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New Test for Lyme Disease: *Borrelia burgdorferi* C6 Peptide Antibody assay

To: Clients of UR Medicine Labs

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Lyme disease, caused by the spirochete *Borrelia burgdorferi*, is the most frequently reported arthropod-borne disease in the United States. The bite of an infected *Ixodes* species tick transmits the spirochete. Until recently, Lyme disease was rare in Monroe County and the Finger Lakes Region. Most of the cases seen here were acquired elsewhere. However, in 2013, we saw numerous locally acquired cases of the tick-borne infection.

The CDC continues to recommend a two-tiered approach to Lyme disease testing that includes a whole cell-sonicate (WCS) immunoassay followed by Western Blot (WB) for confirmation. The two-tiered approach is recommended because WCS assays lack specificity. Unfortunately, the use of the Lyme WB is problematic in terms of timeliness, cost, and accuracy of the Lyme diagnosis.

A new test, the *Borrelia burgdorferi* C6 Peptide Antibody assay, is significantly more specific for detection of *B. burgdorferi* infection than the currently used whole cell sonicate (WCS) screening test. This unique test identifies antibodies to a conserved peptide called C6, which is a component of the variable surface antigen, VlsE1. The test detects (but does not distinguish) both IgG and IgM antibodies in patients with early, chronic or late Lyme disease. Experts in the field found that a 2-tiered EIA approach (WCS + C6) is significantly more sensitive than the current 2-tiered algorithm, but equally specific. Therefore, we are replacing the Lyme WB with the Lyme C6 EIA for confirmation (1,2).

On May 19, 2014 we will begin using the C6 antibody test to confirm all positive Lyme WCS screens. The report for Lyme WCS screen reactive specimens will read "SEE LYME C6 CONF" because reactive results are not definitive. Reactive specimens will be reflexed to the Lyme C6 Peptide Confirmatory assay and will result with a final answer of 'POSITIVE', 'EQUIVOCAL', or 'NEGATIVE'. There will also be a "LYME INTERP" field that will provide some guidance and explanation of the results. The Lyme WB will no longer be routinely available.

Advantages

- Effectively distinguishes between infection (true positives) and false-positives common with whole-cell sonicate EIA tests
- Improved sensitivity when compared to the method now in use
- Better turn around time – all testing done at SMH
- Less expensive

Any questions can be directed to Dan Wheeler, Serology Lab Supervisor. (585) 275-7801

1. Branda, JA et al. Two-tiered antibody testing for Lyme Disease with the use of 2 immunoassays, a whole-cell sonicate enzyme immunoassay followed by a VlsE C6 peptide enzyme immunoassay. Clin Infect Dis. 2011; 541-547
2. Steere, AC et al. Clin Infect Dis. 2008; 188-195
3. Schoen, RT Better laboratory testing for Lyme disease: No more western blot CID 2013; 57:341-343