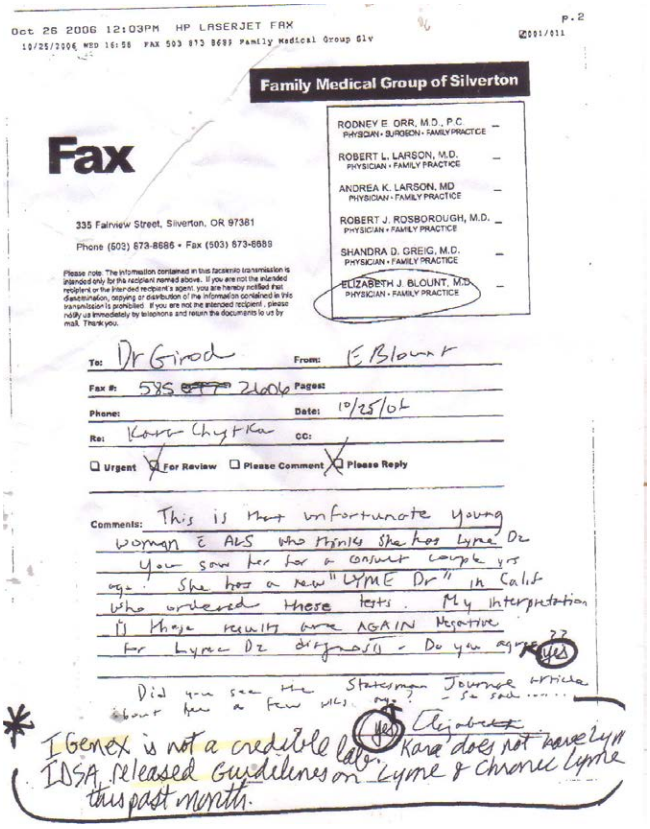
From: CHRIS CHYTKA
To: Sennes Derek
Subject: Kara chytka sb916
Date: Tuesday, March 31, 2015 3:36:52 PM
Attachments: igenex proficiency .pdf

Derek here are Kara's Lyme positive tests and denials from a salem infectious disease Dr.



Oct 26 2006 12:03PM HP LASERJET FAX p.2
10/25/2006 WED 16:56 FAX 503 873 8689 Family Medical Group Slv 001/011

Family Medical Group of Silverton

RODNEY E. ORR, M.D., P.C. – PHYSICIAN • SURGEON • FAMILY PRACTICE
ROBERT L. LARSON, M.D. – PHYSICIAN • FAMILY PRACTICE
ANDREA K. LARSON, MD – PHYSICIAN • FAMILY PRACTICE
ROBERT J. ROSBOROUGH, M.D. – PHYSICIAN • FAMILY PRACTICE
SHANDRA D. GREIG, M.D. – PHYSICIAN • FAMILY PRACTICE
ELIZABETH J. BLOUNT, M.D. – PHYSICIAN • FAMILY PRACTICE

Fax

335 Fairview Street, Silverton, OR 97381
Phone (503) 873-8686 • Fax (503) 873-8689

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To: Dr Girod From: E Blount
Fax #: 585 ~~877~~ 2606 Pages:
Phone: Date: 10/25/06
Re: Kara Chytka CC:
☐ Urgent ☒ For Review ☐ Please Comment ☒ Please Reply

Comments: This is that unfortunate young woman c ALS who thinks she has Lyme Dz. You saw her for a consult couple yrs ago. She has a new "LYME Dr" in Calif who ordered these tests. My interpretation of these results are AGAIN Negative for Lyme Dz diagnosis - Do you agree? (yes)

Did you see the Statesman Journal article about how a few MDs, PhDs? - So sad.....

(yes) Elizabeth

* IGenex is not a credible lab. Kara does not have Lyme
IDSA released Guidelines on Lyme & Chronic Lyme this past month.

and Certificates for the testing Lab.

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

LABORATORY DIRECTOR

JYOTSNA S SHAH DIRECTOR

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, 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

IGeneX, Inc.
795 SAN ANTONIO ROAD
PALO ALTO, CA 94303
(800)832-3200

PATIENT: DEBIE
AGE: SEX: F

SAMPLE ID:

DRWN: 04/22/13
RCVD: 04/25/13
PRNT: 05/21/13

EUGENE, OR
97401

DIRECTOR: JYOTSNA SHAH, PhD

TEST NAME	RESULT	UNITS

LYME IgM WESTERN BLOT .....REVISED 10/18/12

IGeneX interpretation is based on internal validation studies. By IGeneX criteria, IgM WB is considered positive if two or more of the double starred bands below are present. The IgM WB is considered negative if less than 2 starred bands are present. A positive result suggests exposure to B burgdorferi. By CDC/NYS criteria, IgM WB is reported positive if 2 of the following bands are present:23-25,39,41kDa. The IgM WB is negative if less than 2 bands are present.

LIMITATION: Positive result for 31 and/or 34kDa may be present after Lyme vaccination in uninfected persons. Positive result for 83/93 kDa and 41kDa may be present in persons infected with HSV,EBV,HCV and/or syphilis (RPR+)and may give false (+) results.

****PRESENCE OF ONLY ONE DOUBLE STARRED BAND OR INDETERMINATE DOUBLE STARRED BANDS IN A NEGATIVE REPORT MAY INDICATE CLINICAL SIGNIFICANCE.****
THEREFORE, WE RECOMMEND TESTING WITH ANOTHER METHOD AND/OR RETEST IN 4-6 WEEKS.

BAND INTENSITY: Negative (-): No band detected. Indeterminate (IND): Band present with intensity < calibration standard. Positive (1+ to 4+): Band present at an intensity > or = to calibration standard.

IGENEX IGM RESULT	POSITIVE
CDC/NYS RESULT	NEGATIVE
18 kDa.	++
**23-25 kDa.	-
28 kDa.	-
30 kDa.	-
**31 kDa.	+
**34 kDa.	++
**39 kDa.	IND
**41 kDa.	IND
45 kDa.	-
58 kDa.	+
66 kDa.	-
**83-93 kDa.	IND

Diagnosis should not be based on laboratory tests alone. Results should be interpreted in conjunction with clinical symptoms and patient history.

Continued on next page

IGeneX, Inc.
795 SAN ANTONIO ROAD
PALO ALTO, CA 94303
(800)832-3200

PATIENT: DEBIE
DOB:
SEX: F

SAMPLE ID:

DRWN: 03/24/14
RCVD: 03/27/14
PRNT: 04/09/14

EUGENE, OR
97401

DIRECTOR: JYOTSNA SHAH, PhD

TEST NAME	RESULT	UNITS

B. duncani IFA (G/M) .....REVISED 11/25/2013

The Babesia duncani immunofluorescent antibody test is used to detect IgM and IgG antibodies to B. duncani in human serum.

.

Interpretation (titers)

.

IgM <20 Negative IgG <40 Negative

.

IgM at a titer of 20 may or may not indicate active infection.

.

IgM > or = 40 indicates active infection.

.

IgG > or = 40 to <160 may or may not suggest active infection. In patients with previously high titers, such titers may indicate resolving infection.

.

IgG > or = 160 indicates active infection.

.

Presence of IgM and IgG together also indicates active infection.

.

There is a low level of cross-reaction between B. duncani and B. microti IFA tests. In geographic regions where both species are present, we recommend that patient sera be tested by both B. duncani and B. microti IFA tests.

.

A single negative IFA test does not rule out infection. Paired testing of acute and convalescent sera collected six to eight weeks apart is recommended for accurate diagnosis.

.

This test was developed and its performance characteristics determined by IGeneX, Inc. It has not been cleared or approved by the FDA. The FDA has determined that such approval is not necessary. The test is used for clinical purposes and should not be regarded as investigational or for research. IGeneX, Inc. is licensed by CMS and NYS to perform high complexity clinicial laboratory testing.

B duncani IgM	20
B duncani IgG	80

Diagnosis should not be based on laboratory tests alone. Results should be interpreted in conjunction with clinical symptoms and patient history.

Continued on next page

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

PHYSICAL EXAMINATION:
WEIGHT: in wheelchair
TEMP: 98.7
B/P: 120/80
At the time of the exam she was nontoxic. She did have a markedly abnormal speech and was difficult to understand. She also had mild diffuse weakness and lack of coordination. No further exam was done.

LABORATORY DATA:
Her laboratory data is reviewed. The Lyme Western Blot information is available. She had 1 determination which was done in February of this year which is available. It was performed at IGeneX in Palo Alto, California. She had 2 positive bands. Number 39 and number 41 were 1+ positive and 3+ positive respectively. She had no other positive bands. It is noted that this laboratory considers this a positive test. However, the CDC recommendation requires 5 positive bands be present. Thus, this would be considered a negative test by the criteria of the CDC.

IMPRESSION:
I do not believe that her neurologic illness is due to Lyme disease. She has a very aggressive and progressive disease which would be unusual for Lyme. Furthermore, her Western Blot test is actually negative. I have discussed this with Kara and her family. I have offered to retest her and to investigate the records from Dr. Gabr's office. I do not believe that they want further testing, but would like to simply go ahead and treat with Ceftriaxone. I have advised them that they would need to get this treatment through another provider.

JOHN C. GIROD, MD
JCG: sjs

cc: Elizabeth Blount, MD
(Silverton, OR)

RAPHAEL STRICKER MD 4155591057 03/08/03 12:16pm P. 004

IGeneX, INC.
797 SAN ANTONIO ROAD
PALO ALTO, CA 94303
(800)832-3200

PAGE:

PATIENT: CHYTKA, KARA
DOB: 07/03/78 SEX: F

SAMPLE ID: 104072

RAPHAEL B. STRICKER, MD
450 SUTTER STREET, #1504
SAN FRANCISCO, CA
94108

DRWN: 02/07/03
RCVD: 02/10/03
PRNT: 02/18/03

DIRECTOR: BOYD G. STEPHENS, M.

TEST NAME	RESULT	UNITS
LYME IgG WESTERN BLOT	.....	

The IgG WB is considered positive if two of the starred bands are present: 23-25, 31, 34, 39, 41, 93 kDa.

The IgG WB is considered equivocal if one of these bands are present: 23-25, 31, 34, 39, 93 kDa.

41 kDa, by itself, is negative.****REVISED 9/16/99

ASTPHLD/CDC recommendation: An IgG WB is positive if five of these bands are present: 18, 23-25, 28, 30, 39, 41, 45, 58, 66, 93kDa. New York State Department of Health considers Western Blots positive that conform to the ASTPHLD/CDC criteria.

BAND INTENSITY: Low +, Medium ++, High +++, Equiv +/-

LYME IGG WESTERN BLOT	POSITIVE
18 kDa	
22 kDa	-
**23-25 kDa	-
28 kDa	-
30 kDa	-
**31 kDa	-
**34 kDa	+/-
37 kDa	-
**39 kDa	+
**41 kDa	+++
45 kDa	-
58 kDa	+/-
66 kDa	+/-
73 kDa	-
83 kDa	-
**93 kDa	-

Continued on next page

Diagnosis should not be based on laboratory tests alone. Results should be interpreted in conjunction with clinical symptoms and patient history.

RAPHAEL STRICKER MD 4155591057 03/08/03 12:16pm P. 003

IGeneX, INC.
797 SAN ANTONIO ROAD
PALO ALTO, CA 94303
(800)832-3200

PATIENT: CHYTKA, KARA
DOB: 07/03/78 SEX: F

SAMPLE ID: 104072

RAPHAEL B. STRICKER, MD
450 SUTTER STREET, #1504
SAN FRANCISCO, CA
94108

DRWN: 02/07/03
RCVD: 02/10/03
PRNT: 02/18/03

DIRECTOR: BOYD G. STEPHENS, M

TEST NAME	RESULT	UNITS
LYME IgM WESTERN BLOT	.....	

The IgM WB is considered positive for the presence of AB to B. burgdorferi if two of the starred bands are present: 23-25, 31, 34, 39, 41 kDa.

The IgM WB is considered equivocal if one of the starred bands is present.

ASTPHLD/CDC Recommendations: An IgM WB is positive if two of these bands are present: 23-25, 39, 41 kDa. New York State Department of Health considers Western Blots positive that conform to the ASTPHLD/CDC criteria.

BAND INTENSITY: Low +, Medium ++, High +++, Equiv +/-

LYME IgM WESTERN BLOT	POSITIVE
18 kDa	++
22 kDa	-
**23-25 kDa	-
28 kDa	-
30 kDa	++
**31 kDa	+++
37 kDa	-
**34 kDa	+/-
**39 kDa	+/-
**41 kDa	+
45 kDa	+/-
58 kDa	+/-
66 kDa	+
73 kDa	-
83 kDa	-
**93 kDa	+

Continued on next page

Diagnosis should not be based on laboratory tests alone. Results should be interpreted in conjunction with clinical symptoms and patient history.