

Intended use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against *Mycoplasma pneumoniae*
- Differential detection of the different antibody classes facilitates the confirmation of contact with the organism and supports the categorization of the disease stage
- · Detection IgA antibodies is particularly recommended to determine reinfections

Diagnostic Efficiency

The diagnostic performance characteristics of SERION ELISA *classic* Mycoplasma pneumoniae IgA, IgG and IgM were determined by analyzing sera of patients with a suspected infection, as well as blood donor sera, in comparison to results obtained from commercially available ELISA tests of competitors. The SERION ELISA *classic* Mycoplasma pneumoniae IgG test compensates for the background seroprevalence in the population and records only clinically relevant antibody activities.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Mycoplasma pneumoniae IgA	77.1%	95.7 %
SERION ELISA <i>classic</i> Mycoplasma pneumoniae IgG	99.0 %	95.5 %
SERION ELISA <i>classic</i> Mycoplasma pneumoniae IgM	91.3 %	95.5 %

Precision

SERION ELISA classic Mycoplasma pneumoniae IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.272	10.2	0.358	11.7
Serum 2	0.525	7.1	0.578	6.4
Serum 3	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)
Serum 1	0.835	4.9	0.906	11.6
Serum 2	1.269	4.7	1.467	6.9
Serum 3	1.562	4.2	1.790	5.9

value (OD) CV (%) (n=20)

Sample Mean Intraassay Mean Interassay value (OD) **CV (%)** (n=10)Serum 1 0.375 7.7 0.434 12.8 Serum 2 7.2 1.823 5.5 1.581 Serum 3 1.702 79 1.943 83

SERION ELISA classic Mycoplasma pneumoniae IqM

Pathogen

Mycoplasma pneumoniae is a worldwide distributed bacterium, which is not surrounded by a rigid cell wall. With a diameter of 0.2 µm, the organism belonging to the class of *Mollicutes* is one of the smallest human pathogens. It possesses a special organelle that allows attachment to the ciliated epithelium in the respiratory tract. The adhesion is mediated by the highly immunogenic P1-Adhesin (168 kDa).

Disease

Mycoplasma pneumoniae is the most important causative agent of atypical pneumonia. Despite the high seroprevalence, 10-15% of all pneumonias are caused by this pathogen. Children and elderly people are particular at risk of Mycoplasma pneumoniae infection, which may manifest with tracheobronchitis, laryngitis, meningitis and otitis media. Furthermore, disorders of the haematopoietic system, the central nervous system and the cardiovascular system can occur.

Diagnosis

The variety of clinical symptoms of atypical pneumonias and possible causative agents requires a diagnosis that is not exclusively limited to the clinical picture. Serological and direct detection methods can be employed to identify the pathogen and so enable appropriate medical intervention strategies. The direct detection of Mycoplasma pneumoniae by cultivation is difficult and time-consuming. Faster results are achieved by complement fixation tests (CFT). Meanwhile, sensitive and specific ELISA tests are available in order to differentiate between immunoglobulin classes so improving the diagnostic value of the results obtained.

Highlights

- Use of enriched P1-Adhesin from Mycoplasma pneumoniae for the specific detection of all relevant antibody classes
- · Sensitive IgM detection for the diagnosis of acute infections, particularly in children and teenager
- Sensitive demonstration of IgA antibodies for the diagnosis of acute re-(infections), particularly in adults
- Exclusion of background seroprevalence of IgA and IgG antibodies resulting in the specific detection of clinically relevant antibody activities
- · Alternative IgG borderline ranges for children (analytical borderline)
- · Quantitative determination of IgA, IgG and IgM antibodies for the analysis of paired sera for disease stage monitoring and therapy

Product	Order No.
SERION ELISA <i>classic</i> Mycoplasma pneumoniae IgA	ESR127A
SERION ELISA <i>classic</i> Mycoplasma pneumoniae IgG	ESR127G
SERION ELISA <i>classic</i> Mycoplasma pneumoniae IgM	ESR127M

SERION ELISA control

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