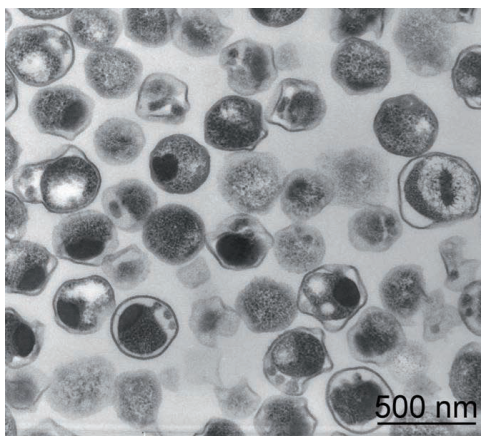


SERION ELISA *classic*

Chlamydia IgA / IgG

SERION ELISA *classic* Chlamydia IgA and IgG tests are quantitative and qualitative immunoassays for the detection of human antibodies in serum or plasma directed against genus specific antigens of *Chlamydia*. SERION ELISA *classic* Chlamydia IgA and IgG tests are recommended for the diagnosis of acute or recent infections.



Electron micrograph of elementary bodies of *Chlamydia pneumoniae*.

Pathogen

The order Chlamydiales currently has one family, the *Chlamydiaceae*, containing two genera, *Chlamydia* and *Chlamydophila*. Three human pathogenic species, *Chlamydia trachomatis*, *Chlamydophila pneumoniae* and *Chlamydophila psittaci* belong to these genera. Nearly all birds and mammals can be infected with *C. psittaci*, whereas man is the primary host of *C. trachomatis*. Workers on poultry farms are at particularly high risk of *C. psittaci* infection which may cause a severe psittacosis disease. The different *Chlamydia* species are transmitted via different infection routes: *C. pneumoniae* via aerosol transmission, *C. trachomatis* via direct contact or smear infection, *C. psittaci* via inhalation of fecal droppings, feather dust or smear infection.

Chlamydia are coccoid, gram-negative bacterial pathogens which are metabolically deficient in their ability to synthesize ATP and thus have an obligate intracellular life cycle. During an infection with *Chlamydia* two characteristic cell forms occur: the highly infectious elementary bodies and the non-infectious intracellular reticular bodies which are able to propagate.

Disease

Infections with *Chlamydia* may be initially mild, but may lead to serious diseases later on if not treated. An infection with *C. trachomatis* can be the cause of nonspecific urethritis, cervicitis



and conjunctivitis. Especially for younger men epididymitis and prostatitis and for women adnexitis, extrauterine pregnancy or sterility may result from repeated infection. Infection of an infant during childbirth is a significant risk (60 - 70 %) in the case of an infected mother resulting in conjunctivitis or pneumonia in the new-born. A *C. trachomatis* infection may also lead to reactive arthritis. Infection with *C. pneumoniae* is often asymptomatic or mild with symptoms such as hoarseness, dry cough and tiredness. However, the infection can also lead to long-term diseases and serious pneumonias. Latest seroepidemiological studies indicate a connection of a chronic *C. pneumoniae* infection with arteriosclerosis. The immunological reaction to the pathogen seems to enhance the risk for coronary heart disease and myocardial infarction. This hypothesis, however, still has to be confirmed by further investigations.

Diagnosis

Approximately two weeks after the first symptoms of a primary infection an increase of the IgA and IgM titers occurs, which peaks after five weeks and will have usually declined by the 10th week. As IgM and IgA antibodies peak, IgG production is initiated, peaking around week 12 and detectable for several years. On reinfection IgA and IgG antibodies reappear rapidly, whereas IgM antibodies are not evident.

Validation of SERION ELISA classic Chlamydia

The SERION ELISA classic Chlamydia IgA was evaluated in an internal study by the analysis of 42 serum samples of blood donors and patients with confirmed Chlamydia infection. The immunofluorescence test (IFT, goldstandard) of a leading European manufacturer was used as

as a reference. The validation of the SERION ELISA classic Chlamydia IgG was performed by the analysis of 86 serum samples in comparison to the assays of three competitors. Serum samples were evaluated positive if at least two of the three ELISA gave positive results. Sera classified as borderline were not included in the calculation.

Sensitivity and Specificity

| SERION ELISA classic | Sensitivity | Spezificity |
|----------------------|-------------|-------------|
| Chlamydia IgA | > 99 % | > 99 % |
| Chlamydia IgG | 88 % | 89 % |

Precision

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

SERION ELISA classic Chlamydia IgA

| Sample | Mean value OD | Intraassay CV (%) (n=20) | Mean value OD | Interassay CV (%) (n=10) |
|-----------------|---------------|--------------------------|---------------|--------------------------|
| weak positive | 0,446 | 8,1 | 0,388 | 12,0 |
| positive | 0,836 | 6,5 | 0,783 | 6,3 |
| strong positive | 1,314 | 4,9 | 1,485 | 9,7 |

SERION ELISA classic Chlamydia IgG

| Sample | Mean value OD | Intraassay CV (%) (n=20) | Mean value OD | Interassay CV (%) (n=10) |
|-----------------|---------------|--------------------------|---------------|--------------------------|
| borderline | 0,324 | 5,0 | 0,333 | 7,5 |
| positive | 0,702 | 5,5 | 0,717 | 9,6 |
| strong positive | 1,445 | 5,1 | 1,528 | 5,8 |

Order Information

SERION ELISA classic Chlamydia IgA

SERION ELISA classic Chlamydia IgG

Reference serum Chlamydia IgA

Reference serum Chlamydia IgG

Please visit our website www.virion-serion.com for more information on our SERION ELISA classic products.

Order Nr.: ESR 137 A

Order Nr.: ESR 137 G

Order Nr.: BR 137 A

Order Nr.: BR 137 G

Institut Virion\Serion GmbH
Serion Immundiagnostica GmbH
Friedrich-Bergius-Ring 19
97076 Würzburg, Germany

Tel.: +49 (0)931 3045-222
Fax: +49 (0)931 3045-100
dialog@virion-serion.de
www.virion-serion.com

Institut Virion\Serion GmbH
Beijing 100005, China
www.virion-serion.cn