Lyme Disease Diagnostics

Lyme Disease: The Embers Lab

With approximately 300 thousand cases of transmission in North America each year, Lyme Disease is one of the most prevalent vector-borne illnesses in the United States – which is why it is an area of focus for the Lab of **Monica Embers**. While more effectively treated with antibiotics if diagnosed early, this tick-transmitted bacterial infection can cause serious complications, including carditis and CNS symptoms. Many patients whose diagnosis is missed or delayed experience symptoms following treatment, as the antibiotics can be less effective at this later stage of infection. These individuals are said to have Post-Treatment Lyme Disease Syndrome (PTLDS).

Currently, clinical diagnosis of the disease relies on either observation of the characteristic *erythema migrans* (bulls eye) rash or a late-stage symptom (cardio-vascular, neural, etc.) combined with laboratory confirmation. The spirochetes themselves, along with their antigens, are not widely disseminated in patient blood, meaning that current methods rely on detection of host antibodies. The gold standard two-tier test for laboratory confirmation is either an enzyme immunoassay or immunofluorescence assay followed by Western blot confirmation.

This laboratory testing approach is most effective during the disseminated stage of the disease. The Embers Lab wanted to develop a test that was more accurate during all stages of the disease, including the acute and chronic stages. This would allow for: 1) early detection of the disease, leading to more timely and effective deployment of antibiotics; 2) evaluation of patients with PTLDS vs. non-PTLDS (i.e. clinically cured) patients for differences in immune responses; and 3) assessment of patients who have a clinical diagnosis of Lyme disease, but may be negative by the two-tier test.

Tulane
SCHOOL OF MEDICINE

Multi-Antigen, Bead-Based Test

The development process included utilizing a rhesus macaque model of Lyme disease to identify additional antigens beyond the C6 peptide currently used for laboratory diagnosis of Lyme. The lab observed that serum antibodies to the OspA, OspC, DbpA, and OppA-2 proteins offer distinct advantages to use over the C6 peptide antibodies alone, and that they all could be combined in a more accurate, multi-antigen, five-plex test. This multi-antigen approach offers the distinct advantage of covering all stages of infection. It is also much more quantitative than traditional tests, meaning that fluctuations in host antibody response can be correlated with clinical outcomes.

This test has been evaluated for sensitivity and specificity and compared to the two-tier test with a panel of very well characterized standard patient samples from the CDC. The test was found to have improved sensitivity while maintaining a high level of selectivity (>90%). Additionally, the lab has tested patient samples from individuals with PTLDS, and found that patients with PTLDS actually had low antibody response to all antigens or had a non-declining antibody response to OppA-2.

Patients with PTLDS that were two-tier (gold standard) negative were often (~60% of the time) five-plex test positive, demonstrating superior sensitivity and strong potential clinical relevance and application for this test over that of two-tier. This test would allow for the ready identification of patients that need treatment both early in infection and those who would benefit from additional antibiotic therapy -two key areas that the current tests are unable to address.

Contact & Further Info:

James R Zanewicz, RTTP
Chief Business Officer
zanewicz@tulane.edu
504.919.3800 (m)

Claiborne M Christian, PhD
Business Development Assoc.
christian@tulane.edu
504.909.3905 (m)

engage.tulane.edu
t: engagetulane

Tulane
SCHOOL OF MEDICINE