

Intended Use

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

Diagnostic Efficiency

The validation of the SERION ELISA *classic* Chlamydia IgA and IgG tests was performed in an internal study by the analysis of 105 serum samples from adult blood donors and more than 90 samples from patients with suspected *Chlamydia* or *Chlamydophila* infection, in particular ornithosis caused by *Chlamydophila psittaci*. The species-specific SERION ELISA *classic* Chlamydia pneumoniae and Chlamydia trachomatis IgG immunoassays were used as reference tests.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Chlamydia IgA	>99%	>99%
SERION ELISA <i>classic</i> Chlamydia IgG	95.0 %	95.1%

Precision

SERION ELISA classic Chlamydia IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.561	4.2	0.552	7.6
Serum 2	0.799	3.1	0.822	8.3
Serum 3	1.300	1.8	1.203	12.2

SERION ELISA classic Chlamydia IgG

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.377	1.7	0.367	3.8
Serum 2	0.883	1.4	0.889	3.8
Serum 3	1.639	1.7	1.703	1.9

Pathogen

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

Disease

Infections with *Chlamydia* can affect the mucous membranes in the eye, airways and genitals and may lead to serious damage. *Chlamydia trachomatis* infection is the most common sexually transmitted bacterial disease in Europe and may result in ectopic pregnancy, premature birth, sterility and arthritis. Untreated chlamydioses are the primary cause of blindness in developing countries. Around 5 to 15% of all cases of pneumonia contracted outside of hospitals are due to infection with *Chlamydia pneumoniae* transmitted through the air by droplets from person to person. Older people and those with weakened immune systems are particularly susceptible.

Chlamydia psittaci is the causative agent of ornithosis (Psittacosis) which occurs worldwide. The natural reservoirs are birds. Transmission occurs by inhalation of aerosols or dust containing the organism. Following an incubation time of around six to 20 days ornithosis manifests as atypical bronchopneumonia with flu-like symptoms, but other organs may also be afflicted.

Diagnosis

Approximately two weeks after the first symptoms of a primary infection an increase of the IgA and IgM antibody activity occurs, which peaks after five weeks and usually declines by the 10th week. The IgG antibody activity reaches a maximum around week twelve and remains detectable for several years. In cases of reinfection IgA and IgG antibodies reappear rapidly.

Highlights

- Demonstration of genus-specific IgA and IgG antibodies against humanpathogen *Chlamydia* and *Chlamydophila* (incl. *Chlamydophila psittaci*)
- IgA detection for the demonstration of acute infections, in particular ornithoses
- Specific 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

Produkt	Order No.
SERION ELISA <i>classic</i> Chlamydia IgA	ESR137A
SERION ELISA <i>classic</i> Chlamydia gG	ESR137G