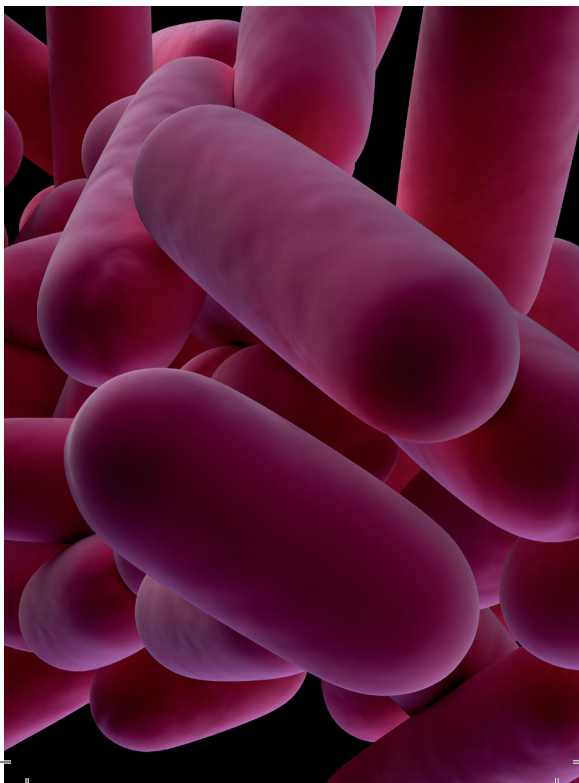


IMMUVIEW™
LEGIONELLA
BLOOD TEST

STATENS
SERUM
INSTITUT



Application

The ImmuView™ *Legionella* Blood Test from Statens Serum Institute is intended for diagnosis of *Legionella* infection by detection of IgM antibodies against *Legionella pneumophila* serogroup 1 and serogroup 3. The principle of the test is immuno-chromatography also called lateral flow. The test is for *in vitro* diagnostic and for professional use only.

Introduction

There are more than 50 known species of the genus *Legionella* of which at least 18 species have been associated with disease in humans. *Legionella pneumophila* and especially serogroup 1 and 3 are responsible for most of the infections in Europe [1,2]. *Legionella pneumoniae* is often associated with systemic manifestations, and is responsible for up to 10 % of the hospitalized pneumonia cases acquired in the community.

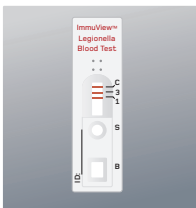
Description

The *Legionella pneumophila* serogroup 1 and 3 antigens are coated on a lateral flow membrane. The test is sold as kits containing 10 or 50 tests, respectively, including running buffer, a positive control, and a scorecard for semi-quantitative measuring. The test can be used approximately 1 - 2 weeks after onset of symptoms. If the test result is negative it is recommended to perform a new test a week later. Seroconvert is often seen in the third week of infection, but in approximately 25 % of the cases seroconvert appears in week 5 to 6.

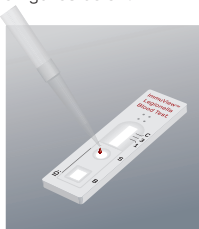
Principle

15 µL blood sample (or serum) is added to the sample port (S). Wait one minute and add four drops of run-

ning buffer to the buffer addition port (B). Read the signal after 20 minutes. See the figures below.



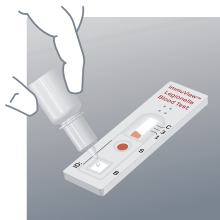
- B** Buffer addition port **1** Serogroup 1
S Sample addition port **3** Serogroup 3
C Control band



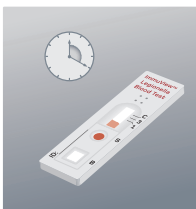
Add 15 μ L serum or blood



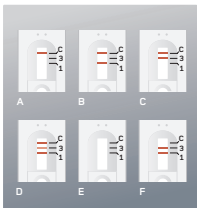
1 minute



Add 4 drops of running buffer



20 minute



- A** Negative **D** The strongest band indicates the serogroup
B Serogroup 1 **E + F** Invalid
C Serogroup 3

Material provided

ImmuView™ *Legionella* Blood Test

15 µL vacuum dried positive control sera

Running buffer

Material required but not provided

Timer

Capillary tubes

Pipette set to 15 µL

Procedure

Sample collection

Blood should be collected aseptically using venipuncture or capillary techniques. Be careful when adding anticoagulants or preservatives. Serum samples are to be refrigerated upon collection or frozen if the test cannot be performed within seven days. Samples should not be repeatedly frozen and thawed. Do not use hyperlipemic and hemolysed sera.

Sample addition

Add 15 µL blood (or serum) to the sample addition port (S). The sample should be carefully added to avoid the formation of air bubbles on the top of the blood separation pad. Do not touch the blood separation pad with the pipette tip.

Positive control

Add one drop of running buffer to the vacuum dried positive control sera. After whirl mixing add 15 µL to the sample addition port (S) as described above.

Buffer addition

Wait one minute until the serum (positive sample) has soaked through the membrane. Then add four drops

of the running buffer (100 μ L) to the buffer addition port (B), using the bottle dropper. Leave the test at room temperature for 20 minutes.

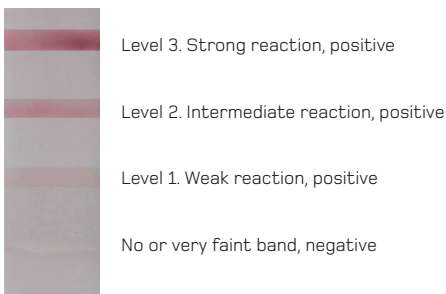
Reading the signal

A visible red serogroup 1 or 3 line represents a positive result for a previous, recent, or current serogroup 1 or serogroup 3 infection. If two bands are visible, the strongest band indicates the serogroup causing the infection. But in some cases it can reflect an infection with another serogroup. The same accounts for the case of two equally strong bands.

The control line must always be positive after 20 minutes, otherwise the test is not valid.

A rise in antibody level is defined as a significant difference in band intensity (rise from one level to a higher level) between two blood/serum samples (preferentially read the same day). A rise in antibody level is diagnostic for a current or recent *Legionella* infection.

For semi quantitative measurement the intensity of the red line can be divided as stated below:



Sensitivity

In house validation on culture positive patients:

Serogroup 1: 80 %

Serogroup 3: 96 %

False positive by testing blood donors: 2 %

Limitations

ImmuView™ *Legionella* Blood Test is intended for test of human blood or serum.

A negative result does not exclude a *Legionella* infection especially in the early phase of the infection, or if the infection is phase by another serogroup than serogroup 1 or 3, or other *Legionella* species.

Blood or serum specimens collected early in the phase of infection may not be positive in the ImmuView™ *Legionella* Blood Test because the antibody titer is too low.

A positive result indicates a current or recent infection with *Legionella pneumophila*, but the test will not discriminate between asymptomatic, non-pneumonic (Pontiac fever) or pneumonic *Legionella* infection (Legionnaires' disease).

The test is not intended to replace urinary antigen test, PCR, or cultivation.

Early antibiotic therapy may suppress antibody response and some patients may not develop antibody levels above detectable limits.

Precautions

All reagents must reach room temperature (18 - 28°C) before testing.

Use kit components only. Do not mix components from different lots of kits. Clean pipette tips must be used for every assay step.

Always handle the blood sample as potentially infectious.

Patient material and other potentially infectious material should be discarded as infectious material.

Storage and shelf life

When receiving the kit, store refrigerated at (2 - 8°C). After breaking the sealing, the tests and the buffer can be stored at room temperature (18 - 28°C) in a dark place. Expiry date is printed on the package.

Support

If there are any questions regarding the ImmuView™ *Legionella* Blood Test please contact: SSI Diagnostica, 2 Herredsvejen, 3400 Hillerød, Denmark, +45 4829 9178, microbiology@ssi.dk.

References

1. Legionella pneumonia 2008, Statens Serum Institut, EPI-News no 40, 2009 and Legionella pneumonia 2007, Statens Serum Institut, EPI-News no 22, 2008.
2. Joseph CA, Ricketts KD (2010) Legionnaires' Disease in Europe 2007-2008. Eurosurveillance 15(8):25, February Article 4.

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