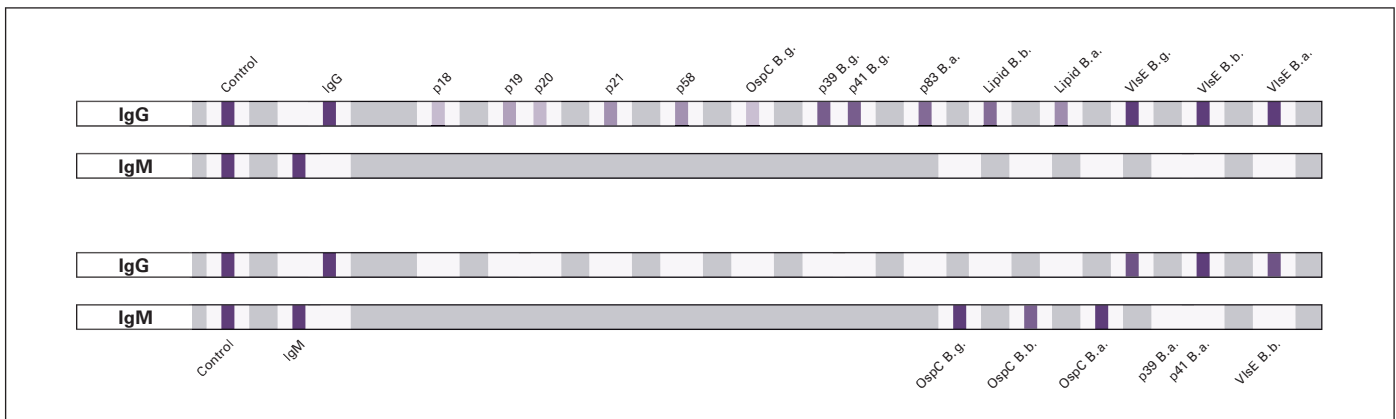


EUROLINE Borrelia RN-AT: Marriage of authentic recombinant and native borrelia antigens in a line immunoassay format

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Introduction

The serological diagnosis of Lyme disease has to rely on both, recombinant and native antigens, as until now not all recombinantly produced borrelia antigens, and in particular the most important IgM marker OspC, display the required sensitivity and specificity. A new line immunoblot was evaluated that combines the most specific and sensitive antigens for the detection of antibodies in Borreliosis.

Methods

The antigens p83, p39 and OspC were cut from a classic westernblot and placed onto the line assay. Immunochips coated with three VisE antigens and two extracted lipid fractions were added. Furthermore, from 68 potentially immunoreactive proteins identified in a bioinformatic analysis of the Borrelia genome, the antigens p58, p21, p20, p19, and p18 were selected and added to the line assay, owing to their high specificity. For the detection of IgM, a special line assay was configured providing three native purified OspC antigens (*B. afzelii*, *B. burgdorferi* and *B. garinii*; isolation by column chromatography), p39, flagellin and VisE. The immunological potential of these test systems was ascertained by analyzing sera from 274/236 (IgG/IgM) clinically characterized and

198/204 suspected borreliosis cases, 28/45 with other infections and 117/159 healthy blood donors.

Results

In comparison to a conventional western-blot system, the EUROLINE Borrelia RN-AT achieved a yet higher sensitivity at an excellent specificity. ROC analysis of the antibody response against each single antigen demonstrated prevalences between 7% and

ROC: EUROLINE Borrelia RN-AT IgG; n=617 EUROLINE-WB = 100%		
Antigen	Prevalence (%)	Specificity (%)
VisE Ba	65.5	98.6
VisE Bb	88.5	98.6
VisE Bg	67.6	95.3
Lipid Ba	25.1	100
Lipid Bb	25.1	99.6
p83 Ba	53.7	95.3
p39 Bg	61.3	98.6
OspC	48.7	95.7
p58	20.7	97.5
p21	8.9	99.3
p20	7.1	100.0
p19	9.1	99.3
p18	22.4	99.3

ROC: EUROLINE Borrelia RN-AT IgM; n=644		
Antigen	Prevalence (%)	Specificity (%)
VisE Bb	4.9	99.4
p39 Ba	15.9	99.0
OspC Ba	88.2	99.0
OspC Bb	77.1	99.2
OspC Bg	84.1	96.8

89% and specificities of at least 95%. The major target antigen for the detection of IgG was VisE (prevalence 89% at a specificity of 99%). For IgM detection, the use of native purified OspC antigens from all three pathogenic genospecies showed specificities of 97% to 99% at a prevalence of up to 88%. The OspC from *B. garinii* contributed selectively to 15 (2%) of the positive IgM reactions; all these cases could be confirmed with a special *B. garinii* westernblot.

Discussion

The broad antigen spectrum of the EUROLINE Borrelia RN-AT, which includes recombinant and native authentic antigens, assures the best reliable serological diagnosis in cases of rare and difficult to interpret antibody constellations. Nevertheless, the test system is also well suited for bulk analyses, since due to the line immunoassay format, test results are easy to interpret.

Recombinant proteins
 Lipids
 Native proteins

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