

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702	DATE(S) OF INSPECTION 8/16/2016-8/18/2016 FEI NUMBER 3010479366
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dave W. Wurtz , Vice President of Regulatory and Quality

FIRM NAME Theranos, Inc.	STREET ADDRESS 1701 Page Mill Rd
CITY, STATE, ZIP CODE, COUNTRY Palo Alto, CA 94304-1210	TYPE ESTABLISHMENT INSPECTED Sponsor

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Part of an investigation was initiated before IRB approval.

Specifically, your clinical investigations for Protocols (b) (4) and (b) (4) were initiated and conducted in site (b) (4) prior to obtaining IRB approval. Of the total (b) (4) samples collected from subjects enrolled in the two investigations, (b) (4) samples were collected from subjects that were consent at site (b) (4) without an IRB approval.

Annotations to Observations

Observation 1: Not annotated

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**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Aneel K Sandhu, Investigator
Ian A Pilcher, ~~Non Reporting User~~
Investigator 8/18/2016

Aneel Sandhu - S
Ian A. Pilcher - S

Digitally signed by Aneel Sandhu - S
DN: cn=A, ou=U.S. Government, email=A.Sandhu@FDA, serial=1, c=US
8.5.2142.19200000.100.1.1=1300167479
Date: 2016.08.18 16:57:18 -0700

Digitally signed by Ian A. Pilcher - S
DN: cn=A, ou=U.S. Government, email=I.Pilcher@FDA, serial=1, c=US
8.5.2142.19200000.100.1.1=1300219462
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DATE ISSUED
8/18/2016