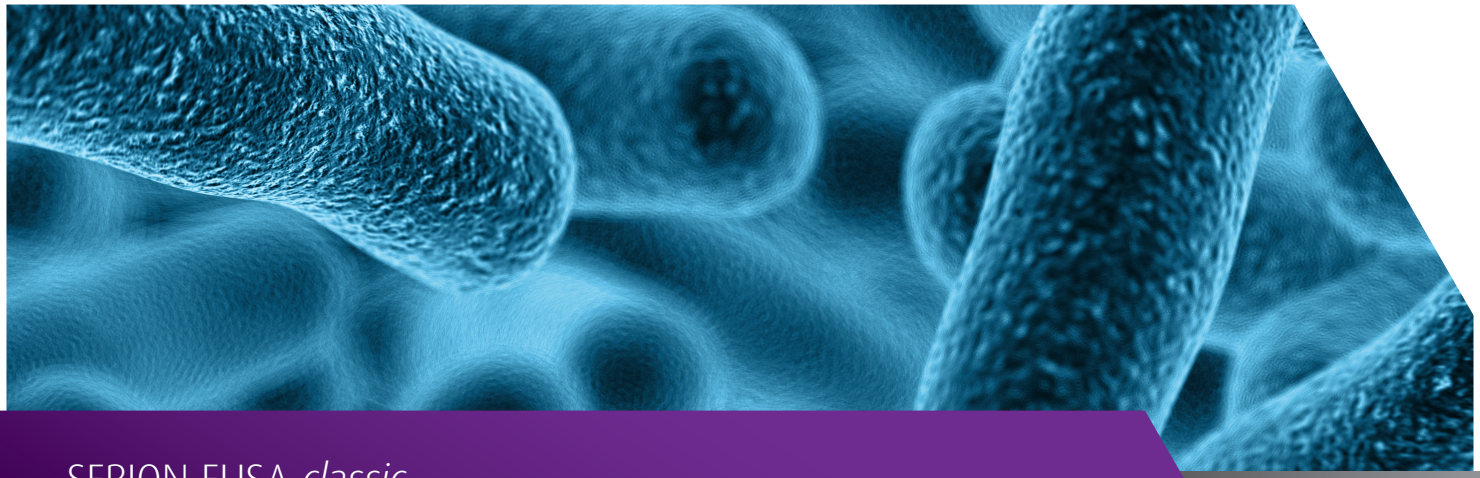

SERION ELISA *classic*

Chlamydia trachomatis IgA/IgG/IgM

Intended use

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

Diagnostic Efficiency

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

Product	Sensitivity	Specificity
SERION ELISA *classic* Chlamydia trachomatis IgA	92.6 %	98.6 %
SERION ELISA *classic* Chlamydia trachomatis IgG	95.1 %	98.4 %
SERION ELISA *classic* Chlamydia trachomatis IgM	91.7 %	95.5 %

Precision

SERION ELISA *classic* Chlamydia trachomatis IgA

Sample	Mean value (OD)	Intraassay CV (%) (n=20)	Mean value (OD)	Interassay CV (%) (n=10)
Serum 1	0.314	2.3	0.352	6.3
Serum 2	0.897	3.5	0.923	4.8
Serum 3	1.695	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)
Serum 1	0.377	2.9	0.404	5.9
Serum 2	0.650	2.2	0.612	9.1
Serum 3	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)
Serum 1	0.160	6.5	0.163	9.1
Serum 2	0.689	6.9	0.841	5.8
Serum 3	1.237	5.8	1.425	4.6

Pathogens

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 females and in up to 50 % of males. Untreated, infections may result in serious damage and complications. The serovars A to C cause ceratoconjunctivits. 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. Salpinigits, endomitritis and perihepatitis are frequently the consequence of untreated cervicitis. Occasionally, tubal obstructions and ectopic pregnancy, which belong to the most common reasons for infertility in women, may occur. Furthermore, the risk of a premature delivery for infected pregnant women is also increased. In addition to urethritis, epidiymitis and prostatitis, which may lead to infertility, are possible consequences for men.

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. Formerly, the Microimmunofluorescence test (MIF) has been accepted as the reference method. More recently, standardized and automated ELISA tests are used in routine laboratories.

Highlights

- Demonstration of species-specific IgA, IgG and IgM antibodies
- Reduced cross reactivity with antibodies 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, even in the clinically negative measurement region, for disease stage monitoring and therapy control

Product	Order No.
SERION ELISA *classic* Chlamydia trachomatis IgA	ESR1372A
SERION ELISA *classic* Chlamydia trachomatis IgG	ESR1372G
SERION ELISA *classic* Chlamydia trachomatis IgM	ESR1372M

SERION ELISA *control*

Please visit our website for more information.

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