Lyme Borreliose

Seramun Diagnostica GmbH

Seraline® Anti-Borrelia IgG
Seraline® Anti-Borrelia IgM

Line - Immunoassay for detection of IgG- or IgM-antibodies against *Borrelia burgdorferi* in human serum or plasma

- sensitive and specific
- ready-to-use colour-coded reagents
- short incubation times
- automatic or visual evaluation

Indication

The investigation of serum or plasma for the presence of anti-Borrelia antibodies by Line immunoassay is recommended in case of a positive anti-Borrelia ELISA result.

- to control the specificity of the ELISA results
- for discrimination of stages of the disease according to the specific band pattern in the case of low reactivity in anti-*Borrelia* ELISA
- for detection of a seroconversion
- to control the specificity of the ELISA results in the case of repeated reactivity in IgM-ELISA

Principle

The *Seraline*® Anti-Borrelia uses highly purified recombinant Borrelia proteins, which are plotted onto strips of nitrocellulose-membranes in defined distances.
Specific antibodies present in the sample react with the respective antigens during the first incubation step. These immune complexes are detected in the subsequent conjugate (anti-human IgG- or anti-human IgM-HRP) incubation step.
Membrane bound immune complexes are finally detected by formation of blue precipitates with the substrate solution.
One function control, 2 conjugate controls and a Cut off control support the evaluation.

Procedure

- incubate nitrocellulose strip with 1.5 ml wash- and incubation buffer (WIB)
- add 15 µl sample to each strip
- incubate for 45 min on a rocking platform
- wash 3 times with 1.5 ml WIB (5 min)
- add 1.5 ml conjugate (IgG or IgM)
- incubate for 45 min on a rocking platform
- wash 3 times with 1.5 ml WIB (5 min)
- add 1.5 ml substrate
- incubate for 10 min on a rocking platform
- wash 3 times with 1.5 ml pure water
- dry strip before evaluation

Evaluation and interpretation

The single bands are assigned to the respective Borrelia antigens by usage of the evaluation template or with the software *Seraline*® scan.

Evaluation criteria

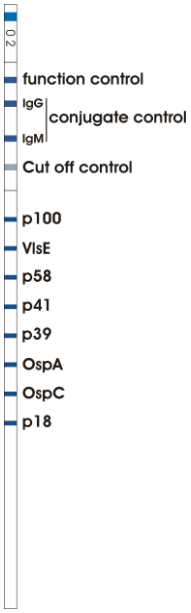
IgG

positive	2 bands except for p41 ≥ Cut off control
borderline	VlsE, 1 band + p41 ≥ Cut off control
negative	max. 1 band except for VlsE ≥ Cut off control

IgM

positive	OspC, p18, 2 other bands ≥ Cut off control
borderline	1 band except for OspC, p41, p18 ≥ Cut off control
negative	no bands except for p41 ≥ Cut off control

Band pattern and characterization



antigens	strain
p100	B. afzelii
VlsE	B. afzelii
p58	B. garinii
p41	B. burgdorferi. s.s.
p39	B. afzelii
OspA	B. afzelii
OspC	Mix*
p18	Mix*

Mix*: B. burgdorferi sensu stricto, B. garinii I + II (only Osp C), B. afzelii, B. spielmanii

Sensitivity

IgG and IgM detection

n = 78 sera		comparative – Line Immunoassay	
		positive	negative
Seraline®	positive	51	10
	negative	1	16

A total of 67 samples delivered concordant results in both assays which means an overall agreement of 85.9% and a comparative sensitivity of 98.1% for the *Seraline*® Anti-Borrelia IgG/IgM in relation to the commercial assay.

Samples with discordant results (n=11) were reinvestigated by immunoblot (*Serablot*® Anti-Borrelia IgG/ IgM). The *Seraline*® results were confirmed by immunoblot for 8 of 10 positive samples.

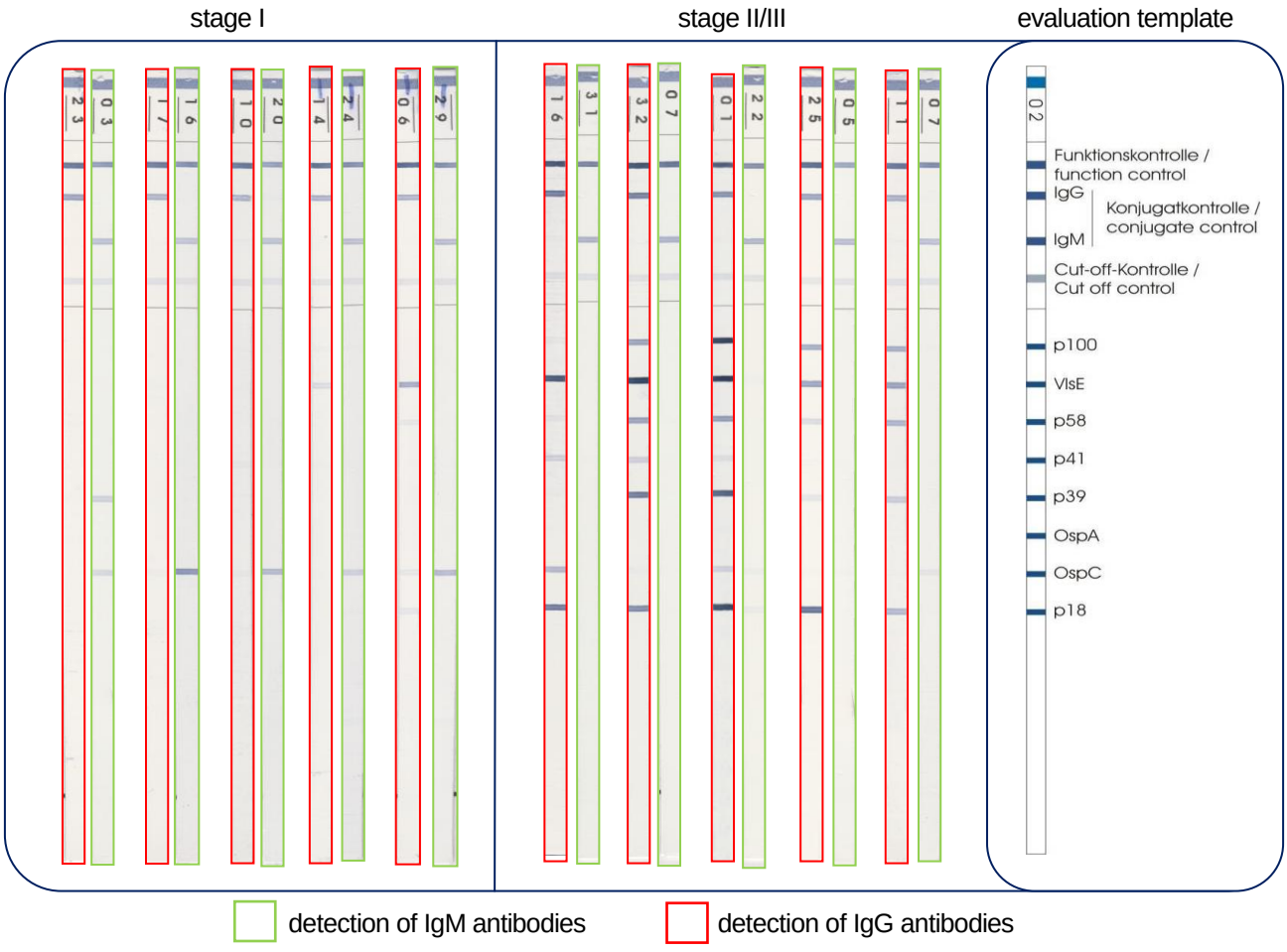
Specificity

The investigation of 400 healthy blood donors revealed a specificity of

88.2 % *Seraline*® Anti-Borrelia IgG

94.5 % *Seraline*® Anti-Borrelia IgM

Serology of different stages of Lyme Borreliosis in the *Seraline*® Anti-Borrelia IgG/IgM



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www.tuv.com TÜVRheinland ID:0000026644
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Katalog- Nr. LIA-006-8 G, LIA-006-8 M

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