## Written response from IGENEX

From the Laboratory Director, Dr. Jyotsna

April 28, 2013

Question: Was IGeneX Inc ordered to cease Lyme testing in 2001 by a federal regulator? For what reason?

Response: Yes. There were issues with documentation, not with the tests.

Question: Did the federal Office of the Inspector General in 2001 put Igenex on a list of noncompliant labs? And did your company pay fines totalling \$48,000?

## Response: Yes.

Question: In that year, was Igenex also cited for a lack of training among lab staff by Californian regulators?

## Response: We are not aware of it

Question: The San Francisco Chronicle writes "In April 2000, the New York Department of Health wrote Stephens that Igenex had failed a "proficiency challenge" involving 20 samples. The test failed to find two samples that had been "spiked" with Borrelia burgdorferi, the bacteria that cause Lyme disease. The tests incorrectly reported as positive four of 14 negative samples". Is this statement correct? If not, what is incorrect? –

Response: Lyme urine antigen test (LUAT) – The LUAT was the 1<sup>st</sup> generation test. In 2001, we decided to discontinue the test and replaced it with Lyme dot blot assay (LDA).

Question: In 2005 did the NY State Dept Of Health open an investigation into IGeneX Inc regarding complaints of positive Lyme tests that could not be replicated elsewhere? What was the result of that investigation?

Response: NYS asked IGeneX to send the validation package for Lyme Western Blots. - On review NYS found no technical issues. They wanted IGeneX to report by CDC criteria. NYS had concerns regarding result reporting by IGeneX criteria.

CDC Criteria: 5/10 bands for IgG 918, 23,28, 30,31,34,39,41,45,58,66,93kDA) and 2/3 bands for IgM (23.39 and 41 kDA)

IGeneX criteria: 2/6 bands for IgG and IgM (23,31, 34, 39, 41 and 93 kDA)

We were able to support scientifically our claims regarding 2 band criteria that IGeneX uses. IGeneX reports by CDC and IGeneX criteria.

Bottom line they found NO DEFICIECIES WITH OUR WESTERN BLOTS.

Question: In total, how many regulatory investigations of IGeneX has there been? What is the total amount of fines paid to state and federal regulatory authorities for non compliance and/or other licensing or validation breaches? –

Response: One in 1999-2000 and the NYS in 2005 - In both instances IGeneX was able to provide validation data for all the tests. IGeneX has only paid fines once, in 2001.

Question: The NYT writes "in each year since 2000, IGeneX had achieved scores of at least 97 percent accuracy on the Western blot and Elisa tests, well above the minimum 80 percent required by the state. But Robert Kenny, a spokesman for the (NY) State Department of Health, said the agency was not convinced that IGeneX was performing the recommended tests for the public in the same manner as it has been performing them to pass the state's proficiency review." Is this correct? If not, what is incorrect?

IGeneX performs all PT in the same way as clinical samples. IGeneX has evidence to prove that point.