Lyme Screen ELISA (IgGM)

- Combination of recombinant VlsE and OspC for simultaneous detection of IgG and IgM antibodies
- Superior sensitivity compared to single antigen ELISAs (based on e.g. the C6 peptide)
- Reduced cross-reactivity compared to whole cell systems

Technical data

Antigen
The microplate wells are coated with recombinant VlsE from Borrelia burgdorferi sensu stricto and Borrelia OspC.

Calibration
Quantitative, in relative units per milliliter (RU/ml)
- Calibration serum 1: 200 RU/ml
- Calibration serum 2: 20 RU/ml; cut-off value
- Calibration serum 3: 2 RU/ml

Result interpretation
EUROIMMUN recommends interpreting results as follows:
- <16 RU/ml: negative
- ≥16 to <22 RU/ml: borderline
- ≥22 RU/ml: positive

Semiquantitative evaluation using a ratio is also possible.

Sample dilution
Serum: 1:101 in sample buffer.

Reagents
Ready to 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
60 min (37 °C) / 30 min / 15 min (room temperature). Fully automatable.

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

Kit format
96 individual break-off wells. Kit includes all necessary reagents.

Order number
EI 2132-9601 O

Clinical significance
Lyme disease is a tick-borne disease caused by bacteria of the genus Borrelia. The diagnosis of Lyme disease is based on the patient anamnesis, clinical findings and the detection of antibodies against Borrelia antigens. With respect to the serodiagnosis of Lyme disease the CDC (Atlanta, USA) calls for a two-tiered strategy. Firstly, a sensitive screening test (ELISA or IIFT) is performed. Sera with a positive or borderline screening result are investigated further using an immunoblot to differentiate between Borrelia-specific and unspecific reactions. Since antibodies against Borrelia are first produced 2 to 6 weeks after infection, serological tests performed in the early stage of Lyme borreliosis can be negative. Early antibiotic treatment may also prevent antibody production. In suspected cases of neuroborreliosis, the presence of intrathecal synthesis of Borrelia-specific antibodies can be investigated by parallel analysis of a CSF/serum sample pair.

Diagnostic application
The Lyme Screen ELISA (IgGM) allows reliable diagnosis of borreliosis already in early disease stages, provided that detectable antibodies are present. The ELISA uses VlsE and OspC, which are the major target antigens in the IgG and IgM mediated immune response to a Borrelia infection. IgM antibodies against OspC and IgG antibodies against VlsE are produced very early after infection. According to guidelines for serological Borrelia diagnostics (e.g. from CDC, Atlanta, USA), a positive or borderline ELISA result should always be followed by a confirmatory test (immunoblot).
Reproducibility

The reproducibility of the test was investigated by determining the intra- and inter-assay coefficients of variation using 5 sera. The intra-assay CVs are based on 20 determinations and the inter-assay CVs on 3 determinations performed in 10 different test runs.

Clinical data

192 clinically and serologically precharacterised patient samples (origin: Columbia University, USA) were examined with the EUROIMMUN Lyme Screen ELISA (IgGM). The specificity was 98% and the sensitivity 99% (excluding borderline sera).

Comparison with other manufacturer’s test

92 sera (2nd Lyme disease reference serum panel, CDC, USA) were tested with the EUROIMMUN Lyme Screen ELISA (IgGM) and the FDA approved bioMérieux Vidas Lyme IgG/IgM assay. 32 sera originated from patients with clinically confirmed Lyme disease (including 20 sera from patients with erythema migrans) and 60 sera from either healthy persons or persons with diseases other than Lyme disease (mononucleosis, fibromyalgia, periodontitis, rheumatoid arthritis, syphilis, multiple sclerosis). The Lyme Screen ELISA (IgGM) showed both a higher sensitivity and a higher specificity than the reference assay from bioMérieux.

Literature