theranos

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Palo Alto, CA 94304

P 650.838.9292
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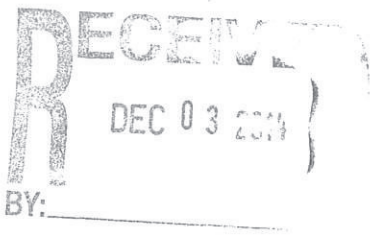
theranos.com

CLF 341367

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



November 29, 2014

Dear Sir or Madam:

Please find an executed copies of Form CMS-116 regarding the addition of a Laboratory Director to Theranos Clinical Laboratory located at 7333 Gateway Blvd, Newark, California. For your reference, the California License number is CLF 00341367 and the CLIA certification number is 05D2025714. Note that LSF Forms 193 and 183 have been sent to you under separate cover.

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

Best regards,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

CLF 341367

Form Approved
OMB No. 0938-0581

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) APPLICATION FOR CERTIFICATION

I. GENERAL INFORMATION

☐ Initial Application ☐ Survey
☐ Change in Certificate Type
☒ Closure/Other Changes (Specify) Director Change
Effective Date November 19, 2014

CLIA IDENTIFICATION NUMBER
05 D 2025714
(If an initial application leave blank, a number will be assigned)

FACILITY NAME
Theranos, Inc.

FEDERAL TAX IDENTIFICATION NUMBER
[redacted]

EMAIL ADDRESS
labsupport@theranos.com

TELEPHONE NO. *(Include area code)*
650-838-9292

FAX NO. *(Include area code)*
650-838-9165

FACILITY ADDRESS — ***Physical Location of Laboratory (Building, Floor, Suite if applicable.)*** *Fee Coupon/Certificate will be mailed to this Address unless mailing or corporate address is specified*

NUMBER, STREET *(No P.O. Boxes)*
7333 Gateway Blvd.

CITY: Newark | STATE: CA | ZIP CODE: 94560

MAILING/BILLING ADDRESS *(If different from facility address) send Fee Coupon or certificate*

NUMBER, STREET
1701 Page Mill Road

CITY: Palo Alto | STATE: CA | ZIP CODE: 94304

SEND CERTIFICATE TO THIS ADDRESS
Physical ☐
Mailing ☐
Corporate ☒

SEND FEE COUPON TO THIS ADDRESS
Physical ☐
Mailing ☐
Corporate ☒

CORPORATE ADDRESS *(If different from facility) send Fee Coupon or certificate*
NUMBER, STREET
1701 Page Mill Road

CITY: Palo Alto | STATE: CA | ZIP CODE: 94304

NAME OF DIRECTOR *(Last, First, Middle Initial)*
Sunil Dhawan, M.D.

CREDENTIALS
M.D., California License and high complexity lab director (see enclosures)

FOR OFFICE USE ONLY
Date Received _____

II. TYPE OF CERTIFICATE REQUESTED *((Check only one) Please refer to the accompanying instructions for inspection and certificate testing requirements)*

☐ Certificate of Waiver *(Complete Sections I – VI and IX – X)*
☐ Certificate for Provider Performed Microscopy Procedures (PPM) *(Complete Sections I – X)*
☒ Certificate of Compliance *(Complete Sections I – X)*
☐ Certificate of Accreditation (Complete Sections I – X) and indicate which of the following organization(s) your laboratory is accredited by for CLIA purposes, or for which you have applied for accreditation for CLIA purposes.

☐ The Joint Commission ☐ AOA ☐ AABB
☐ CAP ☐ COLA ☐ ASHI

If you are applying for a Certificate of Accreditation, you must provide evidence of accreditation for your laboratory by an approved accreditation organization as listed above for CLIA purposes or evidence of application for such accreditation within 11 months after receipt of your Certificate of Registration.

NOTE: Laboratory directors performing non-waived testing (including PPM) must meet specific education, training and experience under subpart M of the CLIA regulations. Proof of these qualifications for the laboratory director must be submitted with this application.

ORIGINAL CMS 116 SENT TO LA/CLIA FOR UPDATE.

0355

In the next three sections, indicate testing performed and annual test volume.

VI. WAIVED TESTING

Identify the waived testing (to be) performed. Be as specific as possible. This includes each analyte test system or device used in the laboratory.

e.g. (Rapid Strep, Acme Home Glucose Meter)

Quidel h. pylori, BD Macro-vue RPR, leadcare II, Bio-rad Tox-see (urine drug screen)

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all waived tests performed 776

☐ Check if no waived tests are performed

VII. PPM TESTING

Identify the PPM testing (to be) performed. Be as specific as possible.

e.g. (Potassium Hydroxide (KOH) Preps, Urine Sediment Examinations)

NA

Indicate the **ESTIMATED TOTAL ANNUAL TEST** volume for all PPM tests performed _____

For laboratories applying for certificate of compliance or certificate of accreditation, also include PPM test volume in the specialty/subspecialty category and the "total estimated annual test volume" in section VIII.

☐ Check if no PPM tests are performed

If additional space is needed, check here ☐ and attach additional information using the same format.

VIII. NON-WAIVED TESTING *(Including PPM testing if applying for a Certificate of Compliance or Accreditation)*

If you perform testing other than or in addition to waived tests, complete the information below. If applying for one certificate for multiple sites, the total volume should include testing for ALL sites.

Place a check (✓) in the box preceding each specialty/subspecialty in which the laboratory performs testing. Enter the estimated annual test volume for each specialty. Do not include testing not subject to CLIA, waived tests, or tests run for quality control, calculations, quality assurance or proficiency testing when calculating test volume. (For additional guidance on counting test volume, see the instructions included with the application package.)

If applying for a Certificate of Accreditation, indicate the name of the Accreditation Organization beside the applicable specialty/subspecialty for which you are accredited for CLIA compliance. (The Joint Commission, AOA, AABB, CAP, COLA or ASHI)

SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME	SPECIALTY / SUBSPECIALTY	ACCREDITING ORGANIZATION	ANNUAL TEST VOLUME
HISTOCOMPATIBILITY 010			**HEMATOLOGY 400**		18147
☐ Transplant			■ Hematology		
☐ Nontransplant			**IMMUNOHEMATOLOGY**		200
MICROBIOLOGY		369	■ ABO Group & Rh Group 510		
■ Bacteriology 110			☐ Antibody Detection (transfusion) 520		
☐ Mycobacteriology 115			■ Antibody Detection (nontransfusion) 530		
☐ Mycology 120			☐ Antibody Identification 540		
☐ Parasitology 130			☐ Compatibility Testing 550		
■ Virology 140			**PATHOLOGY**		
DIAGNOSTIC IMMUNOLOGY		400	☐ Histopathology 610		
■ Syphilis Serology 210			☐ Oral Pathology 620		
■ General Immunology 220			☐ Cytology 630		
CHEMISTRY		28102	**RADIOBIOASSAY 800**		
■ Routine 310			☐ Radiobioassay		
■ Urinalysis 320			**CLINICAL CYTOGENETICS 900**		
■ Endocrinology 330			☐ Clinical Cytogenetics		
■ Toxicology 340			**TOTAL ESTIMATED ANNUAL TEST VOLUME:**		0356

IX. TYPE OF CONTROL (check the one most descriptive of ownership type)

VOLUNTARY NONPROFIT	FOR PROFIT	GOVERNMENT
☐ 01 Religious Affiliation	☒ 04 Proprietary	☐ 05 City
☐ 02 Private Nonprofit		☐ 06 County
☐ 03 Other Nonprofit		☐ 07 State
_____ (Specify)		☐ 08 Federal
		☐ 09 Other Government
		_____ (Specify)

X. DIRECTOR AFFILIATION WITH OTHER LABORATORIES

If the director of this laboratory serves as director for additional laboratories that are separately certified, please complete the following:

CLIA NUMBER	NAME OF LABORATORY
05D0866311	East Bay Dermatology Medical Group

ATTENTION: READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

Any person who intentionally violates any requirement of section 353 of the Public Health Service Act as amended or any regulation promulgated thereunder shall be imprisoned for not more than 1 year or fined under title 18, United States Code or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, United States Code or both.

Consent: The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards found necessary by the Secretary of Health and Human Services to carry out the purposes of section 353 of the Public Health Service Act as amended. The applicant further agrees to permit the Secretary, or any Federal officer or employee duly designated by the Secretary, to inspect the laboratory and its operations and its pertinent records at any reasonable time and to furnish any requested information or materials necessary to determine the laboratory's eligibility or continued eligibility for its certificate or continued compliance with CLIA requirements.

SIGNATURE OF OWNER/DIRECTOR OF LABORATORY *(Sign in ink)*	DATE

NOTE: Completed 116 applications must be sent to your local State Agency.

SEE ATTACHED LIST OF STATE AGENCY CONTACT INFORMATION.

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf

DIRECTOR'S ATTESTATION

I attest that effective November 19, 2014 (date), I am the laboratory director, or a co-director of:

Theranos, Inc. (name of laboratory) clinical laboratory, located at

7333 Gateway Blvd, Newark, California 94560 (street address)

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.

Sunil S. Dhawan — Director's signature

11/20/14 — Date

Sunil S. Dhawan, MD — Print or type director's name and title

CLIA Director: ☑ Yes ☐ No

[redacted] — Director's address (as recorded on personal professional license)

[redacted] — Director's direct contact telephone number

Or

California Board license number: 53340

California Director license number: _____

UNIVERSITY OF SOUTHERN CALIFORNIA

The Trustees of the University by virtue of the authority vested in them and on the recommendation of the faculty of

THE SCHOOL OF MEDICINE

have conferred the degree of

DOCTOR OF MEDICINE

on

SUNIL DHAWAN

who has successfully completed the requirements

Given at Los Angeles, in the State of California, on the thirteenth day of May, in the year of our Lord, one thousand nine hundred and eighty-three

James H. Zumberge
President of the University

Chairman of the Board of Trustees

Dean

0359

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

The Medical Board of California
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815

PHYSICIAN AND SURGEON

CERTIFICATE NO. **G53340** EXPIRATION **04/30/2016**

SUNIL S DHAWAN

[redacted]

ORIGINAL ISSUANCE DATE
08/06/1984

RECEIPT NO.
40500071