The two tier serum test for Lyme antibodies

Testing:

**Issue Number:**
1.1. The 2 Tier methodology widely recommended in Europe and the USA for testing serum samples for Lyme disease detects just over 50% of positive cases, based on trials under strictly controlled research laboratory conditions.

**Source:**
Studies from 1996 to 2010 evaluated commercial ELISA and Western Blot test kits using the “2 Tier” test methodology. The results were produced by teams of researchers and assistants free from many of the factors that govern busy microbiology labs. Using well defined borrelia infected serum panels, sensitivities between 17% and 100% were achieved with a 58% average.

Test failures (false negative results) up to 83% were observed by Steere et al with serum panels selected based on clinical diagnosis and prior positive serology as defined by the US Center for Disease Control.

Summary of Serology Test data using 2 Tier Testing Methodology

<table>
<thead>
<tr>
<th>Author</th>
<th>Symptoms</th>
<th>Test</th>
<th>Sensitivity</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Johnson et al., 1996)</td>
<td>Culture</td>
<td>2 Tier</td>
<td>75%</td>
<td>56% - 100%</td>
</tr>
<tr>
<td>(Trevejo et al., 1999)</td>
<td>EM</td>
<td>2 Tier</td>
<td>31%</td>
<td>29% - 32%</td>
</tr>
<tr>
<td>(Nowakowski et al., 2008)</td>
<td>Clinical</td>
<td>2 Tier</td>
<td>53%</td>
<td>40% - 66%</td>
</tr>
<tr>
<td>(Steere et al., 2008)</td>
<td>CDC</td>
<td>2 Tier</td>
<td>67%</td>
<td>17% - 100%</td>
</tr>
<tr>
<td>(Branda et al., 2010)</td>
<td>CDC</td>
<td>2 Tier</td>
<td>64%</td>
<td>64% - 100%</td>
</tr>
</tbody>
</table>

Average and Range of studies 58% 17% 100%

Culture = Patients selected based on positive culture of Borrelia spirochaetes
EM = Erythema migrans rash
Clinical = Patients with clinical diagnosis of Lyme disease
CDC = Patient meeting Center for Disease Control definition which requires clinical symptoms and positive serology.

**References:**


