EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Western Division of Survey and Certification
San Francisco Regional Office
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

CENTERS FOR MEDICARE & MEDICAID SERVICES

Refer to: WDSC- GKY

IMPORTANT NOTICE – PLEASE READ CAREFULLY

January 25, 2016

Sunil Dhawan, M.D., Director
Theranos, Inc.
7333 Gateway Boulevard
Newark, CA 94560

CLIA Number: 05D2025714

RE: CONDITION LEVEL DEFICIENCIES – IMMEDIATE JEOPARDY

Dear Dr. Dhawan:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42 U.S.C. 263a) and 42 Code of Federal Regulations, Part 493 (42 CFR 493). Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

The Centers for Medicare & Medicaid Services (CMS) conducted a CLIA recertification and complaint survey of the laboratory. The onsite survey was completed on November 20, 2015. However, the survey concluded with the receipt of critical information received from the laboratory on December 23, 2015. As a result of the survey, it was determined that your facility is not in compliance with all of the Conditions required for certification in the CLIA program. In addition, based on the Condition-level requirement at 42 C.F.R. § 493.1215, Hematology, it was determined that the deficient practices of the laboratory pose immediate jeopardy to patient health and safety. (Immediate jeopardy is defined by the CLIA regulations as a situation in which immediate corrective action is necessary because the laboratory's non-compliance with one or more Condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health and safety of the general public.) Specifically, the following Conditions were not met:

D5024: 42 C.F.R. § 493.1215	Condition: Hematology;
D5400: 42 C.F.R. § 493.1250	Condition: Analytic systems;
D6076: 42 C.F.R. § 493.1441	Condition: Laboratories performing high complexity testing; laboratory director;
D6108: 42 C.F.R. § 493.1447	Condition: Laboratories performing high complexity testing; technical supervisor; and,

D6168: 42 C.F.R. § 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

In addition, other standards were also found to be not met. Enclosed is Form CMS-2567, Statement of Deficiencies, listing all the deficiencies found during the survey.

When a laboratory's deficiencies pose immediate jeopardy, CMS requires the laboratory to take immediate action to remove the jeopardy and come into Condition-level compliance. Laboratories that do not meet the Condition-level requirements of CLIA may not be certified to perform laboratory testing under the CLIA program.

The laboratory has 10 CALENDAR DAYS from the date of receipt of this notice to provide CMS' Central Office and San Francisco Regional Office with a credible allegation of compliance and acceptable evidence of correction documenting that the immediate jeopardy has been removed and that action has been taken to correct all of the Condition-level deficiencies in question.

Please document the laboratory's allegation of compliance using the enclosed Form CMS-2567, Statement of Deficiencies, in the columns labeled "Provider Plan of Correction" and "Completion Date" located on the right side of the form, keying your responses to the deficiencies on the left. The laboratory director must sign, date and return the completed Form CMS-2567 documented with a credible allegation of compliance WITHIN 10 CALENDAR DAYS from the date of receipt of this notice. You must also submit documented evidence that verifies that the corrections were made. (Your allegation of compliance will be included in the public record of the inspection.)

For your information, a credible allegation of compliance is a statement or documentation that is:

1) Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2) Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation; and

3) Indicates resolution of the problems.

In addition, acceptable evidence of correction must include:

1) Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2) How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3) What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and

4) How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

If the laboratory submits a credible allegation of compliance and acceptable evidence of correction that the laboratory has removed jeopardy and come into Condition-level compliance, and we are able to verify compliance with all CLIA requirements through a follow-up survey, sanctions will not be imposed. If the laboratory does not submit a credible allegation of compliance and acceptable evidence of correction, we will not conduct a follow-up survey.

If jeopardy is not removed and the laboratory does not come into Condition-level compliance, CMS will take sanction action(s) against the laboratory's CLIA certificate. If necessary, we will advise the laboratory in writing of the sanction(s) to be imposed and/or enforcement action(s) that will be taken. These sanctions may include alternative sanctions (Civil Money Penalty of up to $10,000 per day of non-compliance pursuant to 42 C.F.R. §493.1834, Directed Plan of Correction pursuant to 42 C.F.R. § 493.1832, and/or State Onsite Monitoring pursuant to 42 C.F.R. § 493.1836) and principal sanctions (suspension, limitation and/or revocation of the laboratory's CLIA certificate and cancellation of the laboratory's approval for Medicare payments pursuant to 42 C.F.R. § 493.1814).

Please note that the routine survey takes an overview of the laboratory through random sampling. By its nature, the routine survey may not find every violation that the laboratory may have committed. It remains the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assurance measures to ensure that the deficient practices do not recur.

In addition to the routine CLIA certification surveys, announced or unannounced investigations/ surveys may be conducted by CMS or CMS' agents at any time to address complaints or other non-compliance issues. These investigations/surveys may well identify violations that may not have surfaced during a routine survey using random sampling, but for which the laboratory and its director will still be held responsible.

Instructions for Submitting the Laboratory's Response

All responses as well as any future correspondence pertaining to this survey should be sent to:

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification
Centers for Medicare & Medicaid Services
90 7th Street, Suite 5-300 (5W)
San Francisco, CA 94103-6707

A copy of any response the laboratory makes to CMS' San Francisco Regional Office must also be sent to CMS' Central Office at the following address:

Division of Laboratory Services
Survey and Certification Group (SCG)
Center for Clinical Standards and Quality (CCSQ)
Centers for Medicare & Medicaid Services
7500 Security Blvd – Mail Stop C2-21-16
Baltimore, MD 21244
Attention: Sarah Bennett

If you have questions regarding this letter, please contact Gary Yamamoto of my staff at (415) 744-3738.

Sincerely,

Karen Fuller

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification

Enclosure: Form CMS-2567, Statement of Deficiencies

cc: California Department of Public Health, Laboratory Field Services

CMS, Central Office