



Anti-Chlamydia trachomatis ELISA (IgG)



- Based on Chlamydia trachomatis-specific, purified MOMP (major outer membrane protein)
- Species-specific and sensitive detection of antibodies against C. trachomatis
- Fully automated processing and evaluation

Technical data

Antigen	Purified MOMP antigen from cell lysates of BGM cells infected with C. trachomatis serotype K						
Calibration	Quantitative, in relative units per millilitre (RU/ml)						
Result interpretation	<p>EUROIMMUN recommends interpreting results as follows:</p> <table><tr><td>< 16 RU/ml:</td><td>negative</td></tr><tr><td>≥ 16 to < 22 RU/ml:</td><td>borderline</td></tr><tr><td>≥ 22 RU/ml:</td><td>positive</td></tr></table> <p>Recommended upper threshold of the normal range (cut-off value): 20 RU/ml</p> <p>Semiquantitative evaluation possible via ratio</p>	< 16 RU/ml:	negative	≥ 16 to < 22 RU/ml:	borderline	≥ 22 RU/ml:	positive
< 16 RU/ml:	negative						
≥ 16 to < 22 RU/ml:	borderline						
≥ 22 RU/ml:	positive						
Sample dilution	Serum or plasma, 1:101 in sample buffer						
Reagents	Ready for use, with the exception of the wash buffer (10x); colour-coded solutions, in most cases exchangeable with those in other EUROIMMUN ELISA kits						
Test procedure	30 min / 30 min / 15 min, room temperature, fully automatable						
Measurement	450 nm, reference wavelength between 620 nm and 650 nm						
Test kit format	96 break-off wells; kit includes all necessary reagents						
Order no.	EI 2191-9601 G						
Related products	EI 2191-9601 A Anti-Chlamydia trachomatis ELISA (IgA) EI 2191-9601 M Anti-Chlamydia trachomatis ELISA (IgM)						

Clinical significance

The infectious agent C. trachomatis belongs to the human pathogenic Chlamydia species. They are among the smallest intracellular, gram-negative bacteria and subsist as energy parasites on the ATP of infected cells. Around 700 million people are infected with C. trachomatis worldwide, with approximately 50 million new infections occurring per year. The infectious agent can cause the following diseases:

1. Trachoma, a chronic, follicular keratoconjunctivitis (serotypes A to C). Around 400 million people suffer from trachoma, which is the most frequent cause of blindness worldwide (trachoma blindness).
2. Infections of the urogenital tract (serotypes D to K). In men they cause urethritis, epididymitis and prostatitis, in women urethritis, cervicitis and salpingitis/adnexitis. In Germany, more than 100,000 women suffer from Chlamydia-caused infertility. Chlamydia-induced secondary infertility has also been reported in men. There is an evident connection between acute C. trachomatis infections during the first trimester and early abortions, premature deliveries or stillbirths (32nd to 34th week of pregnancy). Reactive arthritis also develops in 1% to 3% of cases. In reactive arthritis C. trachomatis occurs as a metabolically active agent in the joints.
3. Lymphogranuloma venereum is a rare venereal disease which occurs worldwide but mainly in tropical areas (serotypes L1 to L3). Serotypes A to C are transmitted by infectious eye secretion, serotypes D to K and L1 to L3 by sexual intercourse or perinatally. Chlamydia trachomatis is found exclusively in humans.

Diagnostic application

The determination of antibodies against the species-specific C. trachomatis MOMP antigen is useful in the diagnosis of persisting or chronic C. trachomatis infections and their differentiation from infections with other Chlamydia species. Direct detection (e.g. PCR), however, is the method of choice in the diagnosis of acute, peripherally localised infections with C. trachomatis.



Reference range

The levels of anti-*C. trachomatis* antibodies (IgG) were measured in a panel of 500 healthy blood donors using the EUROIMMUN Anti-Chlamydia trachomatis ELISA (IgG). With a cut-off value of 20 IU/ml, 13.4% of the blood donors were positive for anti-*C. trachomatis* (IgG).

Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using three samples. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on four determinations performed in six different test runs.

Sample	Intra-assay variation, n = 20		Inter assay variation, n = 4 x 6	
	Mean value (RU/ml)	CV (%)	Mean value (RU/ml)	CV (%)
1	8	9.2	7	10.6
2	65	8.2	62	9.5
3	137	3.2	139	6.5

Sensitivity and specificity

69 clinically precharacterised patient samples from a quality assessment provider (INSTAND e.V., Germany) were analysed using the EUROIMMUN Anti-Chlamydia trachomatis ELISA (IgG). The sensitivity was 100%, at a specificity of 97.6% (borderline sera excluded).

n = 69		Quality assessment target		
		positive	borderline	negative
EUROIMMUN- Anti-Chlamydia trachomatis ELISA (IgG)	positive	24	0	1
	borderline	0	0	2
	negative	0	1	41

Clinical studies

Antibodies against *C. trachomatis* were investigated in different samples cohorts. The prevalences were as follows:

Sample cohort	n	Prevalence (IgG)
Patients with a positive direct detection of <i>C. trachomatis</i>	100	67.0%
Risk cohort (prostitutes)	134	42.5%
Patients with reactive arthritis	54	27.8%
Pregnant women	200	12.5%
Healthy blood donors I	200	8.0%
Healthy blood donors II	200	4.0%

Cross reactivity

Sera from patients with infections caused by different pathogens were analysed using the Anti-Chlamydia trachomatis ELISA (IgG). No cross reactions with anti-*C. pneumoniae*-positive samples are known for this ELISA.

Antibodies against	n	Anti-Chlamydia trachomatis ELISA (IgG) positive	Antibodies against	n	Anti-Chlamydia trachomatis ELISA (IgG) positive	Antibodies against	n	Anti-Chlamydia trachomatis ELISA (IgG) positive
Adenovirus	12	0%	Influenza virus A	12	0%	Rubella virus	12	0%
Chlamydia pneumoniae	10	0%	Influenza virus B	12	0%	RSV	12	0%
CMV	12	0%	Measles virus	12	0%	Toxoplasma gondii	12	0%
EBV-CA	12	0%	Mumps virus	12	0%	VZV	12	0%
Helicobacter pylori	12	0%	Mycoplasma pneumoniae	12	0%			
HSV-1	12	0%	Parainfluenza Pool	12	0%			

Literature

1. Robert Koch-Institut. **Infektionen durch Chlamydien (Teil 1): Erkrankungen durch Chlamydia trachomatis**. Epidemiological Bulletin No. 37 (2009).
2. E. Lanjouw, S. Ouburg, HJ. de Vries, A. Stary, K. Radcliffe and M. Unemo. **2015 European guideline on the management of Chlamydia trachomatis infections**. International Journal of STD & AIDS 1-16 (2015).
3. T. Komoda. **Kinetic study of antibodies (IgG, IgA) to Chlamydia trachomatis: importance of IgA antibody in screening test for C. trachomatis infection by peptide-based enzyme immunosorbent assay**. Jpn. J. Infect. Dis., 60, 347-351 (2007).