Anti-Treponema pallidum EUROLINE-WB (IgG)

Indication: Test system for the in vitro determination of antibodies against Treponema pallidum antigens in human serum or plasma for the diagnosis of the following disease: Treponema pallidum infection (various forms of 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 (lues). Transmission occurs almost exclusively by sexual contact, although transmission through blood transfusions, wounds or by diaplacental 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, 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 ahardening 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, papulossquamous, and/or pustular. Condylomata lata is predominant. Various organ disorders may develop, for example, ketaritis, 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 gummatus and interstitial inflammation, perivasculitis, cardiovascular syphilis, neurosyphilis (asymptomatic and symptomatic form), osteitis, and periosteitis.

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 EUROLINE-WB: The Anti-Treponema pallidum EUROLINE-WB is a reliable confirmatory test for the detection of antibodies against Treponema pallidum. The focus of syphilis diagnostics lies in serology, which has proven successful with a three-tiered diagnostics consisting of screening, confirmation and evaluation of the disease activity. Further screening for subsequent diagnostics can be performed using Treponema-specific agglutination tests (TPPA, TPHA) and polyvalent enzyme immunoassays.

In addition to the Anti-Treponema pallidum FTA Abs tests, immunobLOTS such as the Anti-Treponema pallidum EUROLINE-WB are increasingly used for the confirmation of screening results. They contain specific antigens of Treponema pallidum, which are shown separately. The Anti-Treponema pallidum EUROLINE-WB is also suited to determine the disease activity. Due to blood vessel inflammation and tissue damage the activity of the infection correlates with the titre of antibodies against mitochondrial lipids (cardiolipin). As well as RPR (rapid plasma regain test) and VDRL test (venereal disease research laboratory test) the additional cardiolipin antigens on the Anti-Treponema pallidum EUROLINE-WB can be used to detect these antibodies. Bands CL1 to CL3 contain cardiolipin in three different concentrations, which allows differentiation between active and cured past infection using follow-up samples.
Test Characteristics

Anti-Treponema pallidum EUROLINE-WB (IgG)

Reliability of evaluation: For every membrane, strips from the middle and both ends are quality controlled using characterized sera. This verifies that antigen bands on all test strips of one lot are strictly parallel. In addition, a specific evaluation matrix is produced for every membrane, which ensures correct assignment of bands according to the exact electrophoretic separation.

Specificity and sensitivity: A panel of 19 serologically defined samples, precharacterised by an approved reference test (certified by the Paul Ehrlich Institute) and 50 samples of healthy blood donors, all with negative results in TPHA test, were investigated with the EUROMMUN Anti-Treponema pallidum EUROLINE-WB. The Anti-Treponema pallidum EUROLINE-WB IgG has a specificity of 100% and a sensitivity of 100%. The positive predictive value is 100%.

Computer-based evaluation: The EUROLineScan program from EUROMMUN provides automated evaluation of EUROLINE analyses and detailed documentation of results. The incubated membrane strips are either scanned onto a protocol sheet using a flatbed scanner (EUROBlotScanner) or photographed directly in the incubation tray using a camera system (EUROBlot-Camera). EUROLineScan recognizes the position of the strips, even with inexact positioning. It then identifies the bands and measures their intensity. The EUROLi neScan programme facilitates data management and eliminates the need to archive potentially infectious material. A separate results sheet can be produced for each patient. Online connection to other programmes is possible, e.g. laboratory management systems (LIMS).

Correlation of the Anti-Treponema pallidum EUROLINE-WB Cardiolipin Membrane Chip (IgG) with an RPR test: A panel of 38 serologically defined patient samples and samples from 50 healthy blood donors were investigated with the EUROMMUN Anti-Treponema pallidum EUROLINE-WB and an RPR test (Rapid Plasma Reagin Test, CE-certified coagulation test for the detection of antibodies against phospholipids). The cardiolipin membrane chip on the Anti-Treponema pallidum EUROLINE-WB IgG has a specificity of 93% and a sensitivity of 75%.

Technical data:

Antigens

Particularly suited Treponema pallidum preparations with the antigens TpN15 (p15), TpN17 (p17), tmpA (p45) and TpN47 (p47) are used as the antigen source. The antigens were separated according to molecular mass using discontinuous polyacrylamide gel electrophoresis and transferred onto a nitrocellulose membrane. From each nitrocellulose membrane, 2 control test strips were removed and incubated with a reference serum. One of these stained strips is included in the kit. Additionally, each test strip has a membrane chip coated with cardiolipin antigen in 3 concentrations.

Sample dilution

Serum or plasma; 1:51 in Universal buffer.

Test procedure

30 min / 30 min / 10 min. Room temperature.

Automation

Compatible with all commercial blot processing systems, e.g. EUROBlot-Master from EUROMMUN.

Test kit format

16 or 24 membrane strips.

Order numbers

DY 2111-1601-1 G (IgG, 16 strips)
DY 2111-2401-1 G (IgG, 24 strips)