Performance of Two Enzyme and One Strip Immune Assay for the Detection of IgM anti-*Treponema pallidum* Antibodies

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**Background**

The detection of anti-*Treponema pallidum* (Tp) IgM antibodies may be useful in the diagnosis of very early syphilis, re-infection and in the assessment of the newborn.

We evaluated 2 enzyme immunossays and 1 line immunoassay (LIA) assay for the detection of anti-Tp IgM in blood specimens.

**Conclusions**

The highest sensitivity was found with the IgM recomLine line immunoassay. The sensitivity increased further when borderline results were considered positive. Cross reactivity with a specimen containing anti-malaria antibodies was found for the Euroimmun assay.

We observed that Anti-Tp IgM antibodies could be detected before RPR reactivity and that they could remain present for months even after successful treatment.

**Methods**

Blood specimens collected from patients presenting with a syphilitic ulcer, and specimens (N=3 for each containing antibodies against Epstein Barr Virus, *Leptospira* sp, *Borrelia* sp, *Plasmodium* sp, Herpes Simplex Virus 1 and 2 and specimens from pregnant women were analyzed.

The specimens were tested using:
1. Rapid Plasma Reagin (RPR), Macrovue, Becton Dickinson
2. Treponema Pallidum Particle Agglutination (TPPA), Fujirebio
3. recomWell Treponema IgM, Mikrogen Diagnostik
4. Anti-Treponema pallidum ELISA–IgM, Euroimmun
5. recomLine Treponema IgM, Mikrogen Diagnostik

A specimen was considered positive for anti-Tp IgM when both TPPA and IgM, obtained with any of the assays, were positive. Specimens collected from the syphilitic ulcers were tested by in-house qPCR.

**Results**

Anti-Tp IgM antibodies were detected in 23 specimens. The performance characteristics of the IgM assays are presented in the table:

<table>
<thead>
<tr>
<th>Test</th>
<th>Concordant (%)</th>
<th>Sensitivity (%)</th>
<th>95% CI (%)</th>
<th>Specificity (%)</th>
<th>95% CI (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM LIA (A)</td>
<td>96,55</td>
<td>94,74</td>
<td>71,89-99,72</td>
<td>100</td>
<td>65,55-100</td>
</tr>
<tr>
<td>IgM LIA (B)</td>
<td>96,97</td>
<td>95,65</td>
<td>70,53-99,77</td>
<td>100</td>
<td>58,97-97,6</td>
</tr>
<tr>
<td>Euroimmun</td>
<td>77,14</td>
<td>65,71</td>
<td>42,82-82,81</td>
<td>100</td>
<td>69,87-100</td>
</tr>
<tr>
<td>recomWell(A)</td>
<td>84,85</td>
<td>76,19</td>
<td>52,45-90,88</td>
<td>100</td>
<td>69,87-100</td>
</tr>
<tr>
<td>recomWell(B)</td>
<td>85,71</td>
<td>78,26</td>
<td>55,79-91,71</td>
<td>100</td>
<td>69,87-100</td>
</tr>
</tbody>
</table>

Legend: CI: confidence interval; A: excluding borderline results; B: with borderline results defined as positive

Euroimmun tested positive in 1 specimen containing anti malaria antibodies

**Example of individual test results**

**Acknowledgement**

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