DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax: (510) 337-6702 Industry Information: www.fda.gov/oc/industry	08/25/2015 - 09/16/2015* FEI NUMBER 3006231732

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ramesh (NMI) Balwani, President and Chief Operations Officer

FIRM NAME	STREET ADDRESS
Theranos, Inc.	7333 Gateway Blvd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Newark, CA 94560	Medical Device Manufacturer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Devices for which listing is required have not been listed.

Specifically, your (b) (4) Capillary Tube Nanotainer (CTN) is a blood specimen collection device (b) (4) (b) (4) and as such th (b) (4) CTN is a Class II medical device. You have not listed the (b) (4) CTN as a Class II medical device, and you are currently identifying it as a Class I exempt medical device. You are currently shipping this uncleared medical device in interstate commerce, between California, Arizona, and Pennsylvania.

OBSERVATION 2

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, your two written procedures, "Customer Complaints, Document Number SOP-00174, Revision A, Effective Date 07/02/2014", and (b) (4) Document Number CS SOP-05071, Revision A, Effective Date 03/27/2015" do not accurately describe the entire complaint handling procedure that you currently employ to receive, review, and evaluate customer complaints. The procedure that you verbally described during the current inspection is as follows:

(b) (4)

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In written procedure "Customer Complaints, Document Number SOP-00174, Revision A, Effective Date 07/02/2014", Section 6.1.1 states that (b) (4) (b) (4) (b) (4)

(b) (4) Document Number CS SOP-05071, Revision A, Effective Date 03/27/2015", Section 8.1.1 states the (b) (4) (b) (4) (b) (4) (b) (4) Section 7.1 of the same written procedure contains (b) (4) (b) (4) (b) (4) This procedure does not provide instructions for forwarding complaints to the (b) (4) or Theranos QA for product investigation and assessment of MDR reportability.

Your written procedures do not describe your complaint handling as you verbally described it during the inspection. The Theranos QA complaint log that you provided contained no logged complaints; however, the (b) (4) complaint log that you also subsequently provided contained CTN-related complaints.

OBSERVATION 3

Complaints involving the possible failure of a device to meet any of its specifications were not reviewed, evaluated, and investigated where necessary.

Specifically, a complaint that was reported to you via NCR-01926 on 01/30/2015 was not handled as a complaint in compliance with your written procedure "Customer Complaints, Document Number SOP-00174, Revision A, Effective Date 07/02/2014". NCR-01926 was a report of a complaint from your (b) (4) that there were "difficulties in inspecting CTN specimen quality. Reports were that walls of (b) (4) parts were too opaque to be able to see clotting clearly". You did not identify this as a complaint and you did not investigate it as a complaint, nor did you investigate if this complaint required the filing of MDRs. This complaint was not documented in your complaint log.

OBSERVATION 4

Corrective and preventive action activities and/or results have not been documented.

Specifically, you undertook several corrections of your Quality Management System procedures and records without documenting the investigations of causes of the nonconformities, the actions needed to correct or prevent recurrence of similar quality problems, the verification or validation of corrective actions, and the dissemination of information about the quality problems to responsible parties. During this inspection you undertook to correct procedures and records for your

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Complaint Handling, supplier qualifications, DHRs, and internal audits without opening CAPAs to document your investigation into the causes of these deficiencies and their impact on your Quality Management System, an analysis and plan of what corrections were required, whether the corrections impacted other areas of your Quality Management System, and the dissemination of the information about these issues to your firm's employees.

For example, during this inspection you were unable to produce documented supplier qualifications, and you corrected the deficiency by assembling the required supplier qualification documents for your suppliers. You did this without opening a CAPA that investigated the probable cause for not having supplier qualification documentation, or to investigate if these suppliers had met your quality requirements the entire time in the past when you had purchased materials from them with which you had manufactured your finished products, or if your purchasing department personnel required training to ensure future compliance with this required quality activity, and training that may be required by other employees making purchases so that they understand the probable quality impact on products made with materials sourced from unapproved suppliers. This correction of your lack of documented supplier qualification was not documented in a CAPA that contained an effectiveness plan to ensure that the correction you undertook would reduce or eliminate any future recurrence of this situation.

OBSERVATION 5

Software validation activities and results for computers or automated data processing systems used as part of production and the quality system have not been documented.

Specifically, you use an unvalidated Excel spreadsheet to document the results of the (b) (4) during the (b) (4) for your (b) (4) CTN and (b) (4) CTN manufacturing. For example, you record the (b) (4) (b) (4) in the (b) (4) for (b) (4) Lot Numbers (b) (4) however, you recorded the individual raw data in an unvalidated Excel spreadsheet that (b) (4) This unvalidated spreadsheet does not specify what (b) (4) is being recorded, or the (b) (4) or the identity of the person making the (b) (4) This unvalidated Excel spreadsheet does not document a QA review of the data. The spreadsheet is not included with the (b) (4) as part of the Device History File.

OBSERVATION 6

The evaluation of potential suppliers was not documented.

Specifically, your written procedure, (b) (4) Document Number SOP-00171, Revision B, Effective Date 07/08/2015" lays out the procedure for (b) (4) (b) (4) "; however, you did not have documented approved supplier qualifications for at least (b) (4) of the suppliers on your Approved Supplier List until after the start of the current inspection.

For example, your supplier of (b) (4) had no documented approved supplier qualification until after the start of this inspection, yet you purchased a (b) (4) that you use in the manufacture of your (b) (4) CTNs from this

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supplier. On 06/19/2015 you issued Purchase Order Number (b) (4) to your supplier of (b) (4) and on 07/16/2015 you received (b) (4) of (b) (4) from this vendor; however, you had no documented approved supplier qualification for this supplier of (b) (4) until 09/07/2015.

OBSERVATION 7

Records of acceptable suppliers have not been adequately established.

Specifically, not all the suppliers of your goods and services are included on your (b) (4) Section 6.1.1 of your written procedure, "(b) (4) Document Number SOP-00170, Revision B, Effective Date 07/08/2015" states (b) (4) (b) (4) (b) (4) however, on 08/14/2015 you purchased (b) (4) (b) (4) that is used in the manufacturing of your CTNs via Purchase Order Number (b) (4) from a supplier that is not listed on your (b) (4)

OBSERVATION 8

Procedures for device history records have not been adequately established.

Specifically, Sections 6.1 and 6.1.5 of your written procedure "Device History Record (DHR), Document Number SOP-00151, Revision A, Effective Date 01/28/2014" state (b) (4) (b) (4) ; however, your (b) (4) documenting the manufacture of your Capillary Tube Nanotainers (CTNs) do not include a copy of the primary identification label that was applied to the finished product. For example, your (b) (4) for the manufacturing of (b) (4) CTN Lot numbers (b) (4) (b) (4) do not include copies of the primary identification label that was applied to the bags of finished (b) (4) CTNs manufactured with those lot numbers.

OBSERVATION 9

Quality audits have not been performed.

Specifically, you have not monitored your Quality Management System through internal quality audits; you had no documented internal quality audit schedule to monitor your Quality Management System until after the start of this inspection. Section 6.1.1 of your written procedure, "Internal Quality Audit, Document Number SOP-00177, Effective Date 07/02/2014" states (b) (4) ; no internal audits were performed in (b) (4) none have been performed so far in 2015. Section 6.1.1.1 of the same written procedure states (b) (4) (b) (4) eference 7.1" [7.1 = TMP-00032 (b) (4)

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(b) (4) at the start of this inspection, your TMP-00032 (b) (4) was blank..

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Observation Annotations

Observation 1:	Under consideration.	Observation 2:	Promised to correct within 7 days.
Observation 3:	Promised to correct within 7 days.	Observation 4:	Promised to correct within 7 days.
Observation 5:	Promised to correct within 7 days.	Observation 6:	Promised to correct within 7 days.
Observation 7:	Promised to correct within 7 days.	Observation 8:	Promised to correct within 7 days.
Observation 9:	Promised to correct within 7 days.		

*** DATES OF INSPECTION:**
08/25/2015(Tue), 08/26/2015(Wed), 08/27/2015(Thu), 08/28/2015(Fri), 09/01/2015(Tue), 09/02/2015(Wed), 09/04/2015(Fri), 09/08/2015(Tue), 09/10/2015(Thu), 09/16/2015(Wed)

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