

Proposed Bill No. 368 Public Hearing on March 8, 2013

I am Sin Hang Lee, MD, a pathologist practicing laboratory medicine in the New Haven County since 1971, currently with medical privileges at Milford Hospital. One of my interests has been to develop a financially sustainable DNA sequencing-based molecular diagnostic test for Lyme borreliosis. DNA-sequencing technology was recently used to diagnose Lyme disease in an “ice man” called Ötzi who died 5300 years ago. There is no base to believe that similar technology cannot be used to reliably diagnose Lyme disease suffered by the living patients of today. Demonstration of the Lyme bacterial 16S ribosomal gene DNA in a patient’s blood or tissues is a genetic fingerprint proof that the patient is harboring in the body a live infectious agent causing Lyme disease. A DNA-sequencing test was developed at Milford Hospital and approved by the Connecticut Department of Public Health for the diagnosis of Lyme disease. The methodology and the first clinical report were published in 2010 in two peer-reviewed national and international medical journals [see references 1 and 2].

I recommend the Department of Public Health to conduct a general survey by sending out blind-coded simulated blood plasma samples spiked with various species of Lyme disease-causing bacteria and irrelevant microbes, and require all hospital laboratories in the State of Connecticut to use their best method to test for Lyme disease infection in these unknown samples. The laboratories which return the most correct answers would be invited to further develop a state-of-the-art diagnostic test for Lyme disease because, as stated by the CDC, the current two-tiered serology assays are known to be unreliable for the diagnosis of Lyme disease [see CDC Lyme Disease Laboratory Testing in reference 3].

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References

1. Lee SH, Vigliotti VS., Vigliotti JS, Jones W, Pappu S. Increased Sensitivity and Specificity of *Borrelia burgdorferi* 16S Ribosomal DNA Detection. *American Journal of Clinical Pathology* 2010; 133:569-576.
2. Lee SH, Vigliotti VS., Vigliotti JS, Jones W, Williams J, Walshon J. Early Lyme disease with spirochetemia – diagnosed by DNA sequencing. *Biomedical Central Research Notes* 2010; 3:273.
3. <http://www.cdc.gov/lyme/diagnosistreatment/LabTest/>