Indication: Test system for the in vitro determination of antibodies against Treponema pallidum in human serum or plasma for the diagnosis of the following disease: syphilis (lues).

Clinical significance: Treponema pallidum is a bacterial species of the spirochaetaceae family. This family includes five genera: Treponema, Borrelia, Spirochaeta, Cristispira, and Leptospira. Treponema pallidum is the causative agent of the chronic infectious disease syphilis. Transmission occurs almost exclusively by sexual contact, although transmission through blood transfusions or wounds or by disjunct transfer is also possible. The infection spreads through regional lymph vessels and lymph nodes into the blood and further into the organs. Syphilis manifests itself as a chronic generalised illness and can be divided into different stages. The primary and secondary stages are known as early syphilis and the tertiary and quaternary stages as late syphilis.

Primary stage: The typical primary manifestation of an exogenous infection with Treponema pallidum is a very defined, limiting fibrous or crusted erosion at the site of infection which occurs about three weeks after infection. An ulcer or a hardening of the lesion can develop (hard chancre). Local lymph nodes become swollen within a week.

Secondary stage: In addition to a generalised swelling of lymph nodes, 90% of patients show local or generalised skin disorders, which can be symmetrical, blotchy, papular, papulosquamous, and/or purulent. Condylomata lata is predominant. Various organ disorders may develop, for example, keratitis, iritis, hepatitis, vasculitis, and myocardial disorders. Secondary syphilis follows a clinically silent stage (syphilis latens), which can last for years.

Tertiary stage: Typical manifestations of a Treponema pallidum infection in stage III are large papules and ulcers on the skin and mucous membranes, as well as organ or visceral syphilis, including gummatous and interstitial inflammation, periavascular processes, cardiovascular syphilis, neurosyphilis, sexual, and/or pustular. Condylomata lata is predominant. Various organ disorders may develop, for example, keratitis, iritis, hepatitis, vasculitis, and myocardial disorders. Secondary syphilis follows a clinically silent stage (syphilis latens), which can last for years.

Quaternary stage: The quaternary manifestation of a Treponema pallidum infection in the form of neurosyphilis can occur up to 30 years after the initial infection. The neurosyphilis occurs primarily in the form of progressive paralysis and tabes dorsalis.

The diagnosis of syphilis is based on clinical findings according to the disease stage, microscopic detection of the infectious agent (dark field), and serological detection of antibodies against Treponema pallidum.

Application of the Anti-Treponema pallidum ELISA (IgG): Antibodies against Treponema pallidum are determined with a two-step diagnostic method. An antibody screening test (e.g. the EUROIMMUN Anti-Treponema pallidum Screen ELISA IgG/IgM or the Treponema pallidum haemagglutination assay (TPHA)) is followed by the Anti-Treponema pallidum ELISA (IgG) as a confirmatory test. By using specific, recombinant Treponema antigens an excellent specificity is achieved and at the same time a high sensitivity. Moreover, the Anti-Treponema pallidum ELISA (IgG) enables easy and automated processing of large quantities of samples.
Test characteristics Anti-Treponema pallidum ELISA (IgG)

Linearity: The linearity of the test was determined by assaying 4 serial dilutions of 6 serum samples. The linear regression R² was >0.95 for all samples. The Anti-Treponema pallidum ELISA (IgG) is linear in the tested concentration range of 19RU/ml to 166RU/ml.

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-Treponema pallidum antibodies (IgG) were analysed with the EUROMMUN ELISA in a panel of 500 healthy blood donors. With a cut-off of 20 RU/ml, 0.4% of the blood donors were anti-Treponema pallidum positive (IgG), which reflects the known percentage of infections in adults.

Sensitivity and specificity: 177 clinically and serologically characterised patient samples (quality assessment: INSTAND, Germany; LABQUALITY, Finland and NEQAS, U.K.) were investigated using the EUROMMEN Anti-Treponema pallidum ELISA (IgG). The sensitivity of the ELISA amounted to 98%, at a specificity of 100% (borderline sera excluded).

Comparison with Fluorescence Treponema Antibody Absorption (FTA-ABS test): 168 clinically and serologically characterised patient samples (quality assessment: INSTAND, Germany; LABQUALITY, Finland and NEQAS, U.K.) were investigated using the EUROMMEN Anti-Treponema pallidum ELISA (IgG). The qualitative results agreed 99% with the results from the FTA-ABS test.

Technical data:

Antigen: The reagent wells were coated with a mixture of the following Treponema pallidum antigens: p15, p17, p47 and TmpA. The antigens were produced recombinantly and the cDNA was expressed in E. coli.

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

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

Standard kit format: 96 break-off wells. Kit includes all necessary reagents.

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