LABORATORY ALLIANCE of Central New York, LLC

Change in Methodology: Lyme Disease Screen *Borrelia burgdorferi* IgG/IgM

Effective November 20, 2012, Laboratory Alliance of Central New York will begin using a new methodology for Lyme disease screening. The new methodology is a chemiluminescent immunoassay on the DiaSorin Liaison XL® employing the VLsE recombinant antigen. Use of this antigen as the target for antibody detection has been demonstrated to produce fewer false positive reactions. Correlation studies in our laboratory indicate that the new assay has better agreement with Western blot confirmatory testing than does our previous assay. Like the previous assay, the new Liaison XL® assay will detect either IgG or IgM antibodies.

We would also like to take this opportunity to review the current CDC recommendation for Lyme disease testing. The CDC currently recommends a two-step process when testing blood for evidence of antibodies against the Lyme disease bacteria. Both steps can be done using the same blood sample.

The first step uses an enzyme, fluorescent or chemiluminescent immunoassay procedure. If this first step is negative, no further testing of the specimen is recommended. If the first step is positive or equivocal, the second step is performed. The second step uses a test called an immunoblot test, commonly, a "Western blot" test. Results are considered positive only if both steps are positive.

The two steps of Lyme disease testing are designed to be done together. CDC does not recommend skipping the screening test and using only the Western blot. Doing so will increase the frequency of false positive results and may lead to misdiagnosis and improper treatment. Please review the attached educational algorithm which describes clinical decision-making for patients with symptoms of Lyme disease after tick exposure.

As was the case with our previous assay, all specimens with positive or equivocal screen results will have Western blot testing for IgG and IgM antibodies to *Borrelia burgdorferi* reflexively ordered. The screening test appears on the report as LYME IGM/IGG AB@ and the confirmatory test will appear on the patient's report as LYME CONFIRM ABS BLD. **Please note that once a positive Western blot test for Lyme disease has been obtained, repeat Lyme serological tests (screens or Western blots) are not recommended.**

Although this change in methodology will not impact specimen requirements or order/result codes, test information is as follows:

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Test Code:	LYME
Method:	Chemiluminescent Immunoassay
Specimen Requirements:	One 5 mL gold top tube (SST). 2 mL serum required.
Storage and Transport:	Centrifuge within 2 hours of collection. Transport to laboratory refrigerated or ambient.
Stability:	Refrigerated, 7 days.
Unacceptable Conditions:	Plasma, CSF.
Testing Schedule:	Daily
CPT Code:	86618

If additional testing is reflexively ordered, 86617x2

Billing Code:	2010061

Questions regarding these tests may be directed to Cheryl Haskins, MS, MT(ASCP)SC, Manager of Chemistry and Referral Testing, at 315-410-7014 or cherylhaskins@lacny.com.

10/31/12, cmh

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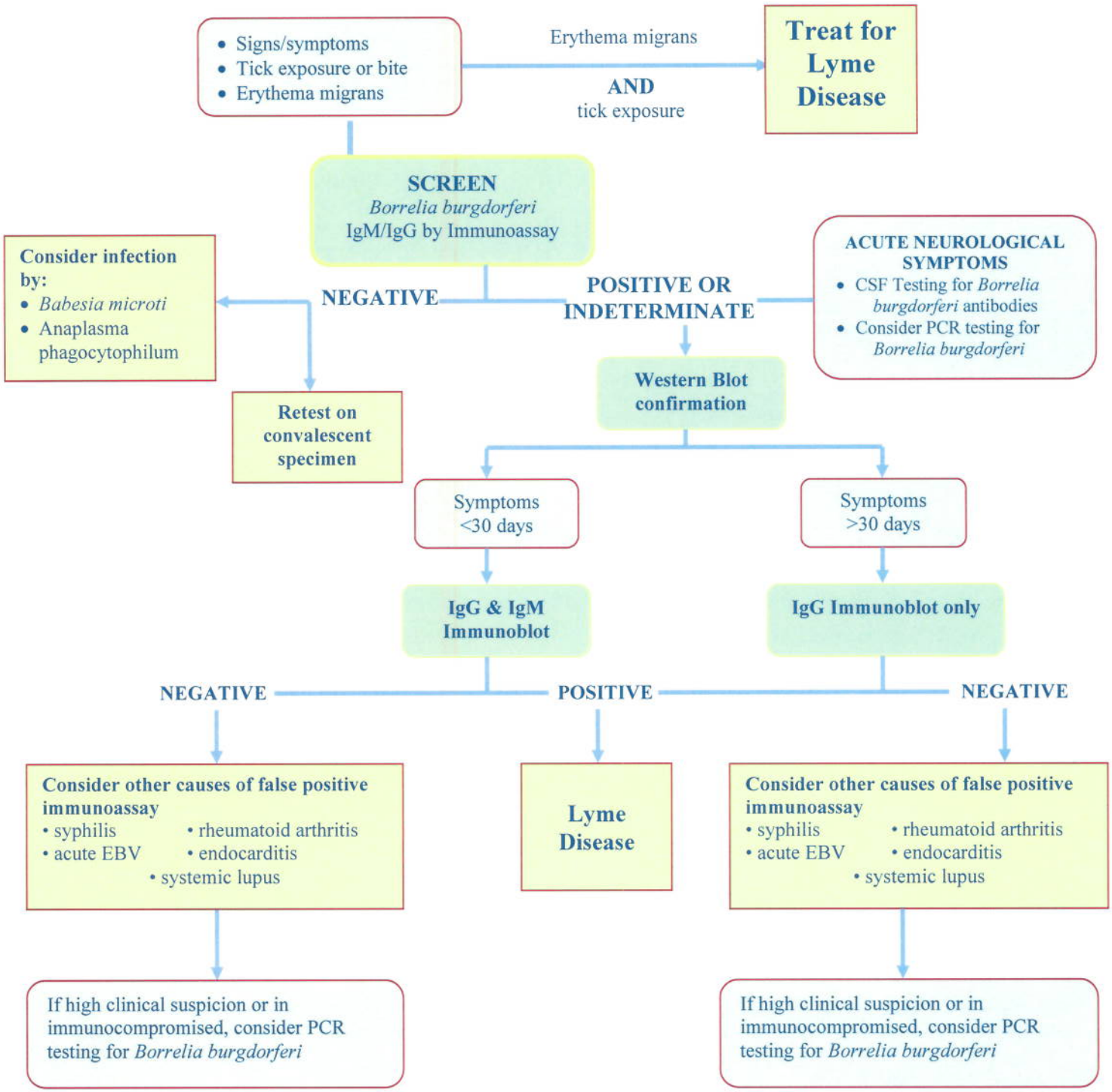
Lyme Testing Algorithm



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