USEFULNESS OF C6-VlsE TEST FOR THE DIAGNOSIS OF LYME BORRELIOSIS
Marie-Lise Tritten, Hans H. Siegrist, Reto Lienhard
ADMED Microbiologie, 2300 La Chaux-de-Fonds, Switzerland

Introduction
Lyme borreliosis is an endemic disease in our region of Switzerland with a prevalence of about 7% positive Western Blot tests in asymptomatic blood donors. Three years ago we introduced the C6-VlsE ELISA IgG+IgM test in our screening scheme along with our usual routine ELISA IgG and IgM capture tests. Our main objective was to better identify patients in whom symptoms were most probably linked to active Lyme borreliosis from those who were presumably asymptomatic carriers, if possible with a single screening test. Our secondary objective was to better target the sera requiring confirmatory Western Blot tests.

Material and Methods
A total of 820 sera (out of 2836 tested) from patients suspected to suffer from Lyme borreliosis were tested with C6 Lyme ELISA™ Kit (Immunetics®) for total antibody response (IgM + IgG) to the C6 peptide of the VlsE antigen of Borrelia burgdorferi sensu lato. All samples were also screened for specific antibody response with two commercial ELISA tests, IDEIA™ Borrelia IgM (DAKO) and RIDASCREEN® Borrelia IgG (r-biopharm). Results were then confirmed with at least one of our three routine home made IgG (Borrelia burgdorferi ss, Borrelia garinii, Borrelia afzelii) Western Blots and our IgM (Borrelia garinii) home made Western Blot.

Results

<table>
<thead>
<tr>
<th></th>
<th>Positive Western Blot</th>
<th>Negative Western Blot</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive C6 test</td>
<td>329</td>
<td>144</td>
<td>473</td>
</tr>
<tr>
<td>Negative C6 test</td>
<td>60</td>
<td>287</td>
<td>347</td>
</tr>
<tr>
<td>Total</td>
<td>389</td>
<td>431</td>
<td>820</td>
</tr>
</tbody>
</table>

Kappa correlation coefficient: 0.51

Discussion
Results from Table 1 show that 60 samples (15%) would have been reported as false negative for Western Blot (WB) confirmed borreliosis if the C6-VlsE test had been used as the only screening test. Among them 48 (80%) were WB IgM positive only, suggesting a lack of sensitivity of the C6-VlsE assay in beginning infections or of specificity of IgM WB. On the other hand 144 samples were detected as positive with the C6-VlsE test and not confirmed by Western Blot underlining the lack of sensitivity of Western Blots in early stages of the disease. A part of these samples are probably true positives revealing the screening potential of this test. The moderate Kappa correlation coefficient suggests that the C6-test cannot replace the Western Blots as confirmation test.

Table 2 shows the good performance our two tests routine screening missing only few (30 sera = 7.7%) potentially positive samples. Interestingly results from Table 3 show that the C6-VlsE test and our combined two tests screening pick different sera needing Western Blot confirmation as highlighted by a poor Kappa correlation coefficient.

Conclusion
The C6-VlsE ELISA test proves to be definitely an interesting additional test. In our setting it cannot be used as a stand alone screening test as it would miss several clinical cases. Our results point out that different screening tests based on different targets give complementary results. Western Blots are still indispensable to refine the diagnosis of borreliosis and give a more accurate picture of the stage of the disease.