

Intended use

- Qualitative and quantitative detection of human IgA, IgG and IgM antibodies in serum or plasma directed against *Chlamydia pneumoniae*
- · Support in the diagnosis and differentiation of acute, recent and chronic infections

Diagnostic Efficiency

The evaluation of SERION ELISA *classic* Chlamydia pneumoniae IgA and IgG (IgM) tests were performed by the analysis of 79 (100) serum samples from adult blood donors and 140 (25) samples from patients with suspected infection. The ELISA of an European manufacturer were used as references.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Chlamydia pneumoniae IgA	96.4%	90.5%
SERION ELISA <i>classic</i> Chlamydia pneumoniae IgG	98.1%	96.0 %
SERION ELISA <i>classic</i> Chlamydia pneumoniae IgM	95.0 %	97.9 %

Precision

SERION ELISA classic Chlamydia pneumoniae IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.461	4.2	0.494	6.3
Serum 2	0.544	4.9	0.589	7.1
Serum 3	1.543	3.7	1.608	4.9

SERION ELISA classic Chlamydia pneumoniae IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.282	2.3	0.270	6.3
Serum 2	0.629	3.5	0.624	4.2
Serum 3	2.061	1.5	2.082	2.6

Pathogen

Chlamydiae are gram-negative, obligat intracellular bacteria. Characteristically, the chlamydial cell wall lacks a peptidoglycan layer. Only the species *Chlamydia trachomatis*, *Chlamydia pneumoniae* (also referred to as *Chlamydophila pneumoniae*) and *Chlamydia psittaci* (also referred to as *Chlamydophila psittaci*) are relevant to human disease.

Disease

Chlamydia pneumoniae is an airborne pathogen spread by inhaled droplets. Infections with *C. pneumoniae* are often asymptomatic or mild. The spectrum of clinical symptoms comprises pharyngitis, sinusitis, bronchitis, pneumonia and myocarditis or endocarditis. Infection may occasionally lead to chronic disease resulting in immunopathological syndromes such as erythema nodosum, arthralgia, Guillain-Barré Syndrome (GBS), or myalgia. In addition, chronic infections with *C. pneumoniae* are implicated with the etiology of asthma, COPD, atherosclerosis and cardiovascular disease. Approximately 10 % of all cases of pneumonia as well as around 5 % of infections of the upper respiratory tract are caused by *Chlamydia pneumoniae*.

Product	Order No.
SERION ELISA <i>classic</i> Chlamydia pneumoniae IgA	ESR1371A
SERION ELISA <i>classic</i> Chlamydia pneumoniae IgG	ESR1371G
SERION ELISA <i>classic</i> Chlamydia pneumoniae IgM	ESR1371M

SERION ELISA control

Please visit our website for more information.

SERION ELISA classic Chlamydia pneumoniae IgM

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.312	4.0	0.470	11.4
Serum 2	0.563	4.6	0.792	8.8
Serum 3	1.922	2.3	2.230	2.7

Diagnosis

Diagnosis of a *Chlamydia pneumoniae* infection is usually based on serological analysis by detection of specific serum antibodies. In the past, the microimmunofluorescence (MIF) test has been used as a reference method. However, it is increasingly replaced by species-specific ELISA tests, which allow for better standardization and automation. Seroprevalence rates rise rapidly in preschool age and reaches >50 % after adolescence. Later on in life, the prevalence of *C. pneumoniae* increases even further due to frequently reoccurring infections and due to its propensity to lead to chronic disease. Beyond 65 years of age, seroprevalence may reach 70–100 %. Seroprevalence rates for IgA are barely lower (approximately 60–70 %) than for IgG.

Highlights

- Use of Complexes of Outer Membrane Proteins (COMCs) from elementary bodies of *Chlamydia* pneumoniae
- Demonstration of Chlamydia pneumoniae species-specific IgA, IgG and IgM antibodies and reduced cross-reactivities with antibodies directed against other Chlamydia ssp.
- Sensitive IgM detection for the demonstration of acute primary infections
- Specific IgA and IgG detection by exclusion of background seroprevalence in order to support the diagnosis and differentiation of acute, recent and chronic infections
- Quantification of antibody activities, starting in the clinically negative measurement range, for the analysis of paired sera for disease stage monitoring and therapy control