3/31/15

Dear Senators of the Senate Committee on Health Care
Dr Gilbert, an infectious disease doctor and previous president of the IDSA (Infectious Disease Society of America) refused to see me twice and then wouldn't return my GP's call when I had been diagnosed with chronic fatigue and bells palsy. He told my GP he wouldn't see chronic fatigue patients. This was about 6 months into my illness when I was mid-stage. My Lyme specialist says if I had been diagnosed with Lyme at that time, it would have made an enormous difference in my health, cost & severity of treatment and overall recovery. Instead I was diagnosed almost a year later with late stage Lyme.

About 12 months into my illness, my GP contacted Dr Gilbert's office again, citing only recurring bells palsy in order to finally get an appointment there for me. When I saw Dr Gilbert, he said "well it can't be Lyme disease". Since I had been told by Dr Anthony Gay, my local GP, that I didn't have Lyme, I responded with, "I think I've already been tested for that." Dr Gilbert had all my medical records in front of him, so he knew I had not been tested. In his medical write-up, Dr. Gilbert said I was a city dweller in Hood River, so I could not have Lyme. Dr Gilbert also said he'd been to Hood River several times so he knows it's not a city. He asked if I had been out of the area prior to the onset of my illness and I said no, in the last year I hadn't travelled further than a 60 mile radius from Hood River. When I saw Gilbert for that appointment, I had obvious BI-LATERAL bells palsy (facial paralysis), which, as infectious disease physicians and neurologists know, can ONLY be caused by Lyme disease. My Lyme specialist said that Dr Gilbert did not meet the basic standard of care by ignoring my bi-lateral bells palsy and failing to test me for Lyme.

I also saw Dr Lisa Grant, neurologist, during my bout with bi-lateral bells palsy. She mentioned Lyme, and I told her I thought I'd been tested. In her write-up, she listed everything I'd been tested for, so she plainly saw that I'd never been tested for Lyme. She never ordered a Lyme test for me and referred me on to another doctor. My Lyme specialist said this was a huge failure to meet the standard of care on her part.

Six months into my illness, after reportedly consulting with Dr Emily Moser - neurologist, my GP, Dr Anthony Gay told me, "Good news, you don't have Lyme disease" without ever ordering a simple blood test, even though he tested me for several diseases far more rare. When I finally asked point blank if I'd been tested for Lyme and Dr Gay's office said no, I asked to be tested by Dr Gay's office. I was positive on an ELISA test and later clinically diagnosed with Igenex test that was suggestive of Lyme. In the end, my bi-lateral bells palsy was undeniable evidence that I had Lyme. I asked Dr Gay why he hadn't tested me earlier. I will never forget his response. At first he didn't answer and changed the subject, when I pressed for a response, Dr Gay said, "well, there is a political controversy about Lyme disease..." That was his excuse for not testing me for Lyme. I discovered later that he already had a couple patients who were diagnosed with Lyme a year earlier and were being successfully treated by an out-of-state specialist. 2 years later, a friend R. spoke with Dr Gay after a known tick bite, Dr Gay refused treatment and told R. that we didn't have Lyme disease here.

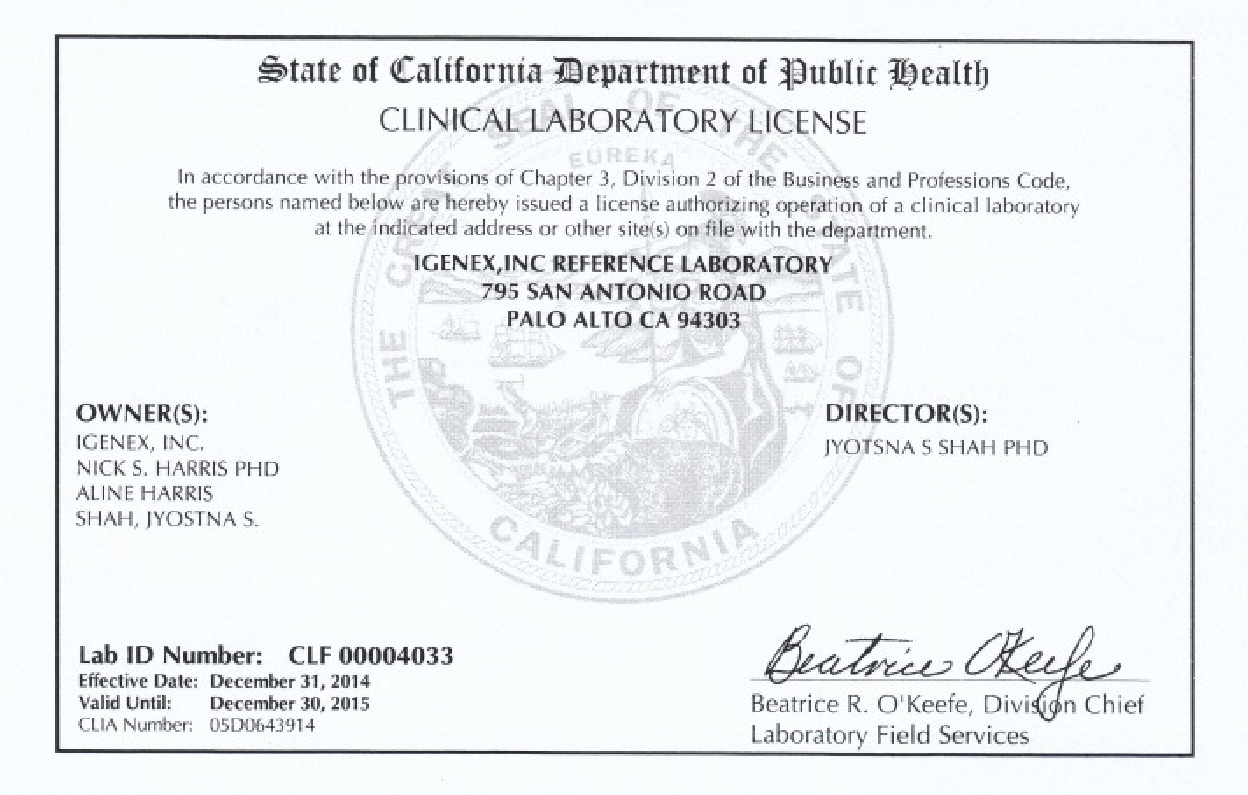
Another Hood River doctor , Dr Ryan Petersen, who I was seeing when I was trying to find a new GP, screamed at me for having Lyme disease. When I made appt with his office, I told staff I had Lyme but didn't need Dr. Petersen to treat me for it, I just needed a GP for flu shots, etc. I insisted the staff check with Dr Petersen FIRST and tell him I had Lyme before they made appt. They said they checked and he agreed he would see me as my GP for treatment of other things besides Lyme. When I saw Dr. Petersen, I told him again I didn't need anyone to treat my already-diagnosed Lyme, that I was seeing a specialist in California. Dr Petersen asked about my Lyme treatment, started to argue with me even though my treatment adhered to ILADS guidelines and then after some discussion Dr Petersen screamed “I can’t be your doctor” and literally stormed out of the room. There was an medical student intern working that day who was in the room during my appointment and witnessed the whole exchange. The medical student saw me burst into tears when Dr Petersen yelled and left. The nurse working that day also saw me sobbing after the appointment, as did everyone in the office and waiting room. As I cried, I recall saying "he said he won't be my doctor..." Prior to that, I had a very nice conversation with both the intern and the nurse. Later I ordered a copy of my medical records from Dr Petersen and his report did not accurately reflect our conversation at all. He said that I told HIM he couldn’t be my doctor. Nothing was farther from the truth.

Lastly, I saw Dr Richard Starrett, a GP in Hood River for other yearly health exams while I continued Lyme treatment. When I needed a picc line for IV antibiotics prescribed by my California specialist, Dr Starrett said he might sign for my line. After a month of delay and reported asking around about Lyme treatment, Dr Richard Starrett agreed to sign for my PICC line insertion at the Hood River Hospital. A few years later, another Lyme patient D., reported that she saw her GP, Dr Starrett. She told Dr Starrett that she was already undergoing Lyme treatment with a specialist and had a Lyme diagnosis supported with tests, Dr Starrett told her that she didn't have Lyme disease and we didn't have it here.

The problem we have with Lyme disease and the cover-up that continues is very serious and life-threatening for those of us who are ill. I very much hope this bill will move forward. Thank you for reading my letter.

Because this letter will become public record and I truly fear repercussions from the physicians I've mentioned, along with many other reasons, I will sign my letter with an initial only.

K.
Hood River, Oregon



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

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

LABORATORY DIRECTOR

JYOTSNA S SHAH DIRECTOR

CLIA ID NUMBER

05D0643914

EFFECTIVE DATE

09/20/2013

EXPIRATION DATE

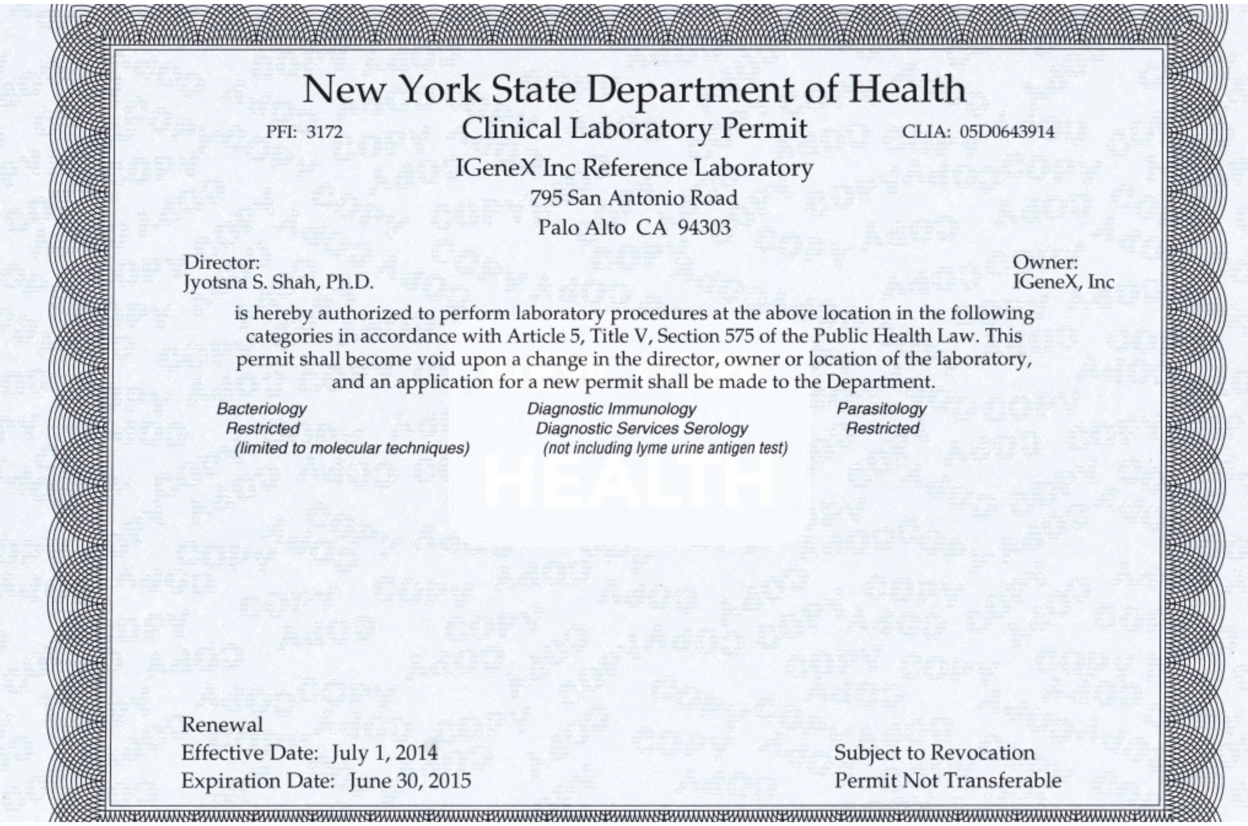
09/19/2015

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 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
Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations



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

Igx®
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.

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