

#3

To Clients and Friends,

At the recent International Lyme Meeting in Munich, Dr. Mark Klempner of the New England Medical Center (NEMC) presented some preliminary results of a study that was performed using the Lyme Urine Antigen Test (LUAT). He presented results which differ from previous well-established studies. Dr. Klempner used this data to conclude that the LUAT is not a valid test. IGeneX entered into this study in good faith, with the knowledge that our test had been subject to years of excellent results, both in our lab and in independent studies. We therefore offer the question: Why would IGeneX be willing and eager to subject itself to this scrutiny by a government-funded study, unless we were **CERTAIN** of the reliability of this test? Answer: **We would not!** Here are the facts:

Clear handling and storage instructions were given in writing to Dr. Klempner at the beginning of the project. The NEMC laboratory did not follow these instructions. This improper handling was verified to us by an employee at NEMC, who admitted that some of the samples were stored in the refrigerator for two months before being shipped to our laboratory. We know through years of experience that such prolonged storage will contaminate samples and provide erratic and inaccurate results for this highly sensitive test, leading to different results even in the case of split samples. Proper handling of the samples is critical to the accuracy of the LUAT.

2. We were suspicious of the skewed results, particularly after knowing of the shoddy handling of samples, and we personally called and e-mailed NEMC, advising that the results were likely meaningless.

3. Dr. Klempner presented the results of his study, emphasizing the failure of the LUAT, at an international meeting without our knowledge and without advising the audience of points 1 and 2 above.

The NEMC study was funded by the NIH, which has gone on record with the premise that Lyme disease can be resolved with a short course of antibiotics and that chronic Lyme disease does not exist. Thus, we are inclined to be skeptical of Dr. Klempner's finding and take issue with his conclusions.

We have proposed a double blind study, with an independent third party referee, to be performed at NEMC at our expense. They have absolutely refused any collaboration or additional studies.

Thank You, Nick S. Harris, Ph.D., ABML President of IGeneX

IGeneX, Inc.

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August 19, 1999

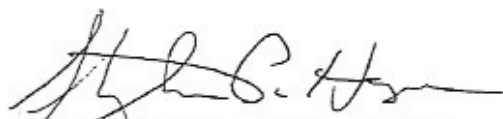
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Nick S. Harris, Ph.D., ABMLI
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Dear Dr. Harris:

I have received your letter dated August 16, 1999 regarding the Lyme Urine Antigen Test and the protocol you are proposing to use to test its reproducibility. I am referring the issue to Dr. Phillip Baker who is the Lyme Disease Program Officer and Project Officer for the Clinical Studies of Chronic Lyme Disease contract. You should anticipate hearing from him about your proposal.

Sincerely,



Stephen P. Heyse, M.D., M.P.H.
Medical Bacteriology Program Officer
Bacteriology and Mycology Branch
Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases

Cc: Dr. Baker

#2

February 26, 2001
 Response to Phil Baker, NIMD, NIH, Press Release
 Re: Klempner paper Am.J.Med 110:217-219,2001

Over two years ago, Dr. Mark Klempner approached me. He was doing a study of chronic Lyme disease funded by the National Institutes of Health and wanted to compare the Western Blot with the Lyme Urine Antigen Test (LUAT). IGeX agreed to the study and told the New England Medical Center (NEMC), which was providing the samples, that certain handling requirements must be met for the samples, since improper handling can lead to flawed results.

IGeX received the samples in late 1998, early 99. IGeX scientists sensed immediately that there was a problem with the samples. I called and spoke with a laboratory supervisor and shared our suspicion that we had received improperly handled specimens. This supervisor confirmed that the samples had not been kept frozen but were refrigerated for many months. (Our written requirements for the study were that samples must be frozen after collection in a -70C freezer and remain frozen prior to testing to test accurately.) I called and informed the laboratory manager at NEMC that I would not release the results due to the improper handling of the samples. He informed me that I must send the results anyway because NEMC had paid for them under an NIH grant. I sent NBMC the results (attachment #1) along with a letter to Dr. Klempner clearly stating that the results could not be considered valid due to improper storage and possible contamination.

Over a half-year later, Munich International Lyme Conference attendees informed me that Dr. Klempner had presented the results of this study, not even mentioning the contamination. I then personally called Dr. Klempner and offered to have IGeX pay for a repeat study involving an independent third party evaluator. He reported the offer to his Medical Officer (#2) at the NIMD, and I personally offered the same to Phil Baker, NIH Lyme Program Director. All three refused the offer. We informed our clients of the situation in September 1999 (#3).

Now two years later, Dr. Klempner has published study results using samples that he was personally told by me were contaminated and improperly handled. Science is based upon conclusions drawn from data objectively obtained under controlled conditions so that the variables are reduced. If the controlled conditions of the study have not been met, the conclusions derived are questionable at best, since the study's basis in science has been lost. The study should have been terminated, but since it has now been published with the flawed data, science itself requires that a repeat study be performed, and IGeX again repeats the offer of a third party independent evaluator study for which IGeX will pay the bill.

Nick Harris, PhD, IGeX Reference Laboratory, Palo Alto, CA

cc:
 The Honorable Arlen Specter, 202.228.1229;
 The Honorable Joseph Pitts, attention Jeri-Lynn Wier, 610.464.2263;
 The Honorable Rick Santorum, attention Pete Stein, 202.228.4991
 The Honorable Christopher Smith, attention Andy Napoli, 202.225.3765;
 Don Keller, USGAO, 202. 512.5805; Hoc Noble, hocnoble@nytimes.com

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