Indication: Test system for the in vitro determination of antibodies against Chlamydia trachomatis in human serum or plasma for the diagnosis of the following diseases: trachoma, conjunctivitis, urogenital infections, pneumonia in infants, lymphogranuloma venereum.

Clinical significance: The infectious agent Chlamydia trachomatis belongs to the human pathogenic genus Chlamydia, together with Chlamydia pneumoniae and Chlamydia psittaci. They are among the smallest intracellular, gram-negative bacteria, which use in particular the high energy compound ATP of the host for their own metabolism. Their unique development cycle plays an important role in diagnosis, therapy and pathogenesis.

Around 700 million people are infected with Chlamydia trachomatis worldwide, with approx. 50 million new infections taking place each year. The infectious agent can cause the following diseases: 1. trachoma, a chronic, follicular keratoconjunctivitis (serotypes A-C), 2. infections of the urogenital tract in men and women (urethritis, cervicitis, salpingitis, reactive arthritis etc., serotypes D-K), 3. lymphogranuloma venereum, a venereal disease which occurs mainly in warm countries (serotypes L1-L3).

Serotypes A-C are transmitted by infectious eye secretion, serotypes D-K and L1-L3 by sexual intercourse or perinasally. Chlamydia trachomatis is found exclusively in humans.

So far, there is no vaccine against Chlamydia. Patients with Chlamydia infections can be successfully treated with antibiotics over 7-14 days, even in pregnancy. In reactive arthritis, a long-term, differentiated treatment is required, which acts locally and systemically.

Clinical study: The prevalence of antibodies against Chlamydia trachomatis was determined in 500 healthy blood donors, 88 children from 0 to 10 years of age, 250 healthy pregnant women, 134 high-risk persons (prostitutes) and 54 patients with reactive arthritis. The prevalences obtained were consistent with values in the literature. For comparison of the EUROMMUN ELISA with a direct test, sera from 100 patients diagnosed with Chlamydia trachomatis infections using a direct pathogen test were investigated for antibodies against Chlamydia trachomatis. The results agreed in 67% of the sera. The patients showing a negative ELISA result for Chlamydia trachomatis probably had a localised infection without production of antibodies.

Application of the Anti-Chlamydia trachomatis ELISA (IgG): Direct detection of the pathogen, e.g. using nucleic acid amplification test (NAT), is the method of choice for the diagnosis of acute, peripherally localised infections with Chlamydia trachomatis. If the pathogen cannot be detected, persisting infections can often be diagnosed by the investigation of specific antibodies. In chronic infections and ascending disease courses the pathogen frequently hides in difficult to access locations (e.g. tubes), where detection using direct methods fails. Here, serology is an important alternative, e.g. for the diagnosis of tube factor infertility caused by persisting infections with Chlamydia trachomatis or for the diagnosis of Chlamydia-associated arthritis.

The lipopolysaccharide coats of the different Chlamydia trachomatis serotypes as well as all three Chlamydia species are very similar. To avoid cross reactions, pathogen-specific MOMP (major outer membrane proteins) of Chlamydia trachomatis are employed as the antigenic substrate in the EUROMMUN ELISA. Thereby, infections with Chlamydia trachomatis can be reliably differentiated from infections with Chlamydia psittaci and Chlamydia pneumoniae with this ELISA.

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Test Characteristics

Anti-Chlamydia trachomatis ELISA (IgG)

Reproducibility: The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 3 sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on 4 determinations performed in 6 different test runs.

Reference range: The levels of anti-Chlamydia trachomatis antibodies (IgG) were analysed with the EUROIMMUN Anti-Chlamydia trachomatis ELISA (IgG) in a panel of 500 healthy blood donors. With a cut-off of 20 RU/ml, 13% of the blood donors were anti-Chlamydia trachomatis positive (IgG).

Sensitivity and specificity: 43 clinically characterised patient samples were investigated using the EUROIMMUN ELISA. The sensitivity was 100%, at a specificity of 96% (borderline sera excluded).

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Cross reactions: 190 sera from patients with different infectious diseases (positive IgG results) who have not previously been infected with Chlamydia trachomatis were investigated with the EUROIMMUN Anti-Chlamydia trachomatis ELISA (IgG). No cross reactions (CR) were found.

Technical data:

Antigen: The antigen used in this ELISA is purified MOMP (major outer membrane protein; a transmembrane protein present in the outer membrane of the elementary bodies), isolated from cell lysates of BGM cells infected with Chlamydia trachomatis serotype K.

Calibration: Quantitative, in relative units per milliliter (RU/ml)

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 automatatable.

Measurement: 450 nm. Reference wavelength between 620 nm and 650 nm.

Test kit format: 96 break-out wells. Kit includes all necessary reagents.

Related products: Anti-Chlamydia trachomatis ELISA (IgA) (EI 2191-9601 A)