Evaluation of Lyme TRACE ELISA, a quantitative IgG anti-VlsE Assay monitoring Lyme borreliosis humoral response.

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Introduction
Lyme borreliosis serology has poor predictive values. As a necessary and convenient diagnostic tool it is often misused by screening patients presenting unclearly defined borreliosis symptoms. Lack of sensitivity in early stage and seroprevalence in endemic region cause people to be treated without any clinical evidence of borreliosis.

Material & Method
A selection of 115 sera was tested from 38 patients and 6 seropositive blood donors. A panel of 2 to 6 sera from seropositive patients were used for the follow up. From the seropositive blood donors 2 samples in a lapse of time from 3 to 12 months were tested.

All patients presented clinically and/or serologically confirmed Lyme borreliosis or symptoms strongly suggesting borreliosis. Among monitored patients 32/35 showed same tendency or quantity in a lapse of time, but in a longer delay expressing the same tendency.

Result & Discussion

Correlation Liaison VlsE IgG vs LYME TRACE (n=115)

Patient Follow up
- Late borreliosis do always show high quantitative IgG anti-VlsE values
- Early borreliosis may show very low quantity of IgG
- Amplitude is assay dependant
- Among monitored patients 32/35 showed same tendency
- The other 3 present major differences in tendencies or quantity in a lapse of time, but in a longer delay expressing the same tendency.
- Both assays show potential to follow quantitative IgG anti-VlsE

Quantitative determination of IgG measures antibody kinetics requested to define patient’s serological status as seroconversion, seroprevalence or response to treatment. A new assay proposes to measure quantitatively IgG anti-VlsE response to monitor serologically Lyme borreliosis infection. A comparison with Borrelia IgG testing by Liaison is presented.

As to the blood donors, a questionnaire enabled us to exclude symptoms of Lyme disease, recent (<3 months) tick bite, fever or antibiotic treatment. Lyme Trace ELISA (Euroimmun, Lübeck) (TRACE) and Borrelia IgG LIAISON® (Diasorin) (LIA) were used for the comparison. Both assays are based on recombinant VlsE antigens from B. burgdorferi s.s. and B. afzelii.

Correlation is very poor making any comparison impossible.
- Blood donor monitoring shows comparable tendencies
- Amplitude of variation is assay-dependant
- Generally values are stable or slow decrease is observed
- Two cases of IgG increase could be confirmed
- Donors B and D show higher decrease with TRACE LYME.
- VlsE sources: B. burgdorferi + B. garinii (LIA); B. burgdorferi + B. afzelii (Trace)

Blood Donors

Fig. Donors A to E with sample 1 and 2 at month 3, 6, 9 or 12

Early localized

Early disseminated

Conclusion
Lyme Trace ELISA and Borrelia IgG LIAISON® have the technical prerequisites to be used for the monitoring of Lyme borreliosis serological response. A large prospective study is now needed to validate the usefulness of such assays to monitor Lyme borreliosis patient presenting new signs after treatment.