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Notice to Readers Recommendations for Test Performance and Interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease

The Association of State and Territorial Public Health Laboratory Directors, CDC, the Food and Drug Administration, the National Institutes of Health, the Council of State and Territorial Epidemiologists, and the National Committee for Clinical Laboratory Standards cosponsored the Second National Conference on Serologic Diagnosis of Lyme Disease held October 27-29, 1994. Conference recommendations were grouped into four categories: 1) serologic test performance and interpretation, 2) quality-assurance practices, 3) new test evaluation and clearance, and 4) communication of developments in Lyme disease (LD) testing. This report presents recommendations for serologic test performance and interpretation, which included substantial changes in the recommended tests and their interpretation for the serodiagnosis of LD.

A two-test approach for active disease and for previous infection using a sensitive enzyme immunoassay (EIA) or immunofluorescent assay (IFA) followed by a Western immunoblot was the algorithm of choice. All specimens positive or equivocal by a sensitive EIA or IFA should be tested by a standardized Western immunoblot. Specimens negative by a sensitive EIA or IFA need not be tested further. When Western immunoblot is used during the first 4 weeks of disease onset (early LD), both immuno- globulin M (IgM) and immunoglobulin G (IgG) procedures should be performed. A positive IgM test result alone is not recommended for use in determining active disease in persons with illness greater than 1 month's duration because the likelihood of a false-positive test result for a current infection is high for these persons. If a patient with suspected early LD has a negative serology, serologic evidence of infection is best obtained by testing of paired acute- and convalescent-phase serum samples. Serum samples from persons with disseminated or late-stage LD almost always have a strong IgG response to Borrelia burgdorferi antigens.

It was recommended that an IgM immunoblot be considered positive if two of the following three bands are present: 24 kDa (OspC) * , 39 kDa (BmpA), and 41 kDa (Fla) (1). It was further recommended that an that IgG immunoblot be considered positive if five of the following 10 bands are present: 18 kDa, 21 kDa (OspC) *, 28 kDa, 30 kDa, 39 kDa (BmpA), 41 kDa (Fla), 45 kDa, 58 kDa (not GroEL), 66 kDa, and 93 kDa (2).

The details of both plenary sessions and the work group deliberations are included in the publication of the proceedings, which is available from the Association of State and Territorial Public Health Laboratory Directors; telephone (202) 822-5227.

References

1. Engstrom SM, Shoop E, Johnson RC. Immunoblot interpretation criteria for serodiagnosis of early Lyme disease. J Clin Microbiol 1995;33:419-22.

2. Dressler F, Whelan JA, Reinhart BN, Steere AC. Western blotting in the serodiagnosis of Lyme disease. J Infect Dis 1993;167:392-400.

- The apparent molecular mass of OspC is dependent on the strain of B. burgdorferi being tested. The 24 kDa and 21 kDa proteins referred to are the same.

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