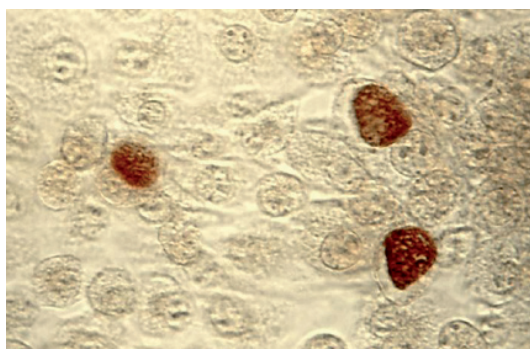


SERION ELISA *classic*

Chlamydia trachomatis IgA / IgG / IgM

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



Elementary bodies of *Chlamydia trachomatis* (Source: Centers for Disease Control and Prevention, United States Department of Health and Human Services).

Pathogen

Chlamydia trachomatis is one of the most common sexually transmitted bacterial pathogens. Depending on the serovar, the pathogen may infect epithelial cells of the urogenital- and respiratory tract as well as the conjunctiva.

Disease

Chlamydia trachomatis infections may be asymptomatic in 70 % of female and in up to 50 % of males. Untreated, infections may result in serious damage and complications. The serovars A to C cause ceratoconjunctivitis. Chronic infections during childhood can result in trachoma or blindness. Serovars D to K are pathogens of the urogenital tract, responsible for urethritis, proctitis and cervicitis. Salpingitis, endometritis and perihepatitis are frequently the consequence of untreated cervicitis. Occasionally, tubal obstructions and ectopic pregnancy, which are one of the most common reasons for infertility in women, may result. Furthermore, the risk of a premature delivery for infected pregnant women is also increased.

In addition to urethritis and proctitis, epididymitis and prostatitis, which may lead to infertility, are possible consequences for men.

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Diagnosis

Following an urogenital infection, the pathogen may migrate to the upper genital tract. This can cause difficulties in direct pathogen detection via cell-culture or PCR. In such cases, serological analysis is essential for the diagnosis of *Chlamydia trachomatis* infections. To date, the Microimmunofluorescence test (MIF) has been accepted as the reference method. More recently, standardized and automated ELISA tests are used in routine laboratories. The SERION ELISA *classic* Chlamydia trachomatis tests are based on a specific domain of the major outer membrane protein (MOMP). The use of this antigen decreases the frequency of false-positive results and consequently increases the sensitivity of the antibody detection in comparison to Microimmunofluorescence tests and other ELISAs.

Validation of SERION ELISA *classic* Chlamydia trachomatis

The SERION ELISA *classic* Chlamydia trachomatis IgG was evaluated in a study by the analysis of 183 serum samples of adult blood donors and 140 serum samples of patients with suspected infection with *Chlamydia trachomatis*. The validation of SERION ELISA *classic* Chlamydia trachomatis IgA was performed by the analysis of 194 serum samples of blood donors and 109 patient samples. The ELISA tests of a leading European manufacturer were used as reference. The evaluation of SERION ELISA *classic* Chlamydia trachomatis IgM test was performed by the analysis of 111 serum samples of healthy individuals and 37 samples of patients with suspected infection with *Chlamydia trachomatis*. Three ELISA tests of leading European manufacturers were used as a reference.

Sensitivity and Specificity

SERION ELISA <i>classic</i>	Sensitivity	Specificity
Chlamydia trachomatis IgA	92,6 %	98,6 %
Chlamydia trachomatis IgG	95,1 %	98,4 %
Chlamydia trachomatis IgM	91,7 %	95,5 %

Precision

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

SERION ELISA *classic* Chlamydia trachomatis IgA

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
borderline	0,314	2,3	0,352	6,3
positive	0,897	3,5	0,923	4,8
positive	1,659	4,7	1,875	5,2

SERION ELISA *classic* Chlamydia trachomatis IgG

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
weak positive	0,377	2,9	0,404	5,9
positive	0,650	2,2	0,612	9,1
positive	1,859	2,1	1,985	6,1

SERION ELISA *classic* Chlamydia trachomatis IgM

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
negative	0,160	6,5	0,163	9,1
positive	0,689	6,9	0,841	5,8
positive	1,237	5,8	1,425	4,6

Order Information

SERION ELISA *classic* Chlamydia trachomatis IgA

SERION ELISA *classic* Chlamydia trachomatis IgG

SERION ELISA *classic* Chlamydia trachomatis IgM

SERION ELISA *control* Chlamydia trachomatis IgA

SERION ELISA *control* Chlamydia trachomatis IgG

SERION ELISA *control* Chlamydia trachomatis IgM

Order Nr.: ESR 1372 A

Order Nr.: ESR 1372 G

Order Nr.: ESR 1372 M

Order Nr.: C 1372 A

Order Nr.: C 1372 G

Order Nr.: C 1372 M

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