

LYME disease

SURVEILLANCE SUMMARY



Bacterial Zoonoses Branch
Division of Vector-Borne
Infectious Diseases
National Center for Infectious Diseases
Centers for Disease Control
and Prevention

Volume 5 — : No. 2

Date: October 1994

SECOND NATIONAL CONFERENCE ON SEROLOGIC DIAGNOSIS OF LYME DISEASE
OCTOBER 28-29, 1994
DEARBORN, MICHIGAN
FINAL REMINDER AND CALL FOR PARTICIPANTS

IS NATIONAL STANDARDIZATION OF SEROLOGIC TESTING FOR LYME DISEASE
NECESSARY?

DON'T MISS YOUR OPPORTUNITY TO CONTRIBUTE TO THE DISCUSSIONS!

Background

The First National Conference on Lyme Disease Testing held November 1-2, 1990, brought together clinicians (from private and public sectors), research scientists, representatives of state and federal agencies, manufacturers and other interested parties to address the problems associated with Lyme disease (Ld) testing. As the result of the 1990 meeting, several key recommendations were made to guide the development of improved Ld testing, and a summary report on the progress of test development and evaluation was recently published in the *Lyme Disease Surveillance Summary (LDSS)*, Vol. 5, No.1, June 1994.

In the same LDSS issue, a set of interim recommendations for the interpretation of Ld IgM and IgG immunoblotting tests were proposed by a Centers for Disease Control and Prevention/Association of State and Territorial Public Health Laboratory Directors (CDC/ASTPHLD) working group. An action plan was adopted by the working group to further evaluate the feasibility of diagnosing early Ld by IgM immunoblotting. Participants from 5 institutions performed IgM immunoblotting of a large panel of coded serum samples using their own *Borrelia burgdorferi* strain as antigen. The CDC laboratory tested the panel against 8 geographic strains of *B. burgdorferi* strains from different areas of the U.S. The results of this study will be presented at the Second National Conference.

Importance of the Second National Conference on Serologic Diagnosis of Lyme Disease

Many laboratories have been actively engaged in improving the serodiagnosis of Ld. A substantial number of articles have been published since the First National Conference. Because of the progress on many fronts in the development of improved Ld diagnostic testing and its applications, the ASTPHLD, CDC, Michigan Department of Public Health and co-sponsors (U.S. Food and Drug Administration, National Institutes of Health, Council of State and Territorial Epidemiologists, and National Committee for Clinical Laboratory Standards) have convened the Second National Conference on Serologic Diagnosis of Lyme Disease. The goal of the Second National Conference is to create a forum in which all individuals and groups interested in Ld serodiagnosis may contribute and express their opinion. Specific topics for discussion include developing a set of recommendations that will establish standards for interpretative criteria; setting the criteria appropriate for the development and evaluation of new diagnostic tests; sharing information on establishment of standard laboratory methods; and discussing the FDA criteria that Ld kit manufacturers must meet to certify their tests.

Conference Program

The format for the Second National Conference on Serologic Diagnosis of Lyme Diseases will be a series of overview presentations followed by workgroups. The workgroups will address specific topics in more detail and provide an open forum for interested participants to share their data and opinions. Presentations during the workgroup sessions will be limited to 5 minutes and an abstract (not more than one page) must be submitted in advance to the workgroup moderator.

CONFERENCE PROGRAM

SPEAKERS/PRESENTATIONS

Welcome/Conference Objectives/Review of Progress

Robert Martin, Dr.P.H.
President-Elect, ASTPHLD
Laboratory Director, Michigan Department of Health

Value of Standardization of Serologic Testing in Clinical Diagnosis of *Borrelia burgdorferi* Infections

Allen Steere, M.D.
Professor of Medicine/Chief of Rheumatology
Tufts, New England Medical Center

Standardization of Serologic Testing for Epidemiological Purposes

David T. Dennis, M.D., M.P.H.
Chief, Bacterial Zoonoses Branch
Division of Vector-Borne Infectious Diseases
National Centers for Infectious Diseases
Centers for Disease Control and Prevention

Standardization of Lyme Disease Serologic Tests

Barbara J.B. Johnson, Ph.D.
Acting Chief, Molecular Biology Branch
Division of Vector-Borne Infectious Diseases
National Centers for Infectious Diseases
Centers for Disease Control and Prevention

Recommendations of the Work Group for Standard Criteria for Lyme Serodiagnosis

Arthur Weinstein, M.D.
Division of Rheumatology
New York Medical College

Evaluation and Standardization of New Diagnostic Tests

Raymond J. Dattwyler, M.D.
Division of Allergy, Rheumatology and Clinical Immunology
SUNY at Stony Brook

Criteria for FDA Clearance of Diagnostic Tests

Sharon Hansen, Ph.D.
Office of Device Evaluation
Food and Drug Administration

Importance of Standardization of Laboratory Methods

National Committee for Clinical Laboratory Standards

CONCURRENT WORKGROUPS

Workgroup A: Standardization and Interpretation

Moderator: Stanley Inhorn, M.D.
Co-director, WI State Laboratory of Hygiene

Co-Moderator: Russell C. Johnson, Ph.D.
Department of Microbiology
University of Minnesota/School of Medicine

TOPICS: Setting cutoffs for EIA and Western Blot; Are there alternatives to a two-test approach?; What should one know about antigens?; Use of IgM and IgG blots in diagnosis of early diseases; Immunoblot band interpretation.

Workgroup B: Technical Issues in Test Performance

Moderator: Eric Blank, Dr.P.H.
Director, State Public Health Lab, MO.

Co-Moderator: Raymond W. Ryan, Ph.D.
Department of Laboratory Medicine
University of Connecticut Health Center

TOPICS: Guidelines for reporting; Proficiency Testing; Education and Training Issues in Lyme Testing
Standardization of Reagents; Personnel Performance; Specimen and Submission Forms; 'Home-brewed'
tests versus commercial kits.

Workgroup C: Certification and New Test Evaluation

Moderator: Ralph J. Timperi
Director, State Laboratory Institute, MA

Co-Moderator: Alan G. Barbour, M.D.
Division of Infectious Diseases
Department of Medicine
University of Texas Science Center

TOPICS: What are the guidelines for evaluation of new antibody tests?; What are the guidelines for
evaluation of new antigen or direct DNA detection tests?; What are the criteria for modification of
currently approved tests and for a new generation of tests?; FDA clearance criteria.

Summary and Future Direction

Duane J. Gubler, Sc.D.
Director,
Division of Vector-Borne Infectious Diseases
National Centers for Infectious Diseases
Centers for Disease Control and Prevention

CONFERENCE REGISTRATION AND HOTEL INFORMATION

The conference will be held October 28-29, 1994 in the Hyatt Regency Hotel, Dearborn, Michigan. To register
for the conference, please remit \$150 before October 7, or \$185 after October 7 to:

ASTPHLD
1211 Connecticut Avenue, N.W.
Suite 608
Washington, D.C. 20036

Payment may be made by check, cash (at the door), MasterCard or VISA.

Hotel reservations must be made **separately** from registration and should be made directly with the Hyatt Regency Hotel at (313) 592-1234. To obtain the group rates (\$90 + 13% tax, double or single), please inform reservations that you will be attending the Association of State and Territorial Public Health Laboratory Directors 1994 Lyme Disease Conference. Attendees please make your travel plans to arrive on Thursday, October 27 (late afternoon) and depart on Saturday October 29 afternoon.

EXHIBITS

Exhibitors are encouraged, companies or organizations should contact Anne Ulm at ASTPHLD at (202) 822-5227.

DEADLINE SUMMARY

Conference: Early registration, October 7, 1994. Late registration, after October 7, 1994
Hotel: By October 7, requests made after cutoff date will be subject to space and rate availability
Exhibits: By October 14, 1994
Presentations: By October 24, 1994

Lyme Disease Surveillance Summary (LDSS) is edited by Drs. Roy Campbell and David Dennis. If you have information to contribute or wish to receive a LDSS, please contact them at:

CDC/DVBID
Lyme Disease Surveillance Summary
P.O. Box 2087
Fort Collins CO 80522