



State of California—Health and Human Services Agency
California Department of Public Health
Laboratory Field Services

DEC 14 2015



NOTIFICATION OF LABORATORY CHANGE

State License/Registration #: (CLF, CLA, CLM, CLR, CLP, COS)	CLF 00341367
CLIA ID #: 05D	05D2025714
Laboratory Name:	Theranos, Inc.
Laboratory Address:	7373 Gateway Boulevard
City, State and Zip Code:	Newark, CA 94560-1149
Telephone Number:	(650) 838-9292
Fax Number:	(650) 838-9165
E-mail Address:	labsupport@theranos.com

Please mail completed form to: California Department of Public Health, Laboratory Field Services, ATT: Facilities Licensing, 850 Marina Bay Parkway, Bldg P, 1st Floor, Richmond, California 94804-6403.

THIS IS TO REQUEST CERTIFICATE CHANGE:

From: _____

TO:

- Certificate of Compliance
- Certificate of Accreditation
Note: Proof of accreditation is required.
- Provider Performed Microscopy Procedures (PPMP)
- Waiver
- Cease Testing, specialty, subspecialty and/or test
- Closure of the Laboratory

THIS IS TO INFORM YOU OF A

- Change of ownership (See note below)
- Change of Director/Add Director (See note)
Note: Items above may require additional forms. See website www.cdph.ca.gov/lfs for additional information
- Change of site address
- Change of laboratory name
- Change of mailing Address
- Change of telephone and/or fax

From: _____

EFFECTIVE DATE OF CHANGE(S): 11/13/2015

To/New: Add Co-Director
Lisa K. Helfend, PhD, MD

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING

Pursuant of 42 U.S.C. 263 a (i)(I)(B) and 42 C.F.R. 493.1840(a)(2) your laboratory's CLIA certificate may be revoked if the laboratory performs any tests not within the category of laboratory examinations authorized by your CLIA certificate. Please be advised that any person who intentionally violates the mandates of CLIA shall be subject to imprisonment, or fines, or both. See 42 U.S.C. 263a(I).

If in the future you wish to reapply for a Certificate for moderate or high complexity testing, you must notify Laboratory Field Services and submit to an inspection before such testing may begin. This inspection must find the laboratory in compliance with all CLIA condition-level requirements found at 42 C.F.R. Part 493 before the laboratory may resume moderate or high complexity testing.

For changes in certificate type, your laboratory must pay the appropriate certificate fee and/or compliance fee before the change can be effective.

NOTE: This notification of change form is acceptable only if signed by the director of the laboratory.

Lisa K. Helfend, PhD, MD

Name of Director Only (print)

Signature of Director

Dec 11, 2015
Date

DEC 14 2015

California Department of Public Health
Laboratory Field Services
Facility Licensing Section
850 Marina Bay Parkway, Bldg P, 1st Floor
Richmond, California 94804

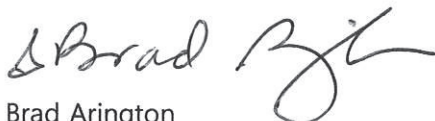
December 11, 2015

Dear Sir or Madam:

Please find enclosed executed copies of LFS Forms 193 and 183 regarding the addition of Lisa Karen Helfend, Ph.D., M.D. as California Co-Laboratory Director to Theranos Clinical Laboratory located at 7373 Gateway Blvd., Newark, California. For your reference, the California License number is CLF 00341367 and the CLIA certification number is 05D2025714.

If you have any questions or need further information, please do not hesitate to contact me as indicated below.

Best regards,



Brad Arington
Associate Director, Regulatory
Theranos, Inc.
1701 Page Mill Road
Palo Alto, California
P 650.856.7304
barington@theranos.com

cc: Heather King, General Counsel

DIRECTOR'S ATTESTATION

DEC 14 2015

I attest that effective November 13, 2015, I am the laboratory director, or a co-director of:

Theranos, Inc. clinical laboratory, located at 7373 Gateway Blvd., Newark, California 94560

CLIA number: 05D2025714 State ID number (if known): CLF 00341367

As the director or co-director, I assume all directorship responsibilities for CLIA and State of California purposes. I understand that as a director of this laboratory, I am responsible for the accuracy and reliability of all testing performed by the laboratory and for ensuring that the laboratory meets all applicable CLIA and state requirements as stipulated in both federal and California laws (Code of Federal Regulations [CFR], Title 42, Sections 493.1407, 493.1445; California Business and Professions Code [BPC], Section 1209).

I understand that I will be held jointly and severally responsible with the laboratory owner(s) for any violations of law by this clinical laboratory (BPC Section 1265(b)). If deficient or unlawful practices are found that occurred while I was serving as laboratory director or co-director, which the laboratory fails or is unable to correct, and which results in the revocation of the laboratory's CLIA certificate or state license or registration, I understand that pursuant to Title 42 of the United States Code (USC), Section 263(a)(i)(3), 42 CFR 493.1840(a)(8), and BPC Section 1324, I would be prohibited from owning, operating, or directing another clinical laboratory for a period of at least two years from the date of revocation. Such action may also be grounds for referral to the Medical Board of California or other licensing board for appropriate action.

I understand that any false statement or representation of material fact in obtaining or retaining CLIA certification or state licensure or registration may be grounds for revocation of the laboratory's CLIA certificate under 42 CFR 493.1840(a)(1), and state license or registration under BPC Section 1320(f).

I understand that I will be responsible, along with the laboratory owner(s), to notify the Department of Public Health in writing of any changes in the laboratory ownership, directorship, name or location within thirty days of the change, and that failure to provide such notification will result in automatic revocation of the state license or registration (BPC Section 1265(g)), and sanctions against the CLIA certificate (42 CFR 493.39(b), 493.45(b)(2), 493.51(a), 493.53(a), 493.57(a)(2), and 493.63(a)).

I understand that I will continue to be held responsible as a laboratory director of this laboratory until the day that the California Department of Public Health receives a signed statement from me notifying the Department of my resignation or termination.

I affirm under penalty of perjury, that all information I have given in this document is true.

Director's signature

Date Dec 11, 2015

Lisa K. Helfend, PhD, MD Print or type director's name and title

CLIA Director: Yes No

Director's address (as recorded on personal professional license)

Director's direct contact telephone number

California Board license number: G68156

California Director license number: