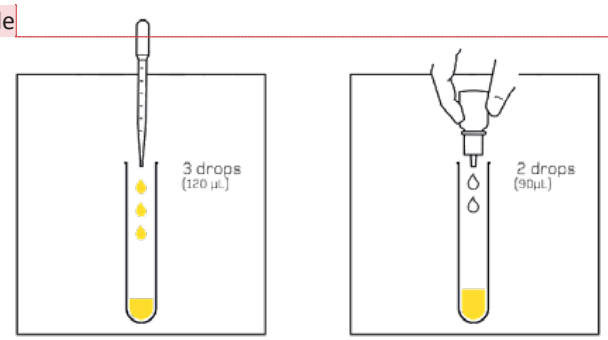
1. Bring the patient urine or CSF sample to room temperature. Whirl thoroughly prior to testing.
2. Apply a test tube in the cardboard holder.
3. Fill the transfer pipette with urine or CSF and add 3 drops (120 µL) of sample to the test tube (hold the pipette vertically). *
4. Add 2 drops (90 µL) of 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.

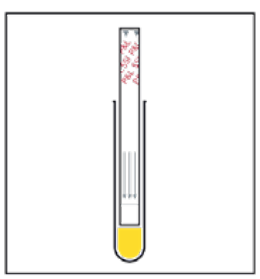
*** Otherwise the test result may be inaccurate.

Quick guide

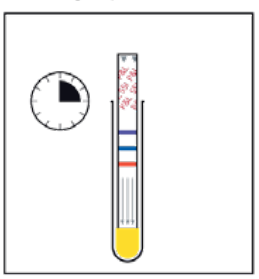


Sample addition

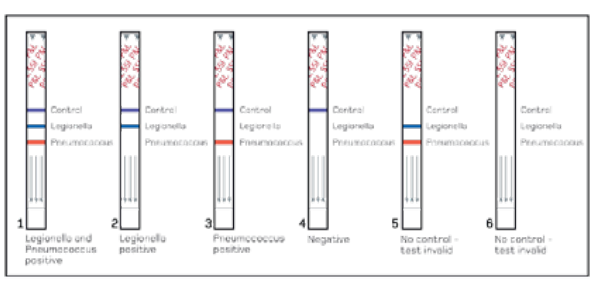
Add running buffer vertically and whirl gently



Add test



15 minutes



Results

Kommenterede [PLE(1]: Vi vil gerne have tilføjet det med grå streger og dotter i tegningen? Samt den skal deles i 2 valid and invalid ligesom PUT indlægsedlen

Interpretation of results

The Control test line in the top will appear purple/grey, but can also be more blue or red depending on whether the sample is positive for either *S. pneumoniae* or *L. pneumophila* serogroup 1. Only a full line indicates a positive result - dots do not indicate a positive result.

A **positive sample for both *Legionella* and Pneumococcus** will show a pink/red line in the bottom half of the test for Pneumo- coccus positive followed by a blue line in the middle for *L. pneumophila* serogroup 1 positive, and at the top of the test a purple/grey Control line will appear (see test number 1, page 9).

A **positive sample for *Legionella*** will show a blue line for *L. pneumophila* serogroup 1 positive, and at the top of the test a purple/grey Control line will appear (see test number 2).

A **positive sample for Pneumococcus** will show a pink/red line for Pneumococcus positive, and at the top of the test a purple/ grey Control line will appear (see test number 3).

A **negative sample** will show a single purple/grey Control line in the top of the test (see test number 4).
A negative result does not exclude an *S. pneumoniae* or *Legionella* infection, see limitations.

Note: Three grey/purple test lines do not indicate a positive result.

If three grey lines are observed the result can be confirmed by

boiling the urine sample for approx. 10 minutes. Boiling can also be used for confirmation of a positive result as *Legionella* and Pneumococcus antigens are heat stabile. Remember to let the urine sample cool down to room temperature before retesting the sample.

If no Control line is observed the test is **invalid** and the sample should be retested (see test number 5 and 6).

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 *L. pneumophila* test line was obtained by testing retrospective urine samples from patients with a confirmed Legionnaires' Disease.

The clinical specificity of the *S. pneumoniae* and *L. pneumophila* test lines was obtained by testing urine samples from patients with urinary tract infections and blood culture negative samp- les. Furthermore, no cross-reaction between *S. pneumoniae* and *L. pneumophila* serogroup 1 urine samples was detected.

Urine	ImmuView® Sensitivity	Other Rapid Tests Sensitivity
S. pneumoniae	85% (60/71)	78% (55/71)
L. pneumophila SG1	89% (88/99)	72% (71/99)
L. pneumophila non-SG1	26% (13/50)	2% (1/50)
Combined	73% (161/220)	58% (127/220)

	Specificity
S. pneumoniae	99% (75/76)
L. pneumophila	100% (76/76)
Combined	99% (75/76)

Analytical Sensitivity and Specificity for urine samples

To determine the analytical sensitivity and specificity of the ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Anti- gen Test a panel of the 92 *S. pneumoniae* serotypes, the 8 subgroups of *L. pneumophila* serogroup 1, 16 *L. pneumophila* non-serogroup 1, 4 *Legionella* species, and a panel of 116 po-

tential cross-reactants were tested. No cross-reactions were detected. The panel of 116 potential cross-reactants was spiked in nega- tive urine at a concentration of 10^7 CFU/mL.

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 = 100) 100 %. Specificity (n = 116) 100 %

Clinical Sensitivity and Specificity for CSF

The sensitivity of the *S. pneumoniae* test line was obtained by testing 12 CSF samples which were culture positive *S. pneumo- niae* and 15 CSF samples spiked with *S. pneumoniae.*
The specificity of the *S.pneumoniae* test line was obtained by testing 170 negative CSF samples from negative donors.

S. pneumoniae

	Sensitivity	Specificity
ImmuView® *S. pneumoniae* and *L. pneumophila* Urinary Antigen Test	100% (27/27)	98.8% (168*/170)

* 2 samples were tested positive and confirmed positive with both BinaxNow *S. pneumoniae* and ImmuLex *S. pneumoniae* Omni. It was not possible to culture any bacteria from thesamples, which can be caused by too many times of freezing and thawing of thesample.

The sensitivity of the *L. pneumophila* test line was not validated as only one cases of *Legionella* meningitis have been reported. The specificity of the *L. pneumophila* test line were 100% (170/170).

Storage and Shelf Life

Store at room temperature. Expiry date is printed on the pack- age.

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 95389

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.

2. Athlin, Iversen, Özenci. (2017) "Comparison of the ImmuView and the BinaxNOW antigen tests in detection of *Streptococcus pneumoniae* and *Legionella pneumophila* in urine". Eur J Clin Microbiol Infect Dis. 2017 Jun 6. doi: 10.1007/s10096-017-3016-6. [Epub ahead of print].

Information and Ordering

SSI Diagnostica A/S
2 Herredsvejen
3400 Hillerød
Denmark
T +45 4829 9100
F +45 4829 9179

@ ssidiagnostica@ssidiagnostica.com W ssidiagnostica.com
shop.ssidiagnostica.com

SSI Diagnostica A/S 2
Herredsvejen
3400 Hillerød
Denmark

T +45 4829 9100
F +45 4829 9179
@ssidiagnostica@ssidiagnostica.com
w ssidiagnostica.com

Feltkode ændret

SSI Diagnostica• 7th Edition • July 2017 • 95603