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

July 7, 2016

Sunil Dhawan, M.D., Director
Elizabeth Holmes, Owner
Ramesh Balwani, Owner
Theranos, Inc.
7333 Gateway Boulevard
Newark, CA 94560

CLIA Number: 05D2025714

RE: IMPOSITION OF SANCTIONS

Dear Dr. Dhawan, Ms. Holmes, and Mr. Balwani:

We are writing to notify you of the determination by the Centers for Medicare & Medicaid Services (CMS) that Theranos, Inc. ("Theranos" or "the laboratory") located at the above address is not in compliance with Clinical Laboratory Improvement Amendments of 1988 (CLIA) Condition-level requirements, has not removed the finding of immediate jeopardy, and of the consequent imposition of the following sanctions:

- Revocation of the laboratory's CLIA certificate
- Limitation of the laboratory's CLIA certificate for the specialty of hematology
- A Civil Money Penalty
- A Directed Portion of a Plan of Correction
- Suspension of the laboratory's approval to receive Medicare and Medicaid payments for any services performed for the specialty of hematology
- Cancellation of the laboratory's approval to receive Medicare and Medicaid payments for all laboratory services

CLIA Survey

CMS conducted a CLIA recertification and complaint survey at Theranos in 2015. The onsite portion of the 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. Based on this survey, the laboratory was found to be out of compliance with five CLIA Condition-level requirements, in addition to numerous CLIA Standard-level requirements.

By letter dated January 25, 2016, CMS provided Theranos with a listing of all deficiencies identified during the survey on Form CMS-2567, Statement of Deficiencies. The January 25, 2016 letter also notified the laboratory that the seriousness of the deficiencies cited under 42 C.F.R. § 493.1215 resulted in the finding of immediate jeopardy to patient health and safety, and requested

that the laboratory take immediate action to remove the jeopardy and bring any unmet Condition-level requirements into compliance. In response to the January 25, 2016 letter, CMS received a submission from the laboratory on February 12, 2016.

After careful review, we determined that the laboratory's submission did not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2015, and did not demonstrate that the laboratory had come into Condition-level compliance and abated the immediate jeopardy.

CMS' Notice of Proposed Sanctions

By letter dated March 18, 2016, we notified Theranos of our determination related to the laboratory's submission; provided the laboratory with our review of the submission; and proposed sanctions against the laboratory's CLIA certificate based on the finding of immediate jeopardy, the laboratory's failure to meet all CLIA Condition-level requirements, and the failure by the owners and director of the laboratory to comply with certificate requirements and performance standards as evidenced by the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2015. This letter described the proposed sanctions and gave the laboratory until March 28, 2016 to submit, in writing, any information or evidence as to why the sanctions should not be imposed.

In response, CMS received a second submission from the laboratory initially dated March 28, 2016, which was followed by a revised submission dated April 1, 2016. Subsequent addendums to the second submission were received by CMS from the laboratory under cover letters dated April 7, 2016, April 18, 2016, and April 26, 2016. (Collectively, these five submissions are referred to herein as the "second submission.")

Review of the Laboratory's Second Submission

After careful review, we have determined that the laboratory's second submission again does not constitute a credible allegation of compliance and acceptable evidence of correction for the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2015, and does not demonstrate that the laboratory has come into Condition-level compliance and abated the immediate jeopardy.

The following explanation details why the laboratory's second submission does not constitute a credible allegation of compliance and acceptable evidence of correction:

General Comments

- ***Flash Drives***

  Although related to all deficiencies cited, this general comment specifically addresses the laboratory's second submission responding to the deficiencies cited under D5413, D5423, D5481, D5779, D5791, D5793, D5805, D6086, D6170, and D6178.

Theranos provided CMS five passcode protected flash drives with its second submission labeled Exhibits KK, MM, NN, OO, and PP. After careful review, we note the following related to these flash drives:

- The information on the flash drives was difficult to evaluate and access. Corrected patient test reports and notification of corrected patient test reports for any specific patient specimen accession number were spread over several flash drives, and the corrected patient test reports were not always associated directly with the confirmation of notifications and receipts. This required all flash drives be reviewed in their entirety for any specific accession number to determine whether complete records were received. We were unable to search the flash drives by any criteria (e.g., patient name, date of visit, etc.) other than by the specimen accession numbers provided in the binder labeled Ex. MM.

- We are uncertain as to what the laboratory intended to submit as a "complete" record for each corrected patient test report submitted. Some of the corrected patient test reports had associated facsimile coversheets, and other corrected patient test reports had associated facsimile receipts, but not both. In other cases, we found only facsimile coversheets or receipts, but no associated correct patient report. We are unclear as to the following:

    - For those specimen accession numbers that had only facsimile coversheets, how did the laboratory verify receipt of the corrected patient reports?

    - For those specimen accession numbers that had only facsimile receipts, how does the laboratory (and CMS) know what information was actually transmitted to the authorized person?

    - How were the receipt confirmations generated?

  It appears the information provided on the flash drives did not include "complete" documentation for all specimen accession numbers listed in the binder labeled Ex. MM. Furthermore, some of the specimen accession numbers listed in binder Ex. MM could not be found on any of the flash drives.

Consequently, we could not determine whether the laboratory provided documented evidence showing what corrective actions were taken for all patients found to have been affected by the deficient practice, and what corrective actions were taken for any other patients identified as having the potential to be affected by the same deficient practice.

- ***Quality Assessment***

Although related to all deficiencies cited, this general comment specifically addresses the laboratory's second submission responding to the deficiencies cited under D2094, D2128, D5217, D5311, D5391, D5393, D5403, D5413, D5421, D5423, D5429, D5437, D5447,

D5449, D5469, D5477, D5481, D5775, D5779, D5781, D5787, D5791, D5793, D5801, D5805, D5821, D6086, D6093, D6102, and D6178.

In the April 1, 2016 portion of its second submission, the laboratory provided a revised quality assessment mechanism, but submitted no documentation to indicate that the revised quality assessment mechanism has been effectuated. In addition, the laboratory's submission states that "training on the revised QMPI [Quality Monitoring and Processing Improvement (quality assessment mechanism)] procedures has occurred. (Ex. BB, Tab 7 B-C)." We note that Ex. BB, Tab 7 B - C contains incomplete training documentation for only three laboratory personnel (one of training records did not include the same documents consistent with the other two records), none of whom appear on the laboratory's "Laboratory Personnel Report (CLIA), Form CMS-209" dated February 8, 2016. There is no evidence that the personnel listed on that form received the revised QMPI training.

The laboratory again failed to adequately address issues related to quality assessment and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters. Specifically, the laboratory failed to indicate what measure has been put in place or what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

Comments Related to Specific D-tags

D2094

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

For ungraded proficiency testing results, Ex. BB, Tab 3, § 9.4.5.11 requires the laboratory to complete the Ungraded Section of Form CL FRM-00006-F1, titled "Proficiency Testing Investigation and Correction Action." The Ungraded Section of Form CL FRM-00006-F1 the laboratory provided in Ex. JJ, Tab 3A shows that only Question 4 was answered and not questions 1, 2, 3, 5, and 6.

The revised SOP (standard operating procedure) at Ex. BB, Tab 3, § 9.4.3.2 states that for proficiency testing (PT) results identified as "No appropriate target/response cannot be graded," the laboratory's PT results should be compared "to a similar method, all methods, or all participants statistics if provided." This allows the laboratory to determine the best fit for its data rather than have a clear-cut hierarchy for review of ungraded PT results. The SOP also did not clearly define who will be responsible for making the determination as to which category of results the laboratory's PT results would be compared against.

The April 1, 2016 letter accompanying the second submission states that the "documentation explains how the laboratory came to its conclusions related to patient outcomes (Ex. JJ, Tab 3A)." However, Ex. JJ, Tab 3A simply states: "**Patient Impact:** Based on PT investigation, no patient impact," and does not explain how the laboratory came to its conclusions that no patients were affected.

It is unclear from the revised procedure titled "PT Investigation and Corrective Action Form," and Patient Impact Assessment documentation what the actual acceptance criteria for PT samples are and what the laboratory should document. The form provided at Ex. JJ, Tab 3A, Question 4 states that the acceptance criteria is "SDI [standard deviation index] < 1.5." However, we note that the Patient Impact Assessment: Alkaline Phosphatase on b4 b4 (Ex. AA, Tab 13) allows ±30% as limits of acceptability. Further, the revised Proficiency Testing Procedure (Ex. BB, Tab 3) at § 9.4.5.3 includes the following:

> 9.4.5.3. Complete the General Section and document the average SDI or any SDI ≥ 2.0 if applicable.
> a. Acceptable results: the lab target +/- PT allowable error
> b. Acceptable results: the average SDI value of -1.5 to 1.5

In addition, we note that the Patient Impact Analysis identified a slight negative bias across all results. It states:

> In all such cases the level of alkaline phosphatase elevation is significant. . .The quantitative testing results themselves are of no clinical significance, with only gross degrees of elevation serving clinical utility. Therefore, any minimal negative bias, such as that identified in this case, when applied to any of these clinical scenarios, would have no clinical significance.

However, the revised Proficiency Testing Procedure (Ex. BB, Tab 3) requires in § 9.4.5.10 that a "review of patient tests results since the last PT event" is required for "incorrect results." There was no documentation submitted to indicate that any patient results were evaluated based on the requirement in the procedure, especially at the borderline abnormal high level.

D2128

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

The second submission included a revised Proficiency Testing Procedure (Ex. BB, Tab 3). Section 9.4.1 of this procedure provides instructions regarding the review of PT results and refers to §§ 9.4.1.1 - 9.4.1.3 of the procedure to evaluate unsatisfactory results, SDI, and bias, trends or shifts, respectively. We note that the procedure refers to incorrect sections; however, §§ 9.4.4.1 – 9.4.4.2 and §§ 9.4.5.2 – 9.4.5.3 did address these issues, and those sections were used to evaluate the laboratory's submission.

Based on the submission at Ex. JJ, Tab 2A, the laboratory did not follow its own procedure to review and evaluate the unacceptable response for BCI-11. The laboratory's revised PT procedure (Ex. BB, Tab 3) requires in § 9.4.5.10 that patient test results since the last PT event must be reviewed and "if the investigation demonstrates a problem with test performance, assess patient impact based on [where] the problem originated. . .Implement corrective action and notification." The latest submission at Ex. JJ, Tab 2 states that the unacceptable response for BCI-11 was investigated and explains how the laboratory came to its conclusions related to patient outcomes.

We note that on the Investigation and Corrective Action form it shows that BCI-11 was unacceptable, and indicates that the "CLS [clinical laboratory scientist] did not correctly identify the BCI-11. . ." and that there was "[n]o patient impact." However, there is no evidence submitted to support that patients were not impacted, nor was there documentation showing that the investigation included a review of patient results as required by the revised procedure.

D5024

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our reviews of D5403, D5447, D5481, and D5801. For D5437, D5469, and D5779, see our Quality Assessment review under the General Comments.

D5217

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In the April 1, 2016 submission, the laboratory states that it "failed to demonstrate proficiency" for troponin for both the first and second PT events of 2014. However, because the laboratory was unable to determine the cause of the PT failures (Ex. JJ, Tab 1A), the laboratory voided all patient test results from March 2014 through October 2014. We are unable to determine if the laboratory's troponin test results for the third PT event of 2013 were also reviewed and found to be acceptable. The laboratory does state that troponin test results for the third PT event of 2014 were acceptable (Ex. JJ, Tab 1A); no documentation was included in the submission for CMS to verify this statement. We are unclear as to why the laboratory did not perform a through retrospective review to determine when the last PT results for troponin were acceptable, and why patient results prior to March 2014 were not reviewed and possibly voided, when these patient test results fell in the time frame between the third PT event of 2013 and the first PT event of 2014 (where the laboratory voided patient troponin test results when the laboratory PT test results were unacceptable).

The April 1, 2016 portion of the second submission states on page 7 that: "Many corrected reports have been transmitted, and the remainder are being transmitted (Ex. KK). Transmission will be complete by March 31, 2016. The remainder of the transmittals and confirmations of receipt will be provided to CMS under separate cover." An additional letter dated April 7, 2016 explained that the flash drive (Ex. OO) "contains copies of most of the remaining corrected reports, including receipt confirmations." A review of binder Ex. MM, Tab 30 revealed 11 troponin specimen accession numbers for which corrected patient test reports were to have been generated, sent, and confirmed. Based on the review of information on the flash drives (Ex. KK, MM, NN, OO, and PP), the records of corrected reports are incomplete. The information provided in Ex. MM and on the four accessible flash drives showed corrected patient test reports for troponin from June 2014 through September 2014, but did not include any reports for March 2014 through May 2014 or October 2014, as it states in Ex. JJ, Tab 1A.

D5311

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In its April 1, 2016 letter accompanying its second submission, the laboratory states: "Among other things, the revised assessment shows that [the] laboratory took corrective action in 2014 and 2015 for patients that may have been affected by offering a redraw and retest at no charge (Ex. AA, Tab 1; Ex. HH, Tab 10)." Included in Ex. AA, Tab 1 are statements of "Investigation" and "Patient Impact" in which the laboratory reiterates that, "if a specimen was not labeled or was mislabeled, it was the laboratory's practice in 2014 and 2015 to offer a redraw at no charge" and that "[the] laboratory took corrective action to address mislabeling by offering patients redraws at no charge." In this exhibit, the laboratory also references Ex. HH, Ex. 10.

Ex. HH, Ex. 10 is an attestation statement made by the laboratory's Corporate Controller stating: "If there is a problem with testing a patient sample because of a specimen labeling issue, the patient is offered a redraw at no additional charge." Other than the references to Ex. AA and Ex. HH, the laboratory provided no additional written evidence indicating such a policy existed in 2014 and 2015, or that the offer to redraw had actually occurred.

D5400
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our reviews of D5403, D5407, D5413, D5421, D5423, D5429, D5447, D5449, D5477, D5481, D5787, D5791, and D5793. For D5437, D5469, D5775, and D5779, see our Quality Assessment review under the General Comments.

D5403
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #2
The laboratory failed to submit documentation of any quality control (QC) procedure prior to May 15, 2014. Rather, the laboratory's submission includes an attestation (Ex. FF, Tab 13) from an employee who, based on documentation and interview at the time of the onsite survey, only performed dilutions on the b4 , but did not perform quality control or patient testing. Both the attestation and the laboratory's written submission state what the employee recalls as to the laboratory's QC procedure. Again, however, the laboratory did not provide any documented evidence that a QC procedure existed or was in use prior to May 15, 2014. We also note that the attestation states that the employee's duties included running QC, which is contrary to the information given to the surveyor at the time of the onsite survey, but did not indicate if he/she had responsibility for evaluating QC prior to releasing patient test results.

The second submission states the following in Ex. AA, Tab 3:

- Upon review of that response, including the entirety of the prior analysis of TPS [Theranos Propriety System] 3.5 QC data and patient test results distribution for all analytes during the time period examined, the laboratory made note of poor QC performance throughout. Therefore, the laboratory conducted an expanded retrospective analysis for 2014 and 2015.

This data is presented in Ex. FF, Tabs 1-12. The laboratory noted multiple and recurrent time periods (across all analytes tested) of abrupt shifts in QC target means, high rates of 1-2s QC rule failures, and QC CVs [Curricula Vitae] far exceeding limits for a stable testing process. (Investigation section)

- Although the magnitude of QC deviations from target means does not necessarily reflect the exact nature and magnitude of bias on patient results because of differences in matrices, the QC failures identified by this comprehensive retrospective analysis reflect a global and long-term failure of the quality control program for this instrument, as well as failures of related quality assurance procedures that should have alerted the laboratory to correct such an unstable process. Therefore, the laboratory has concluded that there is a possible patient impact for every test reported from the laboratory's TPS 3.5 instruments. (Patient Impact section)

- The fraction of patient results truly impacted, and the nature and magnitude of any effect, are unknown. Out of an abundance of caution, the laboratory has voided all patient test results reported from the TPS 3.5 instruments. Many corrected reports have been transmitted... (Corrective Action section)

Review of documents in Ex. FF, Tabs 1-12 revealed that only QC data was submitted. There was no documentation in Ex. FF, Tabs 1-12 related to a "comprehensive retrospective review." In addition, there was no documentation submitted related to "multiple and recurrent time periods (across all analytes tested) of abrupt shifts in QC target means, high rates of 1-2s QC rule failures, and QC CVs far exceeding limits for a stable testing process" that the laboratory noted. We also note that no documentation was submitted in Ex. AA, Tab 3 or Ex. FF, Tabs 1-12 that indicated what the investigation into QC issues found as the root cause for the QC failures.

Based on the laboratory's submission at Ex. AA, Tab 3, the expanded retrospective analysis for 2014 and 2015 centered on QC issues, but failed to include 2013 in the expanded analysis. Four tests (Vitamin D, TSH, Free T4, and Total PSA) were put into use for patient testing in 2013. It is unclear why the 2013 QC data was not included, especially since the laboratory concluded that "there is a possible patient impact for every test reported from the laboratory's TPS 3.5 instruments." We also note that the QC data submitted for the above four tests did not begin until various dates in March 2014. We are unclear as to whether QC was performed from November 2013 through various dates in March 2014.

Based on documentation supplied by the laboratory at the time of the survey, the TPS was not used for patient testing after June 25, 2015. However, the laboratory's submission states that the TPS 3.5 was "**fully retired** in early-August 2015." Patient testing was "retired" later than when the laboratory previously indicated. We note that no explanation was submitted regarding the disparity between the end dates provided at the time of the survey and the portion of the second submission dated April 1, 2016.

D5407

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In CMS' March 18, 2016 letter, we asked the laboratory to explain and provide documented evidence for the laboratory's statement: "The lab's overarching review of its systems and primary instruments has identified the patients affected or having the potential to be affected by this issue." In the April 1, 2016 portion of the second submission, the laboratory states, without submitting supporting documentation, that there is "no potential for this untimely signature by [the former laboratory director] to have affected patients because [the former laboratory director] ultimately approved the SOP without making any modifications or revision to it." However, in the same paragraph, the laboratory states that as a result of its review, "the laboratory issued corrected reports voiding PT/INR test results reported for the period October 2014 through September 2015. (Ex. AA, Tab7). The laboratory **stopped** using the BSC XP instrument on September 17, 2015, and **has not used it since then.**" However, documentation given to the surveyor by the laboratory at the time of the onsite survey indicated that the laboratory did, in fact, use the BCS XP for patient testing after September 17, 2015. The laboratory has not provided sufficient evidence to rebut the information contained in that documentation. Also, these contradictory statements in the submissions call into question the reliability of the information contained in the submissions.

Further, CMS is unclear as to how the laboratory reached the conclusion that the untimely signature of the SOP by the former laboratory director did not affect or potentially affect patient test results given the conclusions that the laboratory reached in Ex. AA, Tab 7. Ex. AA, Tab 7, such as:

- Most results were "high or critical high" (~70%) each month. . .Such fluctuations in percentages of "critical high" and "low" patients in the distribution are not expected, again suggesting that the assay experienced biases that may have impacted patients during this time.

- Among abnormal values (i.e. those above the "normal" range), the laboratory observed an approximately normal distribution centered around the mean/median (~22 sec). However, during each month, there were fluctuations on either ends of those distributions. This fluctuation is observed every month, suggesting that a systemic error is present in this test method that may have affected at least a fraction of patient samples during the time periods evaluated.

- As detailed above, multiple errors and potential biases were detected over the entire time period of this test offering. This includes errors in the calculation of reported INR values, and positive and negative QC biases detected at multiple levels over multiple time periods.

- The laboratory director believes these multiple errors and possible biases call into question the analytical validity of all PT/INR tests resulted. . .the analytical and clinical validity of these results are uncertain. . .the laboratory believes there is a possibility of patient impact for all PT/INR tests resulted.

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1

A new section added to the SOP at Ex. BB, Tab 13, § 8.8.1 states the following: "Any trained laboratory staff may record daily temperatures for all required equipment, including but not limited to CLA [clinical laboratory assistant], CLS, Supervisor, Manager and Director."

We note that in the April 1, 2016 portion of the second submission, the laboratory did not include a "complete set of training records on this SOP, which shows that the relevant laboratory personnel have been trained (Ex. BB, Tabs 13B-13C)" as stated in the submission. Based on the information provided by the laboratory on Form CMS-209, dated February 12, 2016, which was the latest submitted by the laboratory, training documentation was not included for three testing personnel, nor did the "Acknowledgement Form" (Ex. BB, Tab 13C) include six testing personnel listed on the Form CMS-209. In the letter accompanying the laboratory's second submission on page 18, the laboratory states that "the relevant laboratory personnel" have been trained, but did not include a list of the "relevant laboratory personnel."

In the April 1, 2016 portion of the second submission, the laboratory states:

- D5413 identifies six -20C freezers and four -80C freezers. In the lab's submission, we explain that five of those freezers did not contain materials that would be used in the future for clinical patient testing. Rather, they only contained material that might be used in the future for research and development.

- Based on the March 18 letter, it appears that there was a miscommunication when the CMS surveyors were onsite. D5413, Paragraph f, states that CMS had a discussion about these freezers with the "Director of Assay Systems and technical supervisor at 11/19/15 at approximately 11 am." The Director of Assays did not have any regular involvement with those freezers at that time and did not have the knowledge of their contents. The "technical supervisor" in attendance on November 19, 2015 joined the company on October 26, 2015; he also did not have regular involvement with those freezers at the time and did not have knowledge of their contents. (Ex. HH, Tab 8). To the extent CMS understood either of these individuals to be confirming the contents of these freezers or whether these freezers were used in clinical patient testing, there was a miscommunication.

Based on these statements, it is unclear whether the laboratory investigated what was in the freezers at the time of the onsite survey, and what the freezers had been used for prior to the onsite survey as the submission only speaks to future use of the freezers. It is also concerning to CMS that the laboratory claims that there was a miscommunication regarding the use of the freezers at the time of the survey. The technical supervisor (TS) who confirmed the freezer use was not a TS hired by the laboratory on October 26, 2015, but rather an individual identified on personnel documentation as a TS at the time of the onsite survey who had been with the laboratory for several years. The confirmation occurred while the surveyor was touring the laboratory with a group of four or five

laboratory employees who, had the confirmation by the Director of Assays and TS been in error, should have communicated the correct information. Regardless, based on the information provided by the laboratory, it is still unclear to CMS if the freezers now identified by the laboratory as not in use for CLIA activities were being used at the time of, or prior to, the onsite survey.

Finding #2

In the April 1, 2016 portion of the second submission, the laboratory states: "The laboratory **stopped** running tests on the BCS XP on September 17, 2015, and has **not** run any tests on the Siemens BCS XP since then." However, documentation given to the surveyor by the laboratory at the time of the onsite survey indicated that the laboratory did, in fact, use the Siemens BCS XP for patient testing after September 17, 2015.

Review of Ex. HH, Tabs 11A – 11B revealed a photograph of a bottle with unknown contents labeled with open and expiration dates. Given that the package insert provided in Ex. HH, Tab 11B is for IRISpec CA/CB/CC, our review will assume that this is the QC material in the photographed bottle in Ex. HH, Tab 11A. It therefore appears that the laboratory is correctly labeling opened bottles or reagents.

However, we found no document to support correction of the evidence cited in the Statement of Deficiencies, Form CMS-2567. Exhibit BB, Tab 14 D of the laboratory's second submission indicates that training had occurred, via a case study, to specifically address the deficiency related to expired Innovin (thromboplastin). We note that the Form CMS-209 dated February 8, 2016 listed 12 testing personnel. One of the 12 is no longer working in the clinical laboratory based on the April 1, 2016 portion of the second submission (page 82, footnote 14), so the laboratory's submission is based on the remaining 11 testing personnel. The training documents related to the Innovin (thromboplastin) case study include six of the 11 on the Acknowledgement Form provided by the laboratory in Ex. BB, Tab 14D. We are unable to determine if the other five testing personnel have been retrained using the case study. We also note that the laboratory submitted training documents (Ex. BB, Tab 14B) on the revised reagent qualification procedure (CL SOP 07010) in Ex. BB, Tab 14C, which is missing training documentation for one individual. Finally, a change was made to the procedure (CL SOP 07010, Rev. D), which was approved on March 26, 2016. Training for six of the testing personnel was completed prior to March 26, 2016 (training documents show training occurred between February 1 and 4, 2016); therefore, those personnel were not trained on the revised procedure.

D5421

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1

In the second submission, the laboratory states: "The laboratory referred to a 1.5 times %CV in its submission based upon Bio-Rad's coefficient of variation rate. . .Upon further review, the laboratory does not believe that Bio-Rad's coefficient of variation rate is applicable here."

The laboratory provided no further explanation for the inclusion of a "1.5 times %CV" in its first submission to CMS, or why the laboratory believes the Bio-Rad coefficient of variation rate is no longer applicable. This brings into question whether other information provided by the laboratory in its first or second submission to CMS is reliable.

Finding #2

In the second submission, the laboratory states: "The laboratory referred to a 1.5 times %CV in its submission based upon Bio-Rad's coefficient of variation rate. . .Upon further review, the laboratory does not believe that Bio-Rad's coefficient of variation rate is applicable here."

The laboratory provided no further explanation for the inclusion of a "1.5 times %CV" in its first submission to CMS, or why the laboratory believes the Bio-Rad coefficient of variation rate is no longer applicable. This brings into question whether other information provided by the laboratory in its first or second submission to CMS is reliable.

The laboratory states in its February 12, 2016 submission: "Before the lab resumes any test on the Advia XPT, the lab will ensure that the test has been re-verified pursuant to the lab's improved method verification procedures that have been approved by the laboratory director."

The second submission also states that the laboratory stopped running tests on the Advia XPT as of November 17, 2015. Neither the February 12, 2016 submission, nor the April 1, 2016 submission indicates when that laboratory would restart patient testing, therefore, requiring the re-verification as indicated. CMS was unable to determine if the new verification procedure had been effectuated given that the laboratory ceased testing.

While CMS understands that "normal patient distribution" is useful when evaluating, determining, or updating reference ranges (i.e., normal ranges), it is unclear from the laboratory's second submission (General and Ex. AA, Tab 7) how review of the normal patient distribution relates to the accuracy, precision, and reportable range of patient test results. The deficient practice identified by CMS revealed that the laboratory failed to verify the accuracy, precision and reportable range for specific tests performed on the Advia XPT chemistry system.

In response to CMS' March 18, 2016 letter, in the April 1, 2016 portion of the second submission, the laboratory states: "The laboratory has enclosed with this letter documentation supporting the matrix comparisons done by the manufacturer between serum and plasma showed correlation. (Ex. HH, Tab 13)."

Review of the manufacturer information for the tests submitted in Ex. HH, Tab 13 included precision claims for specimen sample types including serum, urine, and cerebral spinal fluid; however, no precision information for plasma samples was included in the submission. The only reference to plasma samples we find is from one of the manufacturer precision documents (alanine transaminase) which includes the following statement with regard to reportable range: "This method is linear from 0-1100 U/L for serum and plasma (lithium heparin)." We also note that no manufacturer information was supplied to support a correlation between serum and plasma

samples, nor did any of the submitted manufacturer documents in Ex. HH, Tab 13 address possible matrix effects.

The laboratory's protocol submitted with the February 12, 2016 submission (Ex. A, Tab 9, §4.2) states: "If the verification is performed by the vendor, the laboratory is involved in all aspects of the verification and the final verification documentation is reviewed and signed off by the Laboratory Director." However, in the second submission, Ex. BB, Tab 5 now states in § 4.1.2 that "the laboratory is responsible for all aspects of the assay verification. . ." This reflects a change in the procedure between the two submissions. The new revision (Rev. C) was approved on March 25, 2016. The training documentation submitted in Ex. BB, Tabs 5 B-C includes documentation for 11 of 12 testing personnel listed on Form CMS-209. However, documentation for eight of the 11 indicated that training occurred prior to the February 12, 2016 submission and the issuance of the new revisions. It is unclear if the eight testing personnel were trained on the change to the method verification procedure found in § 4.1.2.

In its second submission, the laboratory submitted a revised quality assessment mechanism, but submitted no documentation to indicate that the revised quality assessment mechanism had been effectuated. The laboratory simply stated that "the laboratory is capable of ensuring that the deficient practice in D5421 does not recur." It is unclear to CMS how the laboratory can ensure that the deficient practice does not recur when the laboratory has ceased testing.

D5423

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

The laboratory's February 12, 2016 submission states: "Before the lab resumes any test on the Advia XPT, the lab will ensure that the test has been re-verified pursuant to the lab's improved method verification procedures that have been approved by the laboratory director." The April 1, 2016 submission states that the laboratory stopped running patient tests on the Advia XPT as of November 17, 2015. Neither the February 12, 2016 submission nor the April 1, 2016 submission indicates when that laboratory plans to restart patient testing, therefore, requiring the re-verification as indicated. CMS was unable to determine if the new verification procedure had been effectuated as the laboratory ceased testing.

The laboratory provided no further explanation for the inclusion of a "1.5 times %CV" in its first submission to CMS, or why the laboratory believes the Bio-Rad coefficient of variation rate is no longer applicable. This brings into question whether other information provided by the laboratory in its first or second submission to CMS is reliable.

While CMS understands that "normal patient distribution" is useful when evaluating, determining or updating reference ranges (i.e., normal ranges), it is unclear from the laboratory's second submission (General and Ex. AA, Tab 7) how review of the normal patient distribution relates to the accuracy, precision, and reportable range of patient test results. The deficient practice identified by CMS revealed that the laboratory failed to verify the accuracy, precision and reportable range for specific tests performed on the Advia XPT chemistry system.

In the second submission the laboratory states that the alkaline phosphatase (ALP) reportable range should have been 12 - 909 U/L, but provided no documentation reflecting the amended reportable range (e.g., updated procedure) other than page 26 of the letter from the April 1, 2016 submission and Ex. AA, Tab 6. Although training documentation for method verification was included in the submission, it did not include documentation showing that training had occurred related to the amended reportable range for alkaline phosphatase.

Ex. AA, Tab 2 of the second submission asserts in the "Corrective Action" section: "There is no patient impact expected. Therefore, no corrected or voided reports were generated." We note, however, in Ex. AA, Tab 6 in the "Patient Impact" section the following statement: "The laboratory reported some quantitative alkaline phosphatase values outside its verified AMR [analytical measuring range]. Those quantitative values are invalid." In addition, we note in Ex. AA, Tab 6 in the "Corrective Action" section that the laboratory states: "All patient results for alkaline phosphatase reporting less than 12 U/L or greater than 909 U/L have been amended to correct the values to "<12 U/L" and ">909 U/L," respectively. Many corrected reports have been transmitted. . ." This inconsistency brings into question whether any other information provided by the laboratory in its first or second submission to CMS is reliable.

In response to CMS' March 18, 2016 letter, the laboratory's second submission it states: "The laboratory has enclosed with this letter documentation supporting the matrix comparisons done by the manufacturer between serum and plasma showed correlation. (Ex. HH, Tab 13)." Review of the manufacturer information for the tests submitted in Ex. HH, Tab 13 indicated no documentation related to alkaline phosphatase.

In its second submission, the laboratory submitted a revised quality assessment mechanism, but submitted no documentation to indicate that the revised quality assessment mechanism had been effectuated. The laboratory simply stated that "the laboratory is capable of ensuring that the deficient practice in D5421 does not recur." It is unclear to CMS how the laboratory can ensure that the deficient practice does not recur when the laboratory has ceased testing.

D5447

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In the second submission, the laboratory states: "The laboratory referred to a 1.5 times %CV in its response based upon Bio-Rad's coefficient of variation rate. . .Upon further review, the laboratory does not believe that Bio-Rad's coefficient of variation rate is applicable here." The laboratory provided no further explanation for the inclusion of a "1.5 times %CV" in its first submission to CMS, or why the laboratory believes the Bio-Rad coefficient of variation rate is no longer applicable. This brings into question whether other information provided by the laboratory in its first or second submission to CMS is reliable.

D5449

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In its second submission, the laboratory states:

> The laboratory has revised the CT/NG [*Chlamydia trachomatis/Neisseria gonorrhaeae*] SOP [Standard Operating Procedure] to include information about the positive QC materials used, how the statistical parameters of the QC materials would be determined, and how QC test results will be documented. (Ex. BB, Tab 16 § 9.1.5).

We find no information in Ex. BB, Tab 16 § 9.1.5 as the "how the statistical parameters of the QC materials would be determined."

Ex. BB, Tab 16 § 9.1.5 states: "The aliquots will be frozen and each aliquot when thawed will be used for two weeks while being stored at 2°C to 8°C after each run." The laboratory provided no documentation as to how the laboratory determined that thawed aliquots were viable for "two weeks while being stored at 2°C to 8°C."

D5477

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In the second submission, the laboratory states:

> CMS appears to have had difficulty reading the handwriting on the Blood Agar 5% Quality Control Log Sheet, confusing a handwritten "3" with an "8." The "Blood Agar 5% Quality Control Log Sheet" states that the media was received on 1/13/16. . .Therefore, there is no reason to question that accuracy of this entry because the log shows that the media received the day before QC testing of this bacteriology media was completed. For the same reason, the February 11, 2016 review of the completed form was performed correctly, and there is no reason to question the effectiveness of the laboratory's oversight mechanism.

The log sheet from the date in question clearly shows that the media was received on January 18, 2016, and not January 13, 2016 as the laboratory claims, as the log sheet includes the date "1/18/2016" under the heading "Date received." Therefore, there is "reason to question the accuracy of this entry" and "reason to question the effectiveness of the laboratory's oversight mechanism."

D5481

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1

In Ex. AA, Tab 7 of the second submission, the laboratory states that the laboratory had "examined all QC [quality control] data over the entire lifetime of this test offering (10/2014 – 9/2015). . ." (Ex. AA, Tab 7). We note that in the Investigation section at "2," the results of the investigation

only include conclusions from October 2014 through March 2015 which does not include the cited deficient practice from April 2015 through September 2015.

We note in the submission the laboratory states: "The laboratory **stopped** running tests on the BCS XP on September 17, 2015, and has **not** run any tests on the Siemens BCS XP since then." However, documentation given to the surveyor by the laboratory at the time of the onsite survey revealed that the laboratory did, in fact, use the Siemens BCS XP for patient testing after September 17, 2015.

In the laboratory's February 12, 2016 submission, it stated in the Patient Impact Assessment (Ex. I, Tab 1) that "remedial action was taken on 9/25/15," but "corrected reports were issued beginning on 11/10/15 and completed on 11/12/15." In the second submission, the laboratory states that it "undertook a thorough investigation. Given the number of issues to review, the investigation took time to complete properly." Based on the laboratory's February 12, 2016 submission, we assumed the investigation had already been completed which, based on the statement in the second submission, was an incorrect assumption.

We note that the laboratory now states that the "corrective actions were also affected by the absence of a full-time, on-site laboratory director." However, the laboratory director at the time of the onsite survey was still the laboratory director during this period of time, and the new laboratory director did not begin his regulatory responsibilities as the laboratory director until March 11, 2016. There continues to be no acceptable explanation as to why there was such a long period of time between the remedial action and the issuance of corrected reports.

The laboratory again failed to adequately address this deficient practice and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters.

Finding #2

Based on documentation supplied by the laboratory at the time of the onsite survey, the TPS was not used for patient testing after June 25, 2015. However, the laboratory's submission states that the TPS 3.5 was "fully retired in early-August 2015." Patient testing was "retired" later than when the laboratory previously indicated. We note that no explanation was submitted regarding the disparity between the end dates provided at the time of the onsite survey and the second submission. Neither submissions indicates when that laboratory plans to restart patient testing, which would require the laboratory to develop an updated procedure for the TPS. CMS was unable to determine if an updated QC procedure had been effectuated as the laboratory ceased testing.

The following chart outlines the initial use and end use dates of the TPS for patient testing (dates provided by the laboratory at the time of the onsite survey), as well as the range of QC values submitted by the laboratory in Ex. FF, Tabs 1-12.

Test	Initial Use	End Use	QC Data Submitted
Vitamin D	11/6/2013	3/10/2015	3/10/14-3/29/15
TSH	11/7/2013	2/4/2015	3/25/14-2/4/15

FT4	11/11/2013	2/4/2015	3/21/14-2/4/15
TPSA	11/11/2013	6/25/2015	3/21/14-6/16/15
TT3	2/12/2014	2/4/2015	3/15/14-2/3/15
TT4	2/12/2014	2/4/2015	3/15/14-2/4/15
TST	3/19/2014	3/10/2015	4/2/14-3/10/15
HCG	5/9/2014	1/19/2015	5/5/14-1/15/15
SHBG	7/28/2014	6/25/2015	7/30/14-6/9/15
Vitamin B12	8/12/2014	3/6/2015	8/15/14-3/1/15
Estradiol	9/25/2014	12/18/2014	9/26/14-12/17/14
Prolactin	9/25/2014	12/18/2014	9/30/14-12/18/14

It is unclear why the submitted QC records do not cover the entirety of 2014 and 2015 as the submission claims, or why QC information for 2013 was not included in the expanded QC data review. In addition, it is unclear how the laboratory determined in the February 12, 2016 submission that review of QC indicated that a limited number, or no, corrected reports were to be issued but then "voided all patient test results reported from the TPS 3.5 instruments," as stated in its second submission. The voided results provided with the second submission include those from 2014 and 2015; however, the laboratory did not provide any evidence that the QC and patient results from 2013 were reviewed or voided. This brings into question whether other information provided by the laboratory in its first or second submission to CMS is reliable.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters.

D5791

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1

In Ex. BB, Tab 13, § 4.5 of the second submission, the laboratory states that it "has revised this procedure" to clarify that "[i]t is the daily responsibility of the laboratory supervisor to monitor and record the temperatures. . ." We note that the word "designee" was removed from the updated procedure. However, in our March 18, 2016 letter we noted that "the laboratory states that training has occurred, but it was unclear who should be trained as the 'laboratory supervisor or designee' was not defined." We have the same concerns as the "laboratory supervisor" was not defined in the latest submission, and as such, we cannot verify that training has occurred.

The "Temperature-Controlled Storage Setup and Use" procedure submitted in Ex. BB, Tab 13, while signed by the new laboratory director, does not have an effective date as required on the form; however, the approval date is March 24, 2016. The updated procedure (i.e., Revision D) included a change as to who was responsible for monitoring and recording daily temperatures and humidity. It is unclear to CMS whether training occurred prior to March 24, 2016 when the updated procedure was approved. It is also unclear why the training documentation is not consistent for all trainees.

The laboratory's second submission includes the following statements:

- D5413 identifies six -20C freezers and four -80C freezers. In the lab's submission, we explain that five of those freezers did not contain materials that would be used in the future for clinical patient testing. Rather, they only contained material that might be used in the future for research and development.

- Based on the March 18 letter, it appears that there was a miscommunication when the CMS surveyors were onsite. D5413, Paragraph f, states that CMS had a discussion about these freezers with the "Director of Assay Systems and technical supervisor at 11/19/15 at approximately 11 am." The Director of Assays did not have any regular involvement with those freezers at that time and did not have the knowledge of their contents. The "technical supervisor" in attendance on November 19, 2015 joined the company on October 26, 2015; he also did not have regular involvement with those freezers at the time and did not have knowledge of their contents. (Ex. HH, Tab 8). To the extent CMS understood either of these individuals to be confirming the contents of these freezers or whether these freezers were used in clinical patient testing, there was a miscommunication.

Based on these statements, it is unclear whether the laboratory investigated what was in the freezers at the time of the onsite survey and what the freezers had been used for prior to the onsite survey, as the submission only speaks to future use of the freezers. It is also concerning to CMS that the laboratory claims that there was a miscommunication regarding the use of the freezers at the time of the survey. The TS who confirmed the freezer use was not a TS hired by the laboratory on October 26, 2015, but rather an individual identified on personnel documentation as a TS at the time of the onsite survey who had been with the laboratory for several years. The confirmation occurred while the surveyor was touring the laboratory with a group of four to five laboratory employees who, had the confirmation by the Director of Assays and TS been in error, should have communicated the correct information. Regardless, based on the information provided by the laboratory, it is still unclear to CMS if the freezers now identified by the laboratory as not in use for CLIA activities were being used at the time of, or prior to, the onsite survey.

Based on the laboratory's second submission, it is still unclear as to how the article related to mean kinetic temperature (MKT) applies to the deficient practice as it was not incorporated into any procedures or investigations.

It is concerning to CMS how the laboratory's February 12, 2016 submission states that there was no patient impact due to the higher freezer temperatures, yet the April 1, 2016 submission states that this issue "may have had an [effect] on the Immulite controls stored in this freezer. . .based on this review, the laboratory has voided certain test results. (Ex. AA, Tab 4)" (page 48). This contradiction between the submissions brings into question whether any other information provided by the laboratory in its first or second submission to CMS is reliable.

Based on the second submission, it is unclear to CMS what temperature the laboratory is requiring for the storage of bacterial cultures. The laboratory states on page 48 in letter accompanying the

second submission that the "laboratory labels bacterial cultures for storage at -80C or colder only because that allows for the longest period of viability, which is 10 years. (Ex. II, Tab 26). However, bacterial cultures remain viable for 1-3 years when stored at -20C. (Ex. II, Tab 26)." The laboratory did not submit a procedure that stated the acceptable storage temperature for bacterial cultures.

Finding #2:
Based on the laboratory's submissions, CMS understands that the laboratory was using a CV of 20% (25% at the lower and upper limits of detection) for their lab-developed tests (LDTs). The laboratory still has not addressed CVs greater than 20% (25%) cited on the Statement of Deficiencies nor has the laboratory explained why an LDT can be less precise than a predicate device for the same analyte.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters.

Finding #3
The laboratory's second submission states that QC was reviewed for 2014 and 2015 for each assay run on the TPS 3.5 (Ex. AA, Tab 3). The laboratory failed to include 2013 QC information in its review even though four tests were initially put into use in November 2013. Given this missing information, the QC information submitted appears incomplete.

Finding #4
Although the laboratory indicated it has ceased patient specimen testing, no statement has been made by the laboratory that patient specimens are no longer being collected. We are assuming that the laboratory continues to collect patient specimens and send them to another laboratory for testing. Given that the February 12, 2016 submission indicates that the laboratory's QMPI procedure was effective, CMS would expect to see the following documents specified in the laboratory's QMPI protocol as part of the second submission: monthly tracer assessment and QMPI meeting minutes for March and April 2016, and documented corrective actions related to the high number of clotted specimens received by the laboratory. No such documentation was submitted.

D5793
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1
See our review of D5403. For D5437, D5469, and D5779, see our Quality Assessment review under the General Comments.

Finding#4
In the March 28, 2016 submission, the laboratory states:

> The laboratory has reviewed September 2015 Anti-HBs [Hepatitis B surface antibody] QC data under criteria for acceptability that were in effect both prior to and after the September 11 change. (Ex. EE, Tab 4). The laboratory determined that there were no QC results that would have been "acceptable" under the pre-September 11 criteria and unacceptable under the post-September 11 criteria, or vice versa. To determine if these practices were more widespread for Anti-HBs testing, the laboratory examined QC date from 5/2015-9/2015. All QC values falling outside manufacturer's ranges (based on package insert) were noted.

Based on a review of Ex. EE, Tab 4, we note the following:

- On May 2, 2015, the level 2 QC material result was documented as 10.7. The manufacturer's acceptable range for level 2 was 11 - 21.
- On June 8, 2015, the level 2 QC material result was documented as 9.12. The manufacturer's acceptable range for level 2 was 11 - 21.
- On August 15, 2015, the level 3 QC material result was documented as 206. The manufacturer's acceptable range for level 3 was 226 – 340.
- On September 7, 2015, the level 3 QC material result was documented as 190. The manufacturer's acceptable range for level 3 was 226 – 340.
- On September 9, 2015, the level 3 QC material result was documented as 203. The manufacturer's acceptable range for level 3 was 226 – 340.

In Ex. EE, Tab 4, we find no documentation indicating that these QC values, which were outside the manufacturer's ranges, were documented as being unacceptable.

Finding #8

The laboratory's April 1, 2016 portion of its second submission does not address the following statement from CMS' March 18, 2016 letter:

> The laboratory submitted a new quality control (QC) procedure (Ex. A, Tab1) which required in Section 8.2.1.1.a.-c., QC Pass/Fail Criteria, that QC must meet certain criteria as well as ". . .the required Westgard rule pass criteria." Westgard rules include a "10x" rule for rejecting QC when 10 consecutive control measurements fall on one side of the mean. We note that on page 17 of 19 (Ex. A, Tab 6) in the updated protocol that the 10x rule was included as part of the Westgard rules which the lab must follow. The lab provided no documentation that indicated that "10x" rule was evaluated as part of their review.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters.

Finding #9

The laboratory's second submission did not provide any documentation to explain why the laboratory did not follow its AAP protocol for the TPS as cited in the Statement of Deficiencies. In addition, we note that Ex. BB, Tabs 3B-3C contains incomplete training documentation (training records did not consistently include the same documents) and training documentation for

two testing personnel listed on the Form CMS-209, Laboratory Personnel Report (CLIA), was not submitted.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters. Additionally, the laboratory again failed to address and provide acceptable evidence of correction consisting of: what measure has been put in place, what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

Finding #10

In the laboratory's April 1, 2016 submission, Ex. BB, Tab 5, § 8.1.1.1.c states: "If the analyte has a medical decision level, at least 25% of the specimens must have analyte levels below this value and the remaining 25% above. If there are more than one medical decision level, specimen selection are above and below both levels." Although the term "medical decision level" is now defined by the laboratory, we find no documentation to indicate which analytes have a medical decision level, how that medical decision level is determined, and what the distribution of specimens would be if an analyte does not have a medical decision level.

It is continues to be unclear to CMS why medical decision levels were used to measure Vitamin D levels. Clearly, when Vitamin D levels are reported using the medical decision levels (e.g., deficiency, insufficiency, sufficiency, possible toxicity) instead of the reference range a different interpretation of the patient results would be reached. The reference range (9.3 - 47.9 ng/mL) overlaps the deficiency, insufficiency, and sufficiency medical decision levels.

It is unclear to CMS why the laboratory only included a review of QC starting January 1, 2014. The TPS was initially used to measure Vitamin D levels on November 6, 2013, based on documentation given to the surveyor at the time of the onsite survey.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters.

D5801

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In Ex. GG, Tabs 1A-1C of the second submission, the laboratory states that the mean normal prothrombin time (MNPT) is "customer provided" and "established by the laboratory." However, in Ex. AA, Tab 7, the laboratory states that the MNPT is "provided by Siemens analysis of the laboratory's data." Based on these contradictory statements, it is still unclear who establishes the MNPT and how the MNPT is determined. Ex. GG, Tab 1B shows a letter dated October 2015 (after the issue with PT/INR was identified by the surveyor) from Siemens for Innovin (thromboplastin), lot number 539280, which indicated that the laboratory provided Siemens an MNPT of 8.5. We note, however, that at the time of the survey, the MNPT documentation, BCS XP instrument, and staff verified that the MNPT for this lot number was 8.0 as cited on the

Statement of Deficiencies. The second submission indicates a different MNPT. This brings into question whether other information provided by the laboratory in its first or second submission to CMS is reliable. It is unclear to CMS if the laboratory's new QMPI has been effectuated as the above issue with the MNPT has not been recognized by the laboratory.

We also note that in the second submission, the laboratory states it "issued corrected reports voiding PT/INR test results reported for the period of October 2014 through September 2015. (Ex. AA, Tab 7) The laboratory stopped using the BCS XP instrument on September 17, 2015, and has not used it since then." Documentation given to the surveyor by the laboratory at the time of the onsite survey indicated that the laboratory did, in fact, use the BCS XP for patient testing after September 17, 2015.

In its second submission, the laboratory submitted a revised quality assessment mechanism, but submitted no documentation to indicate that the revised quality assessment mechanism has been effectuated. In addition, the laboratory stated that "training on the revised QMPI procedures has occurred. (Ex. BB, Tab 7 B-C)." We note that Ex. BB, Tab 7 B-C contains incomplete training documentation (one of the training records did not include the same documents consistent with the other two records) for only three laboratory personnel, none of whom appear on the laboratory's Form CMS-209, dated February 8, 2016. It is also unclear to CMS if the laboratory's new QMPI will be effective, as the above issue (i.e., disparity of MNPT values for Innovin, lot number 539280) has not been recognized by the laboratory in either submission.

The laboratory again failed to address and provide acceptable evidence of correction consisting of: what measure has been put in place, what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

D5805

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Specifically for PT/INR, the list of accession numbers found in Ex. MM covered a period of time from October 8, 2014 through March 19, 2015. Based on Ex. AA, Tab 7, "the lifetime this test offering" on the Siemens BCS XP was "10/2014-9/2015." Ex. AA, Tab 7 further states: "All PT/INR results have been voided." CMS is unclear why accession numbers of voided PT/INR results were not submitted from March 20, 2015 to September 2015, including those patient specimens tested after September 17, 2015.

D5821

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

The laboratory's February 12, 2016 submission states in the Patient Impact Assessment (Ex. I, Tab 1) that "remedial action was taken on 9/25/15," but "corrected reports were issued beginning on 11/10/15 and completed on 11/12/15." In the second submission, the laboratory states that it "undertook a thorough investigation. Given the number of issues to review, the investigation took

time to complete properly." Based on the February 12, 2016 submission, it appeared that the investigations were already complete making this statement confusing since the statement in the second submission suggests that the laboratory's investigations were ongoing after February 12, 2016. We also note that the laboratory now states that the "corrective actions were also affected by the absence of a full-time, on-site laboratory director." However, the laboratory director at the time of the survey was still the laboratory director during this period of time, and the new laboratory director did not begin his regulatory responsibilities as the laboratory director until March 11, 2016. There continues to be no acceptable explanation as to why there was such a long period of time between the remedial actions being taken and issuing corrected reports.

D6076
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our reviews of D6083, D6085, D6086, D6093, D6094, D6098, and D6102.

D6083
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our reviews of D5413 and D5791.

D6085
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our review of D6115.

D6086
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #2
In the second submission, Ex. BB, Tab 5, § 8.1.1.1.c states: "If the analyte has a medical decision level, at least 25% of the specimens must have analyte levels below this value and the remaining 25% above. If there are more than one medical decision level, specimen selection are above and below both levels." Although the term "medical decision level" is now defined by the laboratory, we find no documentation to indicate which analytes have a medical decision level, how that medical decision level is determined, and what the distribution of specimens would be if an analyte does not have a medical decision level.

Finding #3
In its second submission, the laboratory states:

> Additionally, the CV figures from the manufacturer's package insert are not relevant. . .Under this regulation [42 C.F.R § 493.1253(b)(2)], the precision of an LDT [laboratory

developed test] is established solely by the laboratory. These regulations do **not** require a laboratory to compare the CV it establishes for an LDT – including an LDT that is based on a modification to an FDA-cleared or approved test system – with the %CV of "the predicate device." Likewise, there is nothing in 42 C.F.R. § [493.]1253(b)(1) that requires a laboratory to document why the CV that it has established for an LDT is different from the CV for "a predicate device."

The laboratory references 42 C.F.R § 493.1253(b)(1). However, we believe the laboratory meant to reference 42 C.F.R § 493.1253(b)(2).

It is our understanding that even though the laboratory made modifications to the testing procedures performed using the b4 , the end result of these modifications did not inherently change the manufacturer's testing protocol. Since the end result of the laboratory's modifications compared to the manufacturer's unmodified testing protocol is essentially the same, comparing the %CVs established by the laboratory for its modified protocol to the %CVs established by the manufacturer is reasonable and would establish the precision of the LTDs as required by 42 C.F.R § 493.1253(b)(2). We are unclear as to why the laboratory would not want to establish a test system's precision at least comparable to the precision established by the tests system manufacturer, and why the manufacturer's establish CVs are "not relevant."

Our review of D6086, Finding #3 in our March 18, 2016 notice remains unchanged.

Finding #6

In Ex. GG, Tabs 1A-1C it states that the MNPT is "customer provided" and "established by the laboratory." However, in Ex. AA, Tab 7, the laboratory states that the MNPT is provided by Siemens analysis of the laboratory's data. It is still unclear who establishes the MNPT and how the MNPT is determined. In Ex. GG, Tab 1B, it shows a letter dated October 14, 2015 from Siemens for Innovin (thromboplastin), lot number 539280, which indicated that the laboratory was provided a MNPT of 8.5. We note, however, that at the time of the survey, the MNPT documentation, BCS XP instrument, and staff verified that the MNPT for this lot number was 8.0 as cited on the Statement of Deficiencies. It is still unclear to CMS where the MNPT value of 8.0 or 8.5 for Innovin for lot number 539820 came from, as no documentation other than the letter from Siemens was provided. This brings into question whether other information provided by the laboratory in its first or second submission to CMS is reliable.

We also note in the laboratory's April 1, 2016 and April 17, 2016 portions of its second submission the laboratory states that it "issued corrected reports voiding PT/INR test results reported for the period of October 2014 through September 2015. (Ex. AA, Tab 7). The laboratory stopped using the BCS XP instrument on September 17, 2015, and has not used it since then." Documentation given to the surveyor by the laboratory at the time of the onsite survey indicated that the laboratory did, in fact, use the BCS XP for patient testing after September 17, 2015.

In Ex. BB, Tab 14D of the second submission, the laboratory indicated that training had occurred, via a case study, to specifically address the deficient practice related to expired Innovin (thromboplastin). We note that the Form CMS-209, dated February 8, 2016, listed 12 testing personnel. One of the 12 is no longer working in the clinical laboratory based on the April 1, 2016

portion of the second submission (page 82, footnote 14), so our response is based on the remaining 11 testing personnel. The training documents related to the Innovin (thromboplastin) case study include six of the 11 on the Acknowledgement Form provided by the laboratory in Ex. BB, Tab 14D. We are unable to determine if the other five testing personnel have retrained using the case study. We also note that the laboratory submitted training documents (Ex. BB, Tab 14B) on the revised reagent qualification procedure (CL SOP 07010) in Ex. BB, Tab 14C, which was missing documentation for one individual. We also observed that a change was made to the procedure (CL SOP 07010, Rev. D) which was approved on March 25, 2016. However, training for six of the testing personnel was completed between February 1 and 4, 2016, so they have not been trained on the revised procedure.

Additionally, in its second submission, the laboratory submitted a revised quality assessment mechanism, but submitted no documentation to indicate that the revised quality assessment mechanism had been effectuated. In addition, the laboratory stated that "training on the revised QMPI procedures has occurred. (Ex. BB, Tab 7 B-C)." We note that Ex. BB, Tab 7 B-C contains incomplete training documentation (one of training records did not include the same documents consistent with the other two records) for only three laboratory personnel, none of whom appear on the laboratory's Form CMS-209 dated February 8, 2016. It is also unclear to CMS if the laboratory's new QMPI will be effective as the above issue (i.e., disparity of MNPT values for Innovin lot number 539280) has not been recognized by the laboratory in either submission.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters. In addition, the laboratory again failed to address and provide acceptable evidence of correction consisting of: what measure has been put in place, what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

D6093

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #1

See our review of D5481. For D5469, see our Quality Assessment review under the General Comments.

Finding #2

See our review of D5481.

We note that in the second submission, the laboratory states that it "issued corrected reports voiding PT/INR test results reported for the period of October 2014 through September 2015. (Ex. AA, Tab 7). The laboratory stopped using the BCS XP instrument on September 17, 2015, and has not used it since then." Documentation given to the surveyor by the laboratory at the time of the onsite survey revealed that the laboratory did, in fact, use the BCS XP for patient testing after September 17, 2015.

Additionally, in its second submission, the laboratory submitted a revised quality assessment mechanism, but submitted no documentation to indicate that the revised quality assessment mechanism has been effectuated. In addition, the laboratory stated that "training on the revised QMPI procedures has occurred. (Ex. BB, Tab 7 B-C)." We note that Ex. BB, Tab 7 B-C contains incomplete training documentation (one of training records did not include the same documents consistent with the other two records) for only three laboratory personnel, none of whom appear on the laboratory's Form CMS-209 dated February 8, 2016.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters. The laboratory again failed to address and provide acceptable evidence of correction consisting of: what measure has been put in place, what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

D6094
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Finding #2:
See our reviews of D5413, D5481, D5801, D5805, and D5821.

D6098
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our review of D5805.

D6102
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

Based on the personnel list provided in Ex. HH, Tab 9A, the training documentation in Ex. HH, Tabs 9B and 14-16 is inconsistent or incomplete. This deficiency referred to personnel being untrained or incompletely trained prior to testing and reporting patient results. For CLIA purposes, training and competency are two different requirements.

In the second submission, the laboratory still did not address why personnel were allowed to test patient samples without being fully trained on the TPS and in the venipuncture lab. It is not clear to CMS if training was effective since the laboratory has stated that they have stopped testing and that they were unable to find some training documents (attestations as to training were submitted in lieu of training documentation). We also note that it is unclear if training, in fact, occurred prior to reporting patient test results. Instead, some new documentation has "pending [initials] [date]" indicating that the training is pending, which includes a date prior to or after the survey. When the date reflected on the training documents (Ex. HH, Tabs 9B, 14-16) is prior to the survey, it appears

to have been added to the original documents presented at the onsite survey with no explanation as to why it was added or when training will occur.

The following statements are documented on the Patient Impact Assessment: Training Records (Ex. AA, Tab 12):

- TP6 – "training documents are largely complete"

- TP31 – "informally trained. . .when asked if she [TP31] thought this training was adequate, she stated it was, and that she felt competent to do the work that she was doing"

- The records for TP6 and TP11 show they received training on each instrument they operated even if the records did not comply with all components of the training and competency procedures. In addition, the laboratory's personnel files for TP6 and TP11 contain records of their competency to operate all of the instruments identified in D6102. Because the laboratory documentation reflects that TP6 and TP11 were competent to operate these instruments, there is no potential for patient impact from this deficiency related to TP6 and TP11.

- Instrument training and competency records for TP31 were not contained in her personnel file. However, her attestation that she receiving training and was competent to operate those instruments demonstrate that there is no potential patient impact as a result of this deficiency as it relates to TP31.

We note that in the second submission the laboratory still concedes that it has not provided complete training records. We also note that the attestation from TP31 indicates that she/he felt that she was trained; however, it should be noted that it is the laboratory director's responsibility to make this determination.

It is not clear to CMS how the laboratory can make the assertion that no patient impact or potential impact could have resulted from this deficient practice as the laboratory has voided all patient results from the TPS 3.5 (Ex. AA, Tab 3) and BCS XP (Ex. AA, Tab 7) as well as various results from the Immulite (Ex. AA, Tab 8). In addition, the laboratory's submission from February 12, 2016 indicates that many patient specimens had "corrected reports" issued based on the laboratory's initial review.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters. In addition, the laboratory again failed to address and provide acceptable evidence of correction consisting of: what measure has been put in place, what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

D6108

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our review of D6115.

D6115

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In the April 1, 2016 portion of the second submission on page 84, the laboratory stated that the TPS 3.5 was "fully retired in early-August 2015." However, based on documentation supplied by the laboratory at the time of the onsite survey, the TPS was not used for patient testing after June 25, 2015. We note that no explanation was submitted regarding the disparity between the end date provided at the time of the onsite survey and the end date provided in the second submission. The laboratory's second submission does not provide an explanation for the issues related to corrected results, accuracy, %CV, precision study, reference range, % recovery, and allowable bias.

Although the term "medical decision level" (MDL) is now defined by the laboratory, we find no documentation to indicate which analytes have a medical decision level, how that medical decision level is determined, and what the distribution of specimens would be if an analyte does not have a medical decision level. It is also unclear to CMS if patient results are reported with an MDL, how that will impact the normal and abnormal ranges for a given analyte, especially when the MDL does not overlap with or excludes the normal range.

Since the laboratory ceased patient testing using the TPS 3.5 and voided all patient test results performed using the TPS from 2014 and 2015, CMS was unable to determine if the updated method verification procedure had been effectuated.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters. In addition, the laboratory again failed to address and provide acceptable evidence of correction consisting of: what measure has been put in place, what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

D6124

The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

The "Training and Competency, Revision C" procedure submitted in Ex. BB, Tab 9 has an approval date of March 24, 2016. Revision C includes the competency assessment requirement for direct observation of routine patient testing and performance of instrument maintenance and function checks as well as the six CLIA regulatory procedural requirements set forth at 42 C.F.R. § 493.1451(b)(8). It is unclear as to how training occurred prior to March 24, 2016 when the updated procedure, which included changes to the competency assessment procedure related to

direct observation, was approved. It is also unclear why the training documentation is not consistent for all trainees.

We note that the updated procedure, "Training and Competency, Rev. C," includes the requirement for direct observation (§§ 6.9.4.1 and 6.9.4.4), but the Training and Competency Form (CL FRM-03016-F2) does not reflect this procedural requirement. For the purpose of this review, item "(6)" on the Training and Competency Form would best indicate where the direct observation should be reflected. Review of the submitted training documentation (Ex. BB, Tab 9B) indicated that one of 13 testing personnel had not been trained, and that at "(6)," all training had been by VE (verbal explanation) or RR (record review), not direct observation.

The laboratory's April 1, 2016 portion of the submission states that competency records were included "for the tests [testing personnel] are performing" (page 90), but does not address the incomplete competency records for the instruments the testing personnel were using at the time of, or prior to the onsite survey.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters. In addition, the laboratory again failed to address and provide acceptable evidence of correction consisting of: what measure has been put in place, what systemic changes have been made to ensure the deficient practice does not recur, or how the corrective action is being monitored to ensure the deficient practice does not recur.

D6168
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

See our reviews of D6170 and D6171.

D6170
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In its second submission, the laboratory states:

> The "review" discussed in the submission was simply intended to refer to the analysis conducted to address the deficiency identified by CMS. The issue addressed by the "review" – i.e., failing to document corrective action for QC fails for the Fortessa and Canto – is the same issue identified by CMS in its deficiency, and thus did not constitute a new issue or occurrence.

As in the first submission to CMS, the laboratory again provided no documentation of investigation or corrective action for the "review" in the current submission.

As noted in our March 18, 2016 letter, the laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 letter.

D6171
The laboratory's allegation of compliance is not credible and evidence of correction is not acceptable.

In the second submission, the laboratory states that "the job description for TP14 has been revised to be consistent with the job description of a Clinical Laboratory Associate [CLA] in the laboratory's personnel procedures (Ex. HH, Tab 7B)." We note this job description is essentially unchanged from the laboratory's February 12, 2016 submission and still contains CLIA regulatory responsibilities for testing personnel, and as such TP14 is required to meet the educational requirements. This job description was not signed by TP14. On April 17, 2016, CMS received an additional exhibit, Ex. PP, which states that "the laboratory had revised the job description for clinical laboratory associates and. . .TP14 subsequently executed the new job description form (Ex. PP, Tab 5)." Ex. PP, Tab 5 includes a job description (CL JOB-03027, Rev. A) for CLA's and was signed by TP14 on April 15, 2016. The job description in Ex. PP, Tab 5 is different than the job description submitted in Ex. HH, Tab 7B. We are unclear if the job description submitted in both Exs. HH and PP is specific to TP14 or intended for all CLAs, nor are we clear which job description is currently being used for CLAs.

The laboratory's submission does not provide any additional documentation to show that TP14 is qualified to perform high complexity testing. Based on the information provided to CMS, TP14 remains unqualified to perform high complexity testing. The laboratory's second submission states "that TP14 has not performed any test analyses between November 2015 and his execution of this revised job description (Ex. HH, Tab 7 A);" however, the laboratory still has not addressed any patient impact for testing performed by TP14 prior to November 2015.

The laboratory again failed to adequately address this deficiency and provide acceptable evidence of correction consisting of the required documentation and information as set forth in our January 25, 2016 and March 18, 2016 letters.

Imposed Sanctions

Accordingly, pursuant to 42 C.F.R. §§ 493.1806, 493.1812, 493.1814, and 493.1840(a)(3), **based on the finding of immediate jeopardy and the laboratory's failure to meet all CLIA Condition-level requirements, and based on the failure by the owners and director of the laboratory to comply with certificate requirements and performance standards as evidenced by the deficiencies cited during the CLIA recertification and complaint survey completed on December 23, 2015**, CMS is taking action to impose the following sanctions against the CLIA certificate of Theranos, Inc.:

- 42 C.F.R. §§ 493.1806(b), 493.1840(a)(3), and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate effective **September 5, 2016**. The laboratory has sixty (60) calendar days to appeal the determination to revoke the laboratory's CLIA certificate. If

a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld. *See* 42 C.F.R. 493.1840(e)(1).

- 42 C.F.R. §§ 493.1806(b), 493.1812, 493.1840(a)(3), and 493.1840(d)(2)(i) – Principal Sanction: **Limitation** of the laboratory's CLIA certificate for the specialty of hematology effective **July 15, 2016**, based on the finding of immediate jeopardy. Pursuant to 42 C.F.R. §§ 493.1840(d)(2)(i) and 493.1844(d)(2)(ii), the limitation will take effect regardless of whether a hearing request is filed and will remain in effect until the laboratory's CLIA certificate is revoked.

- 42 C.F.R. §§ 493.1806(c)(3), 493.1810(d), 493.1834, and 493.1844(d)(1) – Alternative Sanction: **Civil Money Penalty (CMP)** in the amount of $10,000 per day for each day of non-compliance effective **July 12, 2016**, and will continue to accrue until it can be verified that all the cited deficiencies have been corrected and the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is limited, whichever occurs first. As the laboratory was advised in our March 18, 2016 letter, if the laboratory requests a hearing, the CMP amount will not be collected until after the hearing decision is rendered. If the laboratory does not request a hearing, CMS may reduce the proposed amount by 35 percent. *See* 42 C.F.R. § 493.1834(e)(2)(iii).

- 42 C.F.R. §§ 493.1806(c)(1), 493.1832, and 493.1844(d)(1) and (g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective **July 12, 2016**. The laboratory is directed to submit to this office within ten (10) calendar days from July 12, 2016, a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services from January 2014 to the present date. CMS may use this list to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of any sanctions imposed against the laboratory's CLIA certificate. An appeal will not delay the due date for this submission or client notification by CMS.

- 42 C.F.R. §§ 493.1804(b), 493.1807(b), 493.1808(b), 493.1826, and 493.1844(d)(1) and (h)(2) – Medicare Alternative Sanction: **Suspension of the laboratory's approval to receive Medicare payments** for any services performed for the specialty of hematology on or after **July 15, 2016**.

  As a consequence of the suspension of the approval to receive Medicare payments for services performed for the specialty of hematology, under Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for all laboratory services performed for the specialty of hematology effective **July 15, 2016**. *See also* 42 C.F.R. § 493.1809.

- 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842, and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory's approval to receive Medicare payments** for all laboratory services effective **September 5, 2016**. This sanction will be effectuated even if the laboratory files a timely appeal.

Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. §§ 440.30(c) and 493.1809, payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for all laboratory services effective **September 5, 2016**. *See* 42 C.F.R. § 440.2(b).

As the laboratory was previously advised, the above sanctions cannot be avoided by the closure of the laboratory, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

Appeal Rights

If Theranos, Inc. does not believe that the determination upon which imposition of the sanction is based is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board (DAB) in accordance with 42 C.F.R. §§ 493.1844 and 498.40 - .78. A request for hearing must be filed **electronically** no later than **sixty (60) calendar days** after the date this letter is received. *See* 42 C.F.R. § 493.1844(f); DAB Civil Remedies Division Procedures (CDRP), § 2(b) (Effective January 1, 2015). You should file your request for an appeal (accompanied by a copy of this letter) via the DAB Electronic Filing System website (DAB E-File) at https://dab.efile.hhs.gov. Should you choose to file an appeal, you are required to e-file your appeal request unless you received a waiver from the DAB. *See* DAB CDRP §§ 2(b) and 6, available at http://www.hhs.gov/dab/divisions/civil/procedures/ divisionprocedures.html. Please note: all documents must be submitted to DAB E-File in Portable Document Format ("pdf").

A hard copy of the hearing request should be sent to:

Karen Fuller, Manager
State Oversight and CLIA Branch
Division of Survey and Certification
Centers for Medicare & Medicaid Services
90 Seventh St., Suite 5-300 (5W)
San Francisco, California 94103-6707

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense.

If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing. *See* 42 C.F.R. § 493.643(d)(2).

As noted above, if a timely request for hearing is filed, i.e., by **September 5, 2016**, CMS will not revoke the CLIA certificate until after an ALJ hearing that upholds the sanction determination. However, cancellation of all Medicare payments is effective **September 5, 2016**, regardless of whether a hearing is requested. *See* 42 C.F.R. § 493.1844(d)(1)-(3) and (h)(1).

When the laboratory's CLIA certificate is revoked, the laboratory will not be permitted to perform any testing, including waived testing and provider performed microscopy procedures, regardless of whether or not the laboratory charges for the testing. Also, pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), the owners and operator(s) (including the laboratory director) are prohibited from owning or operating (or directing) a laboratory for at least two (2) years from the date of the revocation. *See* 42 C.F.R. § 493.2 (defining "operator" and "owner").

In accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper when these actions become effective as referenced above.

If you have any question regarding this notice, please call 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

cc: California Department of Public Health, Laboratory Field Services

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