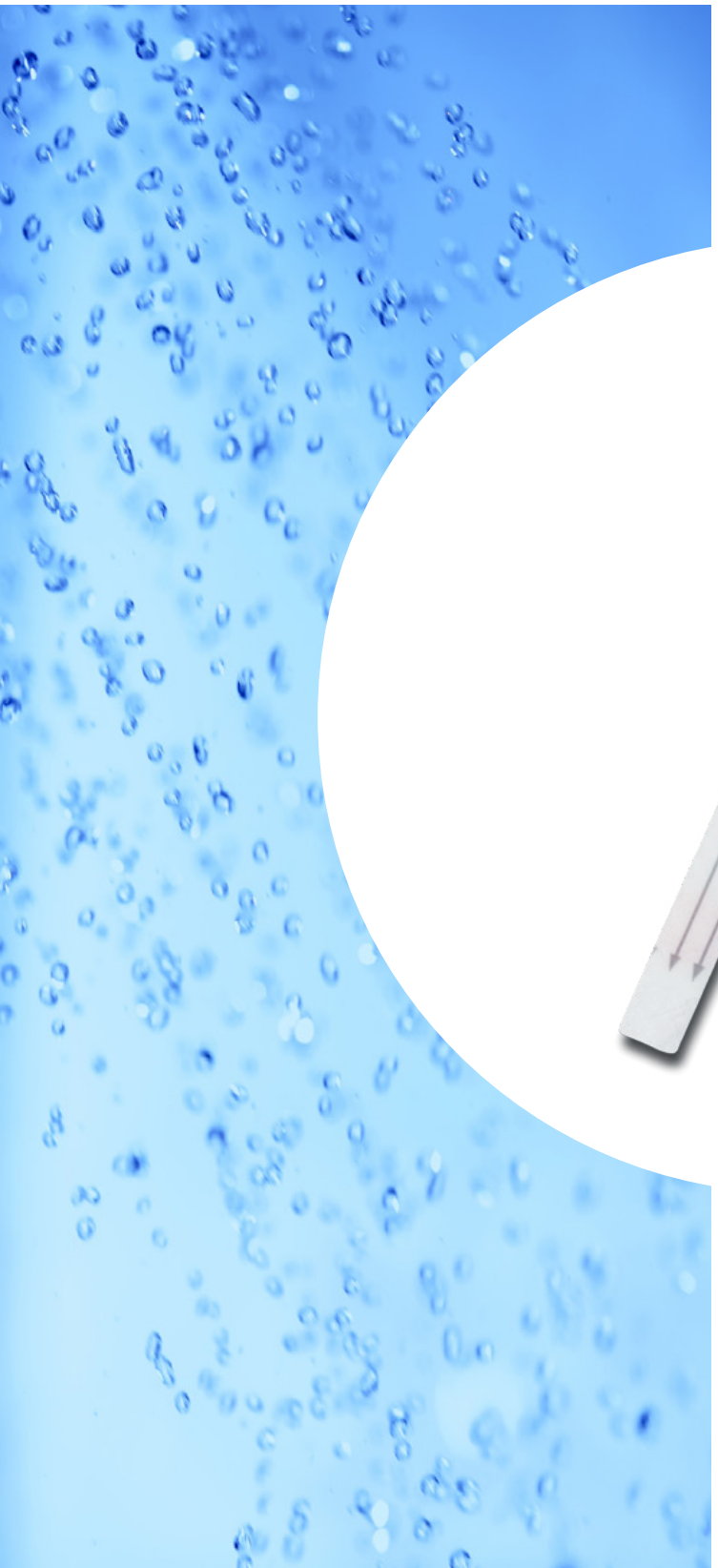
IMMUVIEW®

L. PNEUMOPHILA AND L. LONGBEACHAE URINARY ANTIGEN TEST

SSI DIAGNOSTICA



IMMUVIEW® L. PNEUMOPHILA AND L. LONGBEACHAE URINARY ANTIGEN TEST

For *in vitro* diagnostic use

Intended use

The ImmuView® *L. pneumophila* and *L. longbeachae* Urinary Antigen Test is intended for diagnosis of *Legionella pneumophila* and *Legionella longbeachae* infections by detection of urinary antigens for either or both *L. pneumophila* and *L. longbeachae*. The test is a lateral flow test also known as a lateral flow immunochromatographic assay.

Description

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

The test is effective in presumptive diagnosis of *Legionella* pneumonia (Legionnaires' Disease) caused by *L. pneumophila* or *L. longbeachae*, in conjunction with culture or other methods.

Correct and early treatment is vital for the prognosis of Legionnaires' Disease and therefore quick methods to confirm the disease in the initial phase are very important in order to initiate the proper antibiotic treatment as soon as possible.

Principle

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

Limitations

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

- The diagnosis of a *L. pneumophila* or *L. longbeachae* 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 *L. pneumophila* serogroups or *Legionella* species. There is no single satisfactory laboratory test for Legionnaires' Disease. Therefore, culture results, Polymerase Chain Reaction (PCR), serology and/or antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.

- Reading test results before 15 minutes or after 20 minutes may give incorrect results.

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

Materials Provided

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

- 1 tube with 22 test strips
- 0.5 mL combined positive control for *L. pneumphila* and *L. longbeachae*
- 0.5 mL combined negative control for *L. pneumophila* and *L. longbeachae*
- 2.5 mL running buffer
- 1 tweezer
- 22 transfer pipettes
- 22 test tubes
- 1 cardboard test tube holder

Materials Required but not Provided

Timer or stopwatch.
Sterile standard urine collection containers/transport tubes.

Sample Collection

Collect urine sample in a 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°C for 2 weeks. 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. The positive control should be visible at the control test line, the *L. pneumophila* and *L. longbeachae* test line. The negative control should only be visible at the control line.

1. Bring the patient urine 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 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, Stop watch should be used.

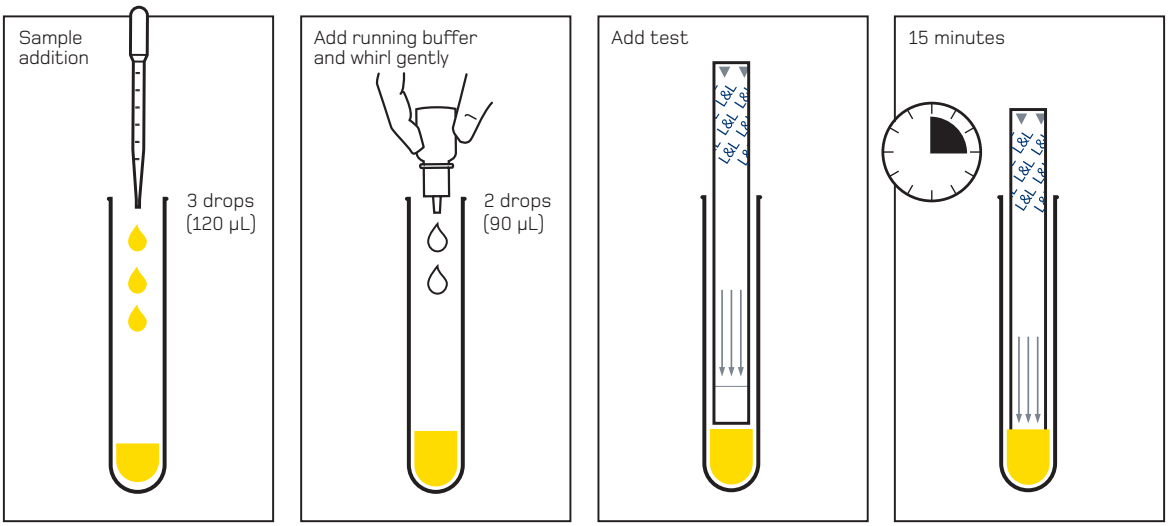
9. Lift the test strip out of the test tube. Read the result within **5 minutes**. **

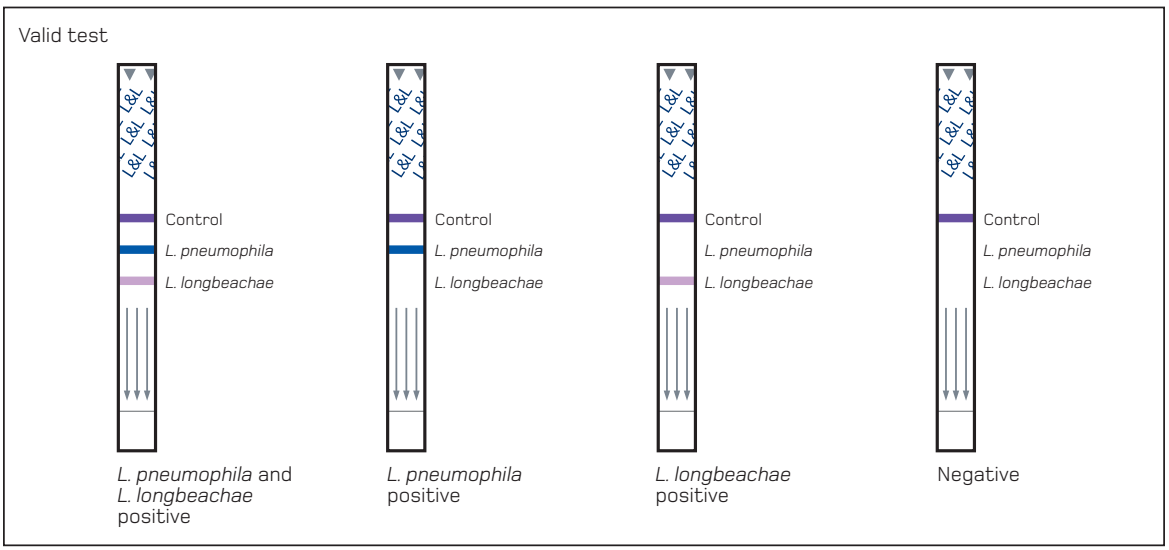
10. Discard the test strip after interpretation of the result.

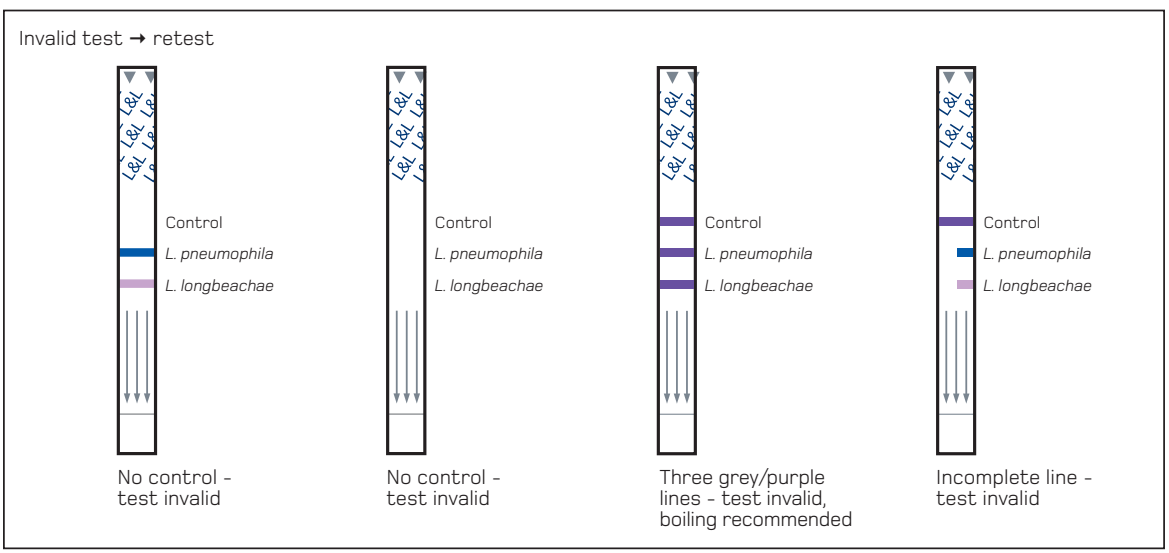
* If the urine sample contains visible blood, please confirm a positive result by boiling the sample for 10 minutes.

** 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
L. pneumophila
L. longbeachae
L. pneumophila and L. longbeachae positive
L. pneumophila positive
L. longbeachae positive
Negative


Invalid test → retest
Control
L. pneumophila
L. longbeachae
No control - test invalid
No control - test invalid
Three grey/purple lines - test invalid, boiling recommended
Incomplete line - test invalid

Interpretation of results

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

A **positive sample for both *L. pneumophila* and *L. longbeachae*** will show a purple line in the bottom half of the test for *L. longbeachae* positive followed by a blue line in the middle for *L. pneumophila* serogroup 1 positive, and at the top of the test a bluish/grey Control line will appear.

A **positive sample for *L. pneumophila*** will show a blue line, and at the top of the test a bluish/grey Control line will appear.

A **positive sample for *L. longbeachae*** will show a purple line, and at the top of the test a bluish/grey Control line will appear.

A **negative sample** will show a single bluish/grey Control line at the top of the test. A negative result does not exclude a *L. pneumophila* and *L. longbeachae* infection, see limitations.

Note: three bluish/grey lines does not indicate a positive result. If no Control line is observed the test is **invalid** and the sample should be retested.

Clinical Sensitivity and Specificity

The clinical sensitivity of the *L. pneumophila* and *L. longbeachae* test line was obtained by testing 68 prospective and retrospective urine samples from patients with a culture confirmed Legionnaires' Disease.

The clinical sensitivity for *L. longbeachae* was also obtained by testing 43 prospective urine samples from patients with a presumtive Legionnaires' Disease confirmed by an inhouse PCR assay for *L. longbeachae*.

The clinical specificity of the *L. pneumophila* and *L. longbeachae* test lines was obtained by testing urine samples from 112 patients with urinary tract infections, 52 patients with a Pneumococcus blood culture positive sample and 51 patients with pneumonia symptoms.

Furthermore, no cross-reaction between *L. pneumophila* and *L. longbeachae* urine samples was detected.

	Overall clinical test performance
Sensitivity (culture confirmed, n=68)	74% (50/68)
Sensitivity (PCR confirmed, n=43)	54% (23/43)
Specificity (n=215)	100% (215/215)

	Sensitivity
L. pneumophila SG1 (culture, n=51)	74% (38/51)
L. pneumophila non-SG1 (culture, n=1)	100% (1/1)
L. longbeachae (culture, n=15)	67% (10/15)
L. longbeachae (PCR, n=43)	54% (23/43)
Other *Legionella* species (culture, n=1)	100% (1/1)

	Specificity
Urinary tract infections (n=112)	100%
Pneumococcal pneumonia (n=52)	100%
Pneumonia symptoms (n=51)	100%

Analytical Sensitivity and Specificity

To determine the analytical sensitivity of the ImmuView® *L. pneumophila* and *L. longbeachae* Urinary Antigen Test a panel ofthe following were tested:

- 8 subgroups of *L. pneumophila* serogroup 1
- 16 *L. pneumophila* non-serogroup 1
- 2 subgroups of *L. longbeachae*
- 2 *Legionella* species

To determine the analytical specificity of the ImmuView® *L. pneumophila* and *L. longbeachae* Urinary Antigen Test a panel of 120 potential cross-reactants (see table on page 12) were tested, and they were all spiked in negative urine at a concentration of 10^7 CFU/mL.

	Overall analytical test performance
L. pneumophila SG1 (n=8)	100%
L. pneumophila non-SG1 (n=16)	100%
L. longbeachae (n=2)	100%
Other *Legionella* species (n=2)	100%
Specificity (n=120)	100%

Acinetobacter (4)	*H. parainfluenzae*	*S. mutans (2)*
Bacillus subtilis	*K. oxytoca (2)*	*S. parasanquis*
Bordetella pertussis	*K. pneumoniae (3)*	*S. sanquis*
Branhamella catarrhalis	*Lactobacillus catenaforme*	*S. thomson*
Candida albicans (4)	*Lacto. rhamnosus*	*S. typhimurium*
C. aquaticum (2)	*Lacto. sp*	*S. glostrup*
Corynebacterium sp.	*Listeria monocytogenes*	*Serratia marcescens*
E. cloacea (4)	*M. morganii*	*Staph. Aureus (6)*
E. coli (10)	*Moraxella olsoensis*	*Staph. epidermis (6)*
E. faecalis (7)	*Mycoplasma sp.*	*Staph. saprophyticus (2)*
E. faecium	*N. cineria*	*Stenotrophomonas maltophilia*
Enterococcus durans	*N. gonorrhoeae (3)*	*Streptococcus gr. A*
G. vaginalis	*N. lactamica*	*Streptococcus gr. A (colindale)*
H. influenzae a	*N. meningitidis*	*Streptococcus gr. B (10)*
H. influenzae b	*N. polysak*	*Streptococcus gr. C*
H. influenzae c	*P. mirabilis (2)*	*Streptococcus gr. F*
H. influenzae d	*P. vulgaris (2)*	*Streptococcus gr. G*
H. influenzae e	*Pseudomonas (2)*	*Streptococcus gr. L*
H. influenzae f	*Ps. aeruginosa (4)*	
H. influenzae non caps	*Ps. stutzeri*	
H. influenzae (4)	*S. bredeny*	

Limit of Detection (LOD)

Species	Pure antigen
L. pneumophila SG 1 Philadelphia	10 ng/mL
L. pneumophila SG 1 Knoxville	10 ng/mL
L. pneumophila SG 1 Olda/Oxford	10 ng/mL
L. pneumophila SG 1 Allentown/France	10 ng/mL
L. longbeachae SG 1	1 ng/mL
L. longbeachae SG 2	1 ng/mL

Interferring study

An internal validation of interfering substances was performed and included;
blood, plasma, protein, glucose, pH influence, caffeine, bilirubin levels, hemoglobin and ascorbic acid.
Each substance was tested individually and in combination at high, medium and low levels. None of the substances influenced the test results.
Two urine preservatives were tested (25 mM PIPES and Boric acid, respectively) and none of these influenced the test results.

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

Article number
98749

References
R. Podmore, M. Schousboe, D. Murdoch, Evaluation of an ImmuView Legionella longbeachae urinary antigen test for the diagnosis of pneumonia. International Legionella congress in Rome 2017, poster 26.

Publications ongoing.

Information and Ordering
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