The diagnosis of Lyme disease is based on the patient anamnesis, clinical findings and the development of antibodies.

Clinical significance: Borrelia burgdorferi is the causative agent of Lyme borreliosis, a bacterial disease which is transmitted through bites from ticks of the genus Ixodes. The infection can manifest itself dermatologically, neurologically or through internal disorders. The clinical manifestation of borreliosis occurs in three stages:

Stage I: A characteristic erythema migrans is in the foreground, which occurs a few days to several weeks after the infection and spreads radially with central clearing. This is often accompanied by influenza-like general symptoms, such as fever, shivering, headaches and vomiting. In rare cases, bulging nodular skin infiltrates develop, which consist predominantly of lymphocytes (lymphadenosis cutis benigna). Serologically, antibodies against Borrelia of the genus Borrelia burgdorferi sensu lato in human serum or plasma for the diagnosis of the diseases: erythema migrans, chronic arthritis, meningitis, unclear neurological symptoms.

Stage II: Stage II of the disease, characterised by neurological, cardiac (e.g. myocarditis) and rheumatological (e.g. arthritis) manifestations, develops several weeks to months after the tick bite. The attack on the nervous system frequently appears as radiculitis (Bannwarth's syndrome), mono- or plexus-neuritis, and motor (mostly facial paralysis) and sensory disorders. Meningitis, myelitis, encephalitis and cerebral vasculitis occur less frequently. IgG antibodies against Borrelia burgdorferi can be detected in more than 90% of stage II patients.

Stage III: The characteristic manifestation of the late stage of the disease, months to years after the occurrence of the borreliosis infection, is a chronic involvement of the joints, skin and CNS. Destructive arthritis develops in many cases, predominantly in the large joints and mostly in the knee joints. A typical acrodermatitis chronica atrophicans is formed in the epidermis of the extremities. IgG antibodies can be detected in 90-100% of stage III patients, while IgM antibodies no longer play a role.

The diagnosis of Lyme disease is based on the patient anamnesis, clinical findings and the detection of antibodies against borreliosis antigens. Serology played a leading role in the discovery of Lyme disease and nowadays helps to achieve a serodiagnostic breakthrough for many patients. The prevalence of antibodies to Borrelia in Germany is around 20% in the case of forest work.

This test system combines the advantages of recombinant antigens and whole antigen extracts in a unique antigen mixture. Native whole antigen extracts provide a secure and highly sensitive differentiation between Borrelia-specific and non-specific reactions.

Importance of the Anti-Borrelia plus ViSE ELISA: This test system combines the advantages of recombinant antigens and whole antigen extracts in a unique antigen mixture. Native whole extracts of the borrelia strains B. burgdorferi, B. garinii and B. afzelii are combined with recombinant ViSE antigen, the main borrelia antigen. With its wide antigen spectrum, the Anti-Borrelia plus ViSE ELISA achieves a high sensitivity and is therefore ideally suited for use as a screening test.
Test characteristics Anti-Borrelia plus VlsE ELISA (IgG)

Linearity: The linearity of the ELISA was determined by assaying serial dilutions of several sera with high titres. The mean regression (R²) of the Anti-Borrelia plus VlsE ELISA was greater than 0.95, thus ensuring linearity of the system for a quantitative measurement.

Reference ranges: Levels of anti-borrelia burgdorferi antibodies were measured in a cohort of 500 healthy blood donors (University Hospital of Luebeck, Germany) using the EUROIMMUN ELISA. With a cut-off value of 20 RU/ml, 5% of the blood donors were anti-borrelia burgdorferi positive (IgG), in agreement with the known prevalence in adults.

Reproducibility: Coefficients of variation (CVs) were determined using data from three sera with values at different points on the standard curve. The intra-assay CVs are based on 20 measurements for each serum and the inter-assay CVs on four measurements repeated on six different days.

Clinical data: 364 sera from patients with clinically characterised borreliosis in different disease stages and 573 control sera (53 patients with other infectious diseases, 20 patients with rheumatic diseases, 500 healthy blood donors) were screened using the EUROIMMUN Anti-Borrelia plus VlsE ELISA (IgG) and the EUROIMMUN Anti-Borrelia ELISA (IgM). In the parallel investigation of IgG and IgM antibodies the test systems achieved a sensitivity of 91% to 100%, depending on the patient cohort.

Agreement with quality assessment results: 66 (IgG) clinically characterised patient samples (quality assessment: EQUALIS, Sweden; INSTAND, Germany and LABQUALITY, Finland) were investigated using the EUROIMMUN Anti-Borrelia ELISA (IgG). The qualitative results of the test systems showed an agreement of 100% (excluding borderline sera).

Technological data:

**Antigen**

The antigens used in the Anti-Borrelia plus VlsE ELISA are whole extracts of the strains B. burgdorferi, B. afzelii and B. garinii, as well as recombinant VlsE. The cultivated bacteria were solubilised with sodium dodecyl sulphate. The antigen mix used contains all relevant proteins, providing high diagnostic sensitivity.

**Calibration**

Quantitative, in relative units per ml (RU/ml)

- Calibration serum 1: 200 RU/ml
- Calibration serum 2: 20 RU/ml; cut-off value
- Calibration serum 3: 2 RU/ml

**Serum dilution**

Serum or plasma; 1:101 in sample buffer.

**Reagents**

Ready to use, with the exception of the wash buffer (10x). Colour-coded reagents, largely interchangeable with other EUROIMMUN ELISA kits.

**Test procedure**

30 min / 30 min / 15 min. Room temperature. Can be fully automated.

**Measurement**

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

**Kit format**

96 individual break-off wells.

**Catalogue No.**

EI 2132.9601-2 G