



SERION ELISA *classic*

Borrelia burgdorferi IgG/IgM

Intended Use

- Qualitative and quantitative detection of human IgG and IgM antibodies in serum, plasma and cerebrospinal fluid directed against *Borrelia burgdorferi*
- Differentiation between acute and previous infections
- Determination of disease status

Diagnostic Efficiency

The SERION ELISA *classic* Borrelia burgdorferi IgG was evaluated by the analysis of 360 serum samples, including serum samples from blood donors and from patients with suspected borreliosis, against a commercially available ELISA of a leading European manufacturer.

The validation of the SERION ELISA *classic* Borrelia burgdorferi IgM was carried out by the analysis of 463 serum samples, including serum samples from blood donors, pregnant women, and patients with suspected borreliosis, compared to a commercially available ELISA of a leading European manufacturer.

Product	Sensitivity	Specificity
SERION ELISA <i>classic</i> Borrelia burgdorferi IgG	93.2 %	99.0 %
SERION ELISA <i>classic</i> Borrelia burgdorferi IgM	94.5 %	98.2 %

Precision

SERION ELISA *classic* Borrelia burgdorferi IgG

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.413	1.8	0.435	4.4
Serum 2	1.105	1.9	1.165	3.8
Serum 3	1.889	2.5	1.903	3.6

SERION ELISA *classic* Borrelia burgdorferi IgM

Sample	Mean Value (OD)	Intraassay CV (%) (n=20)	Mean Value (OD)	Interassay CV (%) (n=10)
Serum 1	0.743	4.8	0.870	4.4
Serum 2	2.156	2.5	2.442	2.7
Serum 3	2.772	1.7	3.000	1.7

Pathogens

Borrelia burgdorferi is the infectious agent of Lyme-Borreliosis. *B. burgdorferi sensu stricto*, *B. garinii*, *B. afzelii* and *B. spielmanii* are the most important human pathogens of the genospecies *Borrelia burgdorferi sensu lato*. All four species are distributed throughout Europe in temperate climate zones. Reservoirs for the bacteria include a variety of mammals, particularly mice. The bacteria are transmitted to human hosts by infected ticks.

Disease

Lyme-Borreliosis is a multisystemic disease. Dermal manifestations with *Erythema migrans* (EM) as a characteristic symptom of early disease are displayed by 70 to 90 % of infected persons. In addition to non-specific symptoms, in particular neurological disorders, e. g. Morbus Bannwarth, may be observed be-

tween a few weeks and several months post infection as signs of a systemic disease with single or multiple organ involvement. Development of late-stage symptoms may occur up to several years after the tick bite and are characterized by dermatological diseases (*Acrodermatitis chronica atrophicans*), 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, serology is the appropriate method to ensure an optimal diagnosis. It is recommended to adopt a logical step-wise approach for serological diagnosis, initially using a sensitive screening assay with subsequent confirmation by another specific test.

Highlights

- High diagnostic efficiency by use of lysates of the strains *Borrelia afzelii* and *Borrelia garinii*
- Sensitive IgM detection for diagnosis of acute infections
- Sensitive IgG detection for diagnosis of acute and past infections through adding recombinant VlsE to the antigen mixture
- Optimal specificity by preabsorption of potentially cross-reacting antibodies directed against *Treponema phagedenis* and by reduction of the Flagellin proportion in the antigen mixture
- Detection of intrathecally synthesized IgG and IgM antibodies for CSF diagnostics

Product	Order No.
SERION ELISA <i>classic</i> Borrelia burgdorferi IgG	ESR121G
SERION ELISA <i>classic</i> Borrelia burgdorferi IgM	ESR121M

SERION ELISA *control*

Please visit our website for more information.

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