Two-Tier Testing for Lyme Disease: How it Evolved

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The Two-tier method of testing is used in the Lyme Disease Surveillance Criteria developed and adopted by the Council of State & Territorial Epidemiologists and used by the Centers for Disease Control and Prevention (CDC).This entails a screening test (e.g., Lyme E.L.I.S.A. – **E**nzyme **L**inked **I**mmuno-**S**orbent **A**ssay) in which a positive or borderline result is followed by a Western blot for confirmation. This protocol was specifically intended strictly for epidemiologic purposes (e.g. to track numbers of cases in a given geographic region and to track the spread of the disease in to other geographic regions).

This type of schema was originally utilized with quite satisfactory results for the H.I.V./A.I.D.S. epidemic. It worked well because the screening test was some 95% sensitive.

It is widely recognized that the screening test for Lyme disease is at best some 50% sensitive. As a result, persons who may have Lyme disease are often missed since Western blot (which may show important clues or even conclusive evidence of infection) is not done, per CDC advice. As a result, individuals may go months, years, or decades without diagnosis or treatment and may become progressively (and sometimes irreversibly) damaged.

Compounding the situation, many physicians, health plans, vertically integrated health care systems and insurers misuse the Two-tier Testing schema as the ***sole*** criterion for a diagnosis of Lyme disease, despite CDC's 'lip-service' that the diagnosis of Lyme disease is a clinical diagnosis with supportive data from the laboratory.

The Two-tier Testing schema was brought forth as a result of the Second National Conference on Lyme disease testing under the auspices of the Association of State and Territorial Public Health Laboratory Directors (ASPHLD), the state health department, the National Committee for Clinical Laboratory Standards (NCCLS), Council of State & Territorial Epidemiologists (CSTE), CDC, NIH, and FDA in Dearborn, Michigan in 1995. Ostensibly the result of a 'consensus', actually this was forced through against the objections of many of the scientists, physicians and laboratorians who had been convened there. It was made to appear as though it had been a 'consensus' whereas this was not the case (1). No minority report was accepted.

Clinicians often mistakenly believe that a negative screening test for Lyme disease 'rules out' Lyme disease. Due to the mischief that has resulted from this situation, the states of Virginia and Maryland have passed legislation requiring

physicians to advise patients, in writing, that a negative screening test does NOT rule out Lyme disease.

Direct detection methods that do not depend on antibody methods have been developed for Lyme disease. One methodology, PCR (polymerase chain reaction), is accepted widely for the diagnosis of virtually all infectious diseases, but inexplicably, its use for the diagnosis of Lyme disease by detecting its DNA, is officially discouraged by CDC for the clinical diagnosis of Lyme disease. This method would allow for early diagnosis before diagnostic antibody levels can be mounted and also for the disease at any stage, including for persons who are seronegative. Although the method is not as sensitive as one would like (due to the low density of the DNA of the Lyme organism in bodily fluids), it remains at present the only well validated method of direct detection that is readily available to clinicians and could be more widely utilized.

(1)Conflicts of Interest in Lyme Disease: Laboratory Testing, Vaccination, and Treatment Guidelines. Special Report. Lyme Disease Association, Inc. 2001.