March 31, 2015

RE: Senate Bill 916

Dear Honorable Senators of the Senate Committee on Heath:

This letter is a follow-up to the meeting yesterday, March 30, 2015, where names of infectious disease doctors were requested.

I was referred to **Dr. Justin Jin, of Providence Portland (Eastside).** Dr. Jin stated in the Progress Notes signed 6/17/14 that he did not feel the IgeneX test results were valid and "Pt's (patient's) testing was sent to non-FDA approved lab Igenex... Suspect that pt likely has Fibromyalgia as cause of her symptoms and would not recommend any further abx (antibiotics) course at this time..."

Dr. Jin recommended I discontinue antibiotics after less than three months even though he acknowledged my symptoms had not improved. As I testified yesterday, I chose to continue my ILADS treatment with a doctor in Washington State. I have improved significantly in one year's time and I will be continuing this course of treatment until I achieve remission.

Thank you for the opportunity to speak at the hearing on March 30th.

Respectfully,

Jessica Brody

Jessica (Spurlock) Brody
P.O. Box 1619
Clatskanie OR 97016

Attachments:

IgeneX laboratory certifications

IGeneX, Inc.

August 29, 2013

IGeneX, Inc. has been offering "high complexity tests" since 1992. It is licensed by Centers for Medicare and Medicaid Services (CMS), formally known as CLIA and bills Medicare in the U.S. In addition, it holds California, New York, Maryland, Pennsylvania and Florida licensure since these States require a separate license to perform testing for patients.

To ensure that it maintains the standards of a High Complexity Testing Laboratory, IGeneX is inspected by the California Department of Public Health (CDPH), CMS and New York State Department of Health (NYDH) biannually. IGeneX was last inspected by CDPH and CMS in 2013 and NYDH in 2011.

Proficiency Testing (PT)
In order to monitor the testing quality, PT must be performed on every test offered by a clinical laboratory. We have passed annual PT for all tests offered in the last 10 years. This includes New York, CAP and Internal Proficiency Testing (for tests where external proficiency is not offered).

Validation Protocol
Before IGeneX offers any laboratory developed test for clinical use, extensive validation is carried out as described in our validation protocol (part of the QC-QA procedure). This process has been reviewed and accepted by CDPH, CMS and NYDH. Before a new test can be offered in New York State, NYPH has to review and accept the new test validation.

The following tests are not offered in New York State: confirmation test for the 31kDa band on the Western blot, Lyme Dot-Blot assay (LDA), Lyme IFA, Bartonella FISH, CD57 and B. duncani IFA.

For further information, feel free to contact me at 800-832-3200.

Regards,

Dr Nick S. Harris

Nick S. Harris, Ph.D., ABMLI
President/CEO
IGeneX, Inc.

IGeneX, Inc.
795/797 San Antonio Road • Palo Alto, California 94303 USA • (650) 424-1191 • FAX (650) 424-1196

New York State Department of Health

PFI: 3172

Clinical Laboratory Permit

CLIA: 05D0643914

IGeneX Inc Reference Laboratory
795 San Antonio Road
Palo Alto CA 94303

Director:
Jyotsna S. Shah, Ph.D.

Owner:
IGeneX, Inc

is hereby authorized to perform laboratory procedures at the above location in the following categories in accordance with Article 5, Title V, Section 575 of the Public Health Law. This permit shall become void upon a change in the director, owner or location of the laboratory, and an application for a new permit shall be made to the Department.

Bacteriology
Restricted
(limited to molecular techniques)

Diagnostic Immunology
Diagnostic Services Serology
(not including lyme urine antigen test)

Parasitology
Restricted

Renewal
Effective Date: July 1, 2014
Expiration Date: June 30, 2015

Subject to Revocation
Permit Not Transferable

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF COMPLIANCE

LABORATORY NAME AND ADDRESS

IGENEX INC
795 SAN ANTONIO RD
PALO ALTO, CA 94303-4801

CLIA ID NUMBER

05D0643914

EFFECTIVE DATE

09/20/2013

EXPIRATION DATE

09/19/2015

LABORATORY DIRECTOR

JYOTSNA S SHAH DIRECTOR

Pursuant to Section 353 of the Public Health Services Act (42 USC 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS

CENTERS for MEDICARE & MEDICAID SERVICES

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

State of California Department of Public Health

CLINICAL LABORATORY LICENSE

In accordance with the provisions of Chapter 3, Division 2 of the Business and Professions Code, the persons named below are hereby issued a license authorizing operation of a clinical laboratory at the indicated address or other site(s) on file with the department.

IGENEX,INC REFERENCE LABORATORY
795 SAN ANTONIO ROAD
PALO ALTO CA 94303

OWNER(S):
IGENEX, INC.
NICK S. HARRIS PHD
ALINE HARRIS
SHAH, JYOSTNA S.

DIRECTOR(S):
JYOTSNA S SHAH PHD

Lab ID Number: CLF 00004033
Effective Date: December 31, 2014
Valid Until: December 30, 2015
CLIA Number: 05D0643914

Beatrice R. O'Keefe, Division Chief
Laboratory Field Services