DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

Dave Mon

April 19, 1988

CDC Number: 88 024375
Patient's Name: COTNER, Grady W.
Submitting Lab. Number: 9963
Hospital Number: 2090-24-52

Dr. Michael R. Skeels, Director
Oregon State Public Health Laboratory
P. O. Box 275 (1717 SW 10th Avenue)
Portland, Oregon 97207

Dear Dr. Skeels:

We have received a serum specimen on the above patient; however, it is necessary to return the specimen to you because the Center for Infectious Diseases has discontinued serological testing for Lyme Disease (see attachment). If you have any questions you may wish to contact Dr. Patrick Moore, Meningitis and Special Pathogens Branch, (404) 639-3687.

Sincerely yours,

Albert Balows

Albert Balows, Ph.D.
Assistant Director of Laboratory Science
Center for Infectious Diseases

Attachment

MENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Atlanta GA 30333

To: State and Territorial Public Health Laboratory Directors

Subject: Changes in criteria for submitting sera for Lyme disease serology to the Centers for Disease Control

Serologic testing for Lyme disease, a recently recognized tick-borne illness caused by Borrelia burgdorferi, is based on an immunofluorescent assay (IFA) or an enzyme-linked immunoassay (ELISA) using whole cell antigens. Since 1985, the Centers for Disease Control has undertaken ELISA testing of sera from suspected cases of Lyme disease in an effort to evaluate the utility of the test. A recent evaluation of the data on the ELISA indicates that only 13-16% of clinical cases of Lyme disease with erythema chronicum migrans (ECM) have positive serology in the first three weeks after onset of symptoms. Sensitivity with this test increases to only 27% in the 3-6 weeks after onset of illness. Use of early antibiotic therapy did not explain the low sensitivity. The specificity of the test, however, is high. When sera from patients in nonendemic areas of the country who do not meet the CDC case definition of Lyme disease are tested, only 2% are positive.

Because of the low sensitivity of these tests, the diagnosis of Lyme disease in endemic areas should depend primarily on the clinical presentation of the patient. For most patients, the case definition should require the characteristic ECM skin lesion. For the minority of patients presenting with only atypical symptoms, serology is not definitive since 2-10% of individuals living in an endemic area will be asymptomatically seropositive. The low sensitivity of this test means that it is not useful to rule out the diagnosis of Lyme disease.

In nonendemic areas of the country, Lyme disease is a rare illness and positive serologies in the absence of ECM are more likely to be false positive than true positive, despite the test's high specificity. It is likely that the case definition of Lyme disease in nonendemic areas will require the presence of ECM as well as positive serology.

Effective April 15, 1988, Lyme disease serology will be discontinued as a reference surveillance service at the Centers for Disease Control. Many public health laboratories now have their own Lyme serologic testing services, and both commercial testing kits and commercial testing services are also currently available. We will continue to accept serum samples for testing only when there is a special need. Submission of samples will require prior consultation with Meningitis and Special Pathogens Branch, CDC, and patients should be carefully prescreened for symptoms suggestive of Lyme disease (skin rash, arthritis, neurologic or cardiac involvement). Samples will only be

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epted through State or territorial health laboratories after prior nsultation in order to ensure appropriate use of the tests, and to ensure hat needed information is accurately compiled by both the CDC and the State and territorial health departments.

Although this policy change will eliminate routine Lyme serologic testing at the CDC, we will continue to perform testing for special studies. Reducing routine Lyme testing services will permit more time for improving the serologic test for this disease.

This change in serologic testing does not indicate changes in surveillance and reporting of cases to CDC in order to monitor geographic and temporal changes in this disease. In order to improve case reporting, the current case definition for Lyme disease will be simplified and a shortened report form is being formulated in collaboration with CSTE. We appreciate your continued cooperation with the Lyme disease surveillance system.

We are interested in making this transition in serological testing as smooth as possible, and we would appreciate hearing comments about this proposed change. Please contact Patrick Moore, M.D., Meningitis and Special Pathogens Branch at our new number (404) 639-3687 if you have questions, comments or suggestions about Lyme serology.

Frederick A. Murphy, D.V.M., Ph.D.
Director
Center for Infectious Diseases

cc:
State and Territorial Epidemiologists
Director, Epidemiology Program Office
Director, Training and Laboratory Program Office