



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Centers for Disease Control and Prevention
National Center for Emerging & Zoonotic Diseases
Division of Vector-Borne Diseases
3156 Rampart Road
Fort Collins, Colorado 80521

July 16, 2019

Bruce Alan Fries, President
Patient Centered Care Advocacy Group
3320 Belle Cote Drive
Burtonsville, MD 20866
PCCAGroup@Gmail.com

Dear Mr. Fries,

We have reviewed your information quality request related to posting of disclaimers for the national Lyme disease surveillance case definition as it appears on CDC's website, publications, and presentations. This request is listed as #69 on the HHS website on Information Quality Requests at: <https://aspe.hhs.gov/information-requests-corrections-and-hhs-responses>.

The request intermingles two separate issues. The first is the Lyme disease surveillance case definition, which was developed by the Council of State and Territorial Epidemiologists (CSTE). The requestor is correct that this definition is intended for surveillance purposes. A statement to this effect can be found on CDC's website in the overview section on surveillance case definitions.¹ A version of this statement was also included in previous versions of the Lyme disease case definition; however, CSTE removed the wording when the definition was revised in 2017. The contention that the new wording promotes misdiagnosis is speculative, and the information currently on CDC's webpage is neither inaccurate nor misleading. Nevertheless, CDC is amenable to repeating the general statement on all individual case definition pages, including the 2017 Lyme disease case definition page. This change is being implemented.

The second issue concerns laboratory testing for Lyme disease, specifically recommendations for serologic testing using a two-tier approach.² These recommendations were developed to help laboratories and clinicians in the diagnosis of individual patients. Although some components of these recommendations are included under laboratory criteria in the 2017 case definition, the belief that these testing criteria are for surveillance purposes only is incorrect, and publishing disclaimers to suggest otherwise would be inaccurate and potentially harmful to patients. After careful consideration, we respectfully decline to include a disclaimer that the criteria for interpretation of the two-tier test for Lyme disease are intended for *surveillance purposes only* in any publications or presentations.

If you wish to appeal this response to your request for a correction, you may send a written hard copy or electronic request for reconsideration within 30 days of receipt of the agency's decision. The appeal must state the reasons why the agency response is insufficient or inadequate. You must attach a copy of the original request and the agency's response to it. Clearly mark the appeal with the words, "Information Quality Appeal," and send the appeal by mail to CDC/ATSDR, Attn: Mailstop H21-8 (attn.: Office of Science Quality); 1600 Clifton Road, N.E., Atlanta, GA 30333 or by e-mail to InfoQuality@cdc.gov.

Best Regards,

/S/

Lyle Petersen, MD, MPH
Director, Division of Vector-Borne Diseases
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

References

1. Nationally Notifiable Diseases Surveillance System (NNDSS). Case Definitions for Current and Historical Conditions. Available at: <https://www.cdc.gov/nndss/conditions/>
2. Notice to Readers Recommendations for Test Performance and Interpretation from the Second National Conference on Serologic Diagnosis of Lyme Disease. Morb Mort Weekly Rep (MMWR) 1995; 44:590-591. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/00038469.htm>