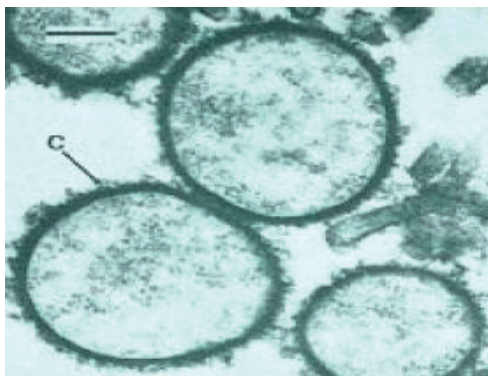


## SERION ELISA *classic*

# Mycoplasma pneumoniae IgA / IgG / IgM

SERION ELISA *classic* Mycoplasma pneumoniae IgA, IgG and IgM tests are quantitative and qualitative immunoassays for the detection of human antibodies, directed against *Mycoplasma pneumoniae*, in serum or plasma. The use of these products to detect individual immunoglobulin classes provides information regarding exposure to the pathogen and disease state.



Electron micrograph of *Mycoplasma*.

### Disease

*Mycoplasma pneumoniae* infections are responsible for a variety of respiratory syndromes which range from trivial to life-threatening, with primary atypical pneumonia, pharyngitis and tracheobronchitis being the most common clinical manifestations. The frequency of infection is illustrated by the fact that each year approximately 20% of ambulatory cases of pneumonia in the USA are the result of *M. pneumoniae* infection.

Various clinical symptoms, particularly the presence of atypical pneumonia may complicate the identification of the causal agent when dealing with *M. pneumoniae* infections (e.g. RSV-, Influenza Virus-infections). *Mycoplasma pneumoniae* colonizes epithelia of the trachea, bronchia and bronchiolae leading, after an incubation time of 10-20 days, to non-specific symptoms such as headache and fever accompanied by a non-productive, dry cough. During the course of infection an interstitial pneumonia may develop.

*M. pneumoniae* is responsible for some 15-20 % of ambulant obtained cases of pneumonia in older children and young adults. Super infections with *M. pneumoniae* after viral (e.g. measles) or bacterial infections (e.g. *Streptococcus pneumoniae*) are observed primarily in children.

*Mycoplasma pneumoniae* infections in children younger than 5 years of age are often asymptomatic or associated with mild symptoms of the respiratory tract. Immunity following infection is not complete and consequently repeated infections, which can be protracted and more severe, are possible.

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## Diagnosis

The variety of clinical symptoms and possible causal agents requires that diagnosis not be limited to the clinical picture alone. Serological and direct detection methodologies must be employed to identify the pathogen responsible and so enable appropriate medical intervention strategies to be employed. The CFT has been used for many years in *M. pneumoniae* diagnosis; however it suffers from low specificity due to the cross-reactive nature of the LPS on which it is based. ELISA tests use more specific antigen preparations and are able to differentiate between immunoglobulin classes so improving the diagnostic value of the results obtained.

### Validation of SERION ELISA *classic M. pneumoniae*

For validation of SERION ELISA *classic Mycoplasma pneumoniae* IgG and IgM 11 serum samples from patients with clinically confirmed infection, 31 serum samples from patients with suspected mycoplasma infection, 58 serum samples from patients where mycoplasma infections could not be excluded and 59 serum samples from patients with improbable mycoplasma infection were analysed. The results were compared with the test results of ELISAs of two leading European manufacturers. Sera classified as borderline were not included in the calculation.

### Sensitivity and Specificity

SERION ELISA <i>classic</i>	Sensitivity	Specificity
Mycoplasma pneumoniae IgA	76,9 %	96,1 %
Mycoplasma pneumoniae IgG	> 99 %	88,9 %
Mycoplasma pneumoniae IgM	96,4 %	92,9 %

## Precision

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

### SERION ELISA *classic Mycoplasma pneumoniae* IgA

sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
weak positive	0,525	7,1	0,578	6,4
positive	1,155	8,6	1,295	7,1

### SERION ELISA *classic Mycoplasma pneumoniae* IgG

sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
weak positive	0,835	4,9	0,906	11,6
positive	1,269	4,7	1,470	6,9
strong positive	1,562	4,2	1,790	5,9

### SERION ELISA *classic Mycoplasma pneumoniae* IgM

sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
negative	0,375	7,7	0,434	12,8
positive	1,581	7,2	1,823	5,5
strong positive	1,702	7,9	1,943	8,3

## Order Information

**SERION ELISA *classic Mycoplasma pneumoniae* IgA**

**Order Nr.: ESR 127 A**

**SERION ELISA *classic Mycoplasma pneumoniae* IgG**

**Order Nr.: ESR 127 G**

**SERION ELISA *classic Mycoplasma pneumoniae* IgM**

**Order Nr.: ESR 127 M**

**Reference serum Mycoplasma pneumoniae IgA**

**Order Nr.: BR 127 A**

**Reference serum Mycoplasma pneumoniae IgG**

**Order Nr.: BR 127 G**

**Reference serum Mycoplasma pneumoniae IgM**

**Order Nr.: BR 127 M**

Please visit our website [www.virion-serion.com](http://www.virion-serion.com) for more information on our SERION ELISA *classic* products.

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