

SERION ELISA *classic*

Borrelia burgdorferi IgG / IgM

SERION ELISA *classic* *Borrelia burgdorferi* IgG and IgM tests are quantitative and qualitative immunoassays for the detection of human antibodies in serum, plasma or cerebrospinal fluid directed against *Borrelia burgdorferi*. The detection of different immunoglobulin classes allows the differentiation between acute and previous infections as well as determination of disease status.

Pathogen

Borrelia burgdorferi is the infectious agent which causes the disease syndrome known as Lyme-Borreliosis. *B. burgdorferi sensu stricto*, *B. garinii* and *B. afzelii* are the most important human pathogens of the genospecies *Borrelia burgdorferi sensu lato*. All three are distributed throughout Europe in all temperate climate zones. Reservoirs for the bacteria include a variety of small wild mammals, particularly mice. The bacteria, belonging to the taxonomic group of the spirochetes, are transmitted to human hosts by infected ticks (*Ixodes ricinus*, Europe; *Ixodes scapularis*, USA). The infection rate in adult ticks, nymphs and larvae with *Borrelia burgdorferi* ranges from 0 to 50 %, dependent upon geographical region and tick populations.

In Europe, *Borrelia burgdorferi* is transmitted to humans by infected ticks of the genus *Ixodes ricinus*.



Disease

Lyme Disease is a multisystemic infection with many possible manifestations. Single or multiple organs may be involved. The time course of Lyme Disease can be divided into three separate stages. Stage I starts a few days up to several weeks after tick bite and subsequent infection with *Borrelia burgdorferi*. Patients suffer from non-specific symptoms such as fever, headache, muscle pain, joint pain, and exhaustion. Dermal manifestations with *Erythema migrans* (EM) as a characteristic symptom of early disease are displayed by 30 to 60 % of infected persons.

Erythema migrans is recognized as a specific clinical symptom which clearly demonstrates an early phase of Lyme borreliosis. Stage II occurs between a few weeks and several months post infection as a systemic disease. In addition to non-specific symptoms, in particular neurological disorders (Morbus Bannwarth), less frequently Lyme carditis and ophthalmological disorders may be observed. Development of stage III symptoms may occur up to several years after the tick bite and are characterised by dermatological diseases (*Acrodermatitis chronica atrophicans* (ACA), diseases of the joints (Lyme-Arthritis), and neurological diseases (chronical encephalomyelitis).

Diagnosis

Due to the complexity of the clinical picture and the generally unspecific symptoms, serological diagnosis is the appropriate method to ensure an optimal differential diagnosis. It is recommended to adopt a logical step-wise approach to serological diagnosis, using initially a sensitive screening test such as ELISA with subsequent confirmation of positive and borderline ELISA results by another specific test such as immunoblot. A European strain of the genospecies *Borrelia garinii* in addition to the strain PKo has been used as antigen for coating on microtiter wells, thus achieving a high diagnostic sensitivity. The genospecies we use contain the proteins OspC and VlsE, which are important for diagnosis in the early phase of Borreliosis and P100, which is important for the late phase. To increase the sensitivity, recombinant VlsE is also included. Specificity of the assay is optimized by supplementing the dilution buffer with a treponema phagedenis lysate, which absorbs potentially cross-reactive treponema antibodies.

Validation of SERION ELISA *classic* *Borrelia burgdorferi*

The SERION ELISA *classic* *Borrelia burgdorferi* IgG was evaluated by the analysis of 244 serum samples from blood donors, pregnant women and from patients with suspected borreliosis against two commercially available ELISA of leading European manufacturers. The validation of the SERION ELISA *classic* *Borrelia burgdorferi* IgM was carried out by the analysis of 172 serum samples from blood donors and patients with suspected borreliosis compared to the commercially available ELISA of a leading European manufacturer. Discrepant serum samples were further analysed by immunoblot. Sera classified as borderline were not included in the calculation.

SERION ELISA <i>classic</i>	Sensitivity	Specificity
<i>Borrelia burgdorferi</i> IgG	97,6 %	97,1 %
<i>Borrelia burgdorferi</i> IgM	97,3 %	> 99 %

SERION ELISA *classic* *Borrelia burgdorferi* IgG

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
negative	0,24	2,6	0,26	6,4
positive	0,56	6,4	0,76	10,3
strong positive	2,80	2,6	2,50	8,1

SERION ELISA *classic* *Borrelia burgdorferi* IgM

Sample	Mean value OD	Intraassay CV (%) (n=20)	Mean value OD	Interassay CV (%) (n=10)
negative	0,19	5,0	0,19	7,7
positive	0,81	6,6	0,90	9,5
strong positiv	3,75	4,5	3,84	5,8

Order Information

SERION ELISA *classic* *Borrelia burgdorferi* IgG
SERION ELISA *classic* *Borrelia burgdorferi* IgM
Reference serum *Borrelia burgdorferi* IgG
Reference serum *Borrelia burgdorferi* IgM

Order Nr.: ESR 121 G
Order Nr.: ESR 121 M
Order Nr.: BR 121 G
Order Nr.: BR 121 M

The SERION ELISA *classic* *Borrelia burgdorferi* IgG and IgM are evaluated for the analysis of cerebrospinal fluid. Please visit our website www.virion-serion.com for more information on our SERION ELISA *classic* products.