Performance of the EUROblotOne – EUROLINE WB system (Euroimmun) compared to an in-house Western-blot procedure for the confirmatory serological diagnostics of Lyme Borreliosis

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The diagnostics of the Lyme Borreliosis mainly relies on the detection of IgM and IgG antibodies directed against *Borrelia burgdorferi sensu lato*. Due to specificity issues, positive screening tests should be confirmed by Western-blot or other methods allowing detection of antibodies against specific antigens. Our laboratory has a long experience in production and routine use of in-house Western-blot for this confirmatory diagnostics. However, this method is time consuming, requires a high level of standardization for the production of the membrane strips and can only be partially automatized. We evaluated the EUROLINE WB system (Euroimmun, Germany) that allows fully automated sample processing, digitalization and analysis of Western-blot strips, thereby reducing the turnaround-time from approximately 8h to 3h. The interpretation criteria were modified to match the in-house criteria, resulting in improved specificity of the EUROLINE WB system.

**Home made Western-blot**
- Whole antigen from cultured *Borrelia garinii*
- Electrophoretic separation and blotting to nitrocellulose membrane
- Semi-automated processing on Tecan ProFlex 48
- Optical reading by operator
- Comparing to calibrated reference membranes

**EUROBlotOne – EUROLINE WB system**
- Whole antigen from cultured *Borrelia afzelii*
- Spotted recombinant VlsE
- Fully-automated processing on EUROBlotOne
- Optical reading by camera
- Automated interpretation by software
- CE-IVD labelled

**Conclusions**
- By using adapted interpretation criteria, the EUROLINE WB system showed a good correlation compared to our in-house Western-blot protocol in a retrospective study including clinically well characterized samples.
- The specificity of the EUROLINE WB test was significantly improved by using the adapted criteria.
- The adapted interpretation criteria had some negative impact on the sensitivity in the prospective analysis. However, the overall performance of the remained satisfactory.
- The EUROLINE WB system has strong advantages in terms of shorter turnaround-time and higher degree of integration to the laboratory information system.

**Laboratory integration**
- The turnaround time of the EUROLINE WB system is significantly reduced compared to the in-house Western-blot (173 min vs. 513 min).
- The EUROLINE WB system includes bi-directional connectivity to laboratory information system.
- A common processing protocol allows to run other tests (e.g. auto-immunity panels) simultaneously on the EUROblotOne.

**Phase 1: retrospective analysis**
Retrospective analysis of 74 samples from patients with:
- early localized Lyme disease (erythema migrans: 19 cases)
- early disseminated Lyme disease (lymphocytoma: 5 cases)
- late Lyme disease (arthritis: 15 cases; acrodermatitis chronica atrophicans: 5 cases)
- neuroborreliosis (2 cases)
- unspecified clinical presentation (28 cases)
- Western-blot were performed for IgG and IgM.

The use of interpretation criteria closer to those used for the in-house Western-blot improves significantly the specificity for both IgM and IgG, without decreasing the sensitivity.

**Phase 2: prospective analysis**
- Prospective analysis of 251 samples tested in the routine setting
- Western-blot were performed for both IgG and IgM, if either was positive in the screening test.

The use of the adapted criteria improves significantly the specificity, but with some impact on the sensitivity both for IgM and IgG, especially for borderline positive samples.

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**The turnaround-time comparison of both WB systems**
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