

Re: FDA on testing

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>

> *But the thrust of it is to use the two step testing method which pretty*

> *much rules out most positives, true or false and doesn't begin to*

> *address the huge problem of false negatives.*

"Wise Man", you're a filthy liar. You care jack***t about false negatives. If you gave the slightest damn about the unknown, but likely staggering, number of people whose lives have been ruined because of false negatives you would not behave the way you do and you would not say the things you say.

Anyone can just dip into the archive and see that you are a lying Steere camp provocateur.

>

> *And, as to "fair and reliable" I can't see any reason that we should*

> *trust Bowen, Mattman, Igenex or MdLabs.*

So you think it's more "trustworthy" to insist that people's blood should be tested using a CDC western blot, which deliberately leaves out two of the most specific Bb antigens known to mankind, so specific they were chosen as the basis for vaccines? And requires that people have several bands of 95%= specificity, even if they were bitten by 500 ticks and have every Lyme symptom in the book, and all other pathology excluded?

These labs have often been the only means by which people have been able to demonstrate that their negative results were red herrings, and that they indeed had Lyme. For many people these labs' results were what convinced an unsure doctor treat, and made the difference between life and a life that's death, for the patient.

Not that you care, or have ever cared , about the patients.

These labs and the doctors who use them are the only ones who have

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spoken out against the problem of false negatives. Your camp has finessed false negatives out of existence.

And you were central to that, McSweegan.

Which is why you wont show your stupid cowardly face on live webcam.

Lisa

>
> *Do you?*
>
> *Show us the validation studies for their testing whether published or*
> *not.*
>
> *Go on, show us.*
>
> *That really is not too much to ask of a lab and a test.*
>
> *Or is there some reason they should all be exempt from these basic*
> *fundamental requirements?*
>
>>
>> <http://www.fda.gov/medbull/summer99/Lyme.html>
>>
>> *FDA Medical Bulletin * Summer 1999 * Final Issue*
>>
>> *Lyme Disease Test Kits: Potential for Misdiagnosis*
>> *By S. Lori Brown, Ph.D., M.P.H., Sharon L. Hansen, Ph.D., John J.*
>> *Langone, Ph.D., Nancy Lowe, M.A., and Nancy Pressly, B.S. Engr.,*
>> *Center for Devices and Radiological Health*
>>
>> *The Food and Drug Administration (FDA) is concerned about the*
>> *potential for misdiagnosis of Lyme disease based on the results of*
>> *commonly marketed tests for detecting antibodies to Borrelia*
>> *burgdorferi, the organism that causes Lyme disease. It is important*
>> *that clinicians understand that a positive test result does not*
>> *necessarily indicate current infection with B. burgdorferi, and a*
>> *patient with active Lyme disease may have a negative test result.*
>> *(1-5)*
>>
>> *The tests should be used only to support a clinical diagnosis of*
Lyme
>> *disease and should never be the primary basis for making diagnostic*
> *or*
>> *treatment decisions. Diagnosis should be based on a patient*
history,
>> *which includes symptoms and exposure to the tick vector and*
physical
>> *findings. The most definitive diagnostic procedure is biopsy and*
>> *isolation of B. burgdorferi in culture.*
>>

> > *Assays for anti-Borrelia burgdorferi (anti-Bb) can provide evidence*
> *of*
> > *previous or current infection, but to improve reliability FDA*
> *supports*
> > *the Centers for Disease Control and Prevention (CDC) recommendation*
> > *for two-step testing and interpretation of results (1).*
> >
> > *The first step is to perform an assay that detects either total or*
> > *class-specific antibodies (IgM or IgG) by using enzyme-linked*
> > *immunosorbent technology ("ELISA" or "EIA") or indirect*
> > *immunofluorescence microscopy ("IFA"). IgM levels usually peak 3 to*
> *6*
> > *weeks after infection. IgG antibodies begin to be detectable*
several
> > *weeks after infection and may continue to develop for several*
months
> > *and generally persist for years.*
> >
> > *A negative result indicates only that there was no serologic*
evidence
> > *of infection with B. burgdorferi. It should not be used as the*
basis
> > *for excluding B. burgdorferi as the cause of illness, especially if*
> > *the blood was collected within 2 weeks of when symptoms began.*
> > *A positive or equivocal result is presumptive evidence of the*
> *presence*
> > *of anti-Bb. It should always be followed by second-step testing and*
> > *should not be reported until the second step testing is completed.*
> >
> > *The second step is to perform a Western-blot (immunoblot) assay, a*
> > *more specific assay than that used for the first step*
> >
> > *A negative result indicates that no reliable serologic evidence of*
B.
> > *burgdorferi infection was present. A negative result should not be*
> > *used as the sole basis for excluding B. burgdorferi as the cause of*
> > *illness. If Lyme disease is suspected, a second specimen collected*
> *2*
> > *to 4 weeks after the first specimen should be tested. If retesting,*
> *do*
> > *the first step and if the result is positive or equivocal, do the*
> > *second step.*
> >
> > *A positive result provides serologic evidence of past or current*
> > *infection with B. burgdorferi. Because the presence of even*
specific
> > *antibodies to B. burgdorferi does not always indicate current*
> > *infection, a positive result can support, but not establish, a*
> > *clinical diagnosis of Lyme disease.*
> > *Even using the two-step approach, the sensitivity and specificity*
of

> > *the combined test results are inadequate. Because assays for anti-Bb should be used only for supporting a clinical diagnosis of Lyme disease and not for "screening" asymptomatic individuals, the result of the first-step assay is best described as "initial" rather than "screening." Likewise, the second-step Western-blot assay is best described as "supplemental" rather than "confirmatory", because of the low specificity for detecting IgM anti-Bb. Thus, a positive IgM anti-Bb result alone is not adequate for supporting a diagnosis of Lyme disease in persons with illness of greater than one-month duration.*

> >

> > *Several factors contribute to the limitations of using ELISA, IFA, or Western blot tests for supporting a diagnosis of Lyme disease. The stage of disease in which the specimen was taken is critical. Many patients with active or recent infections do not have detectable anti-Bb in a single specimen. This happens because such antibodies often develop after manifestations of early infection or because detectable anti-Bb may diminish or never develop in patients treated with antibiotics. Further, a positive test result can be true evidence of previous infection with *B. burgdorferi* and unrelated to a current illness. Assays for anti-Bb may yield false-positive results, because antibodies to *B. burgdorferi* antigens may cross react with antigens associated with autoimmune diseases or from infection with other spirochetes, rickettsia, ehrlichia, or other bacteria such as *Helicobacter pylori*. (6,7)*

> >

> > *In summary, serologic testing is not useful early in the course of Lyme disease, because of the low sensitivity of tests in early disease. Serologic testing may be more useful in later disease at which time sensitivity and specificity of the test is improved.*

> >

> > *References*

> >

> > *Center for Disease Control and Prevention. Recommendations for test performance and interpretation from the second national conference on serologic diagnosis of Lyme Disease. MMWR 1995; 44:590-591. Association of State and Territorial Public Health Laboratory Directors and the Centers for Disease Control and Prevention. Recommendations. In: Proceedings of the Second National Conference on Serologic Diagnosis of Lyme Disease (Dearborn, Michigan). Washington,*

