

SERION ELISA *classic*

Legionella pneumophila 1-7 IgG / IgM

SERION ELISA *classic* Legionella pneumophila 1-7 IgG and IgM tests are quantitative and qualitative immunoassays for the detection of human antibodies in serum or plasma directed against *Legionella pneumophila* serotypes 1 to 7. The assays are recommended to complement the findings of direct detection methods and for differential diagnosis in case of atypical pneumonia.



Electron micrograph of *Legionella pneumophila* in a lung fibroblast (Source: Centers for Disease Control and Prevention, United States Department of Health and Human Services).

Pathogen

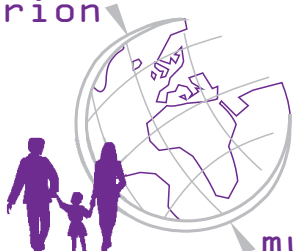
Legionella belongs to the family of *legionellaceae*, genus *Legionella*. It is a gram-negative, aerobic, pleomorphic non-spore-forming bacillus which is motile by means of a single or multiple polar or subpolar flagella. The *legionellaceae* comprises more than 45 species, which are subdivided into various serovars. The most important human pathogen is the species *Legionella pneumophila* which comprises 14 serovars. Most Legionella-associated pneumonias (80 - 85 %) are caused by serovars 1 to 6.

Disease

The classic legionellosis (Legionnaires' disease) starts 2 to 10 days after infection with uncharacteristic prodromal symptoms such as general indisposition, headache, muscle aches and dry cough, chest pain, chill, temperature rise to 39 to over 40 °C. Occasionally gastrointestinal disturbances accompanied by diarrhoea and vomiting may be early onset symptoms. In 2 to 5 % of cases, severe pneumonia may result from the infection by *Legionella pneumophila* with lethality varying from 10 to 20 %. If not treated, lethality of immunosuppressed patients may increase up to 80 %.

The so-called Pontiac fever is a benign, non-pulmonary form of legionellosis characterized by a short incubation period

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of one to two days and mild, influenza-like course of disease. The disease starts with headache, muscle- and chest pain, cough and fever. Despite severe discomfort, patients generally recover completely within five days.

Diagnosis

Direct pathogen detection in culture or in direct immunofluorescence assays (DFA) are of primary importance because fast diagnosis is often decisive for the patient. Sputum, tracheobronchial secretion and pleura punctates are ideal sample materials. However, the performance of the direct detection methods in culture or DFA is limited, since maximum sensitivities from 50 to 60 % are described for both techniques.

The SERION ELISA *classic* Legionella pneumophila 1-7 IgG and IgM are based on a mixture of the diagnostic relevant serovars 1 to 7.

Validation of SERION ELISA *classic* Legionella pneumophila

138 sera originated from different French cities, were provided by the National Reference Center for Legionella (Lyon, France). These sera were taken from 82 patients during the years 1998 and 1999. Selection and classification of sera was performed according to *Legionella pneumophila* antibody titers determined by IFT. These sera were tested in parallel with SERION ELISA *classic* Legionella pneumophila 1-7 IgG and IgM and in different in-house IFTs.

The determination of sensitivities and specificities of SERION ELISA *classic* Legionella pneumophila 1-7 was performed using the IFT as reference (gold standard).

SERION ELISA <i>classic</i>	Sensitivity	Specificity
L. pneumophila IgG / IgM	94,3 %	82,5 %

Precision

The intra- and interserial precisions were determined by the analysis of serum samples of different reactivities.

SERION ELISA *classic* Legionella pneumophila 1-7 IgG

Sample	Mean Value OD	Intraassay CV (%) (n=20)	Mean Value OD	Interassay CV (%) (n=10)
weak positive	0,721	7,1	0,663	11,6
positive	0,833	9,1	0,829	10,2
strong positive	1,092	6,6	2,733	8,6

SERION ELISA *classic* Legionella pneumophila 1-7 IgM

Sample	Mean Value OD	Intraassay CV (%) (n=20)	Mean Value OD	Interassay CV (%) (n=10)
neg. or. pos.	0,301	9,8	0,690	16,7
positive	0,846	10,2	1,469	15,3
strong positive	1,092	8,8	3,390	1,9

Order Information

SERION ELISA *classic* Legionella pneumophila 1-7 IgG
SERION ELISA *classic* Legionella pneumophila 1-7 IgM
Reference serum Legionella pneumophila 1-7 IgG
Reference serum Legionella pneumophila 1-7 IgM

Order Nr.: ESR 106 G
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