STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	493.1256(f)(g) CONTROL PROCEDURES (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on review of the prothrombin time/international normalized ratio (PT/INR) procedure, quality control (QC) records, patient results and interview with the general supervisor, the laboratory failed to ensure that the QC for PT/INR was acceptable prior to reporting patient results from April 2015 through September 2015. Findings include: a. CL SOP-10001 Revision A, "Measuring Prothrombin Time-Innovin (PT on the Siemens BCS XP Instrument" stated on page 6, section 8.6 that if control values are outside of the determined range, the controls, reagents and instrument performance should be checked and that identification and correction of the problem shoud be documented prior to reporting patient results. b. QC records for Citrol 3 (Lot number 548425) were reviewed from 4/1/15 through 9/23/15. c. The general supervisor stated that QC was acceptable if the values were +/- 2 SD from the	D5481		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 36 mean. d. On 9/7/15, Citrol 3 was run seven times without obtaining an acceptable QC value. e. On 9/8/15, Citrol 3 was run twelve times without obtaining an acceptable QC value. f. On 25 of 32 days, Citrol 3 was not rerun when the QC value was greater than - 2 SD. g. On 5/15/15, 8/13/15, 8/21/15 and 9/10/15, Citrol 3 was run twice. All QC results were unacceptable. h. The Rule Check report revealed that 13 of 13 QC values in April 2015, 2 of 17 in May 2015, 7 of 7 in June 2015, 13 of 13 in July 2015, 16 of 16 in August, and 24 of 24 during September 1-16, 2015 showed rule violation messages related to Citrol 3. i. 81 patients were reported from 4/1/15 through 9/16/15. 2. Based on review of the quality control (QC) procedure, QC records, and raw data from patient test runs and interview with the general supervisor, the laboratory failed to ensure that the QC was acceptable for the Theranos Proprietary System (TPS) prior to reporting patient test results: Findings include: a. CL SOP-15026 Revision A, "Edison 3.5 Theranos System Daily QC Procedures", stated the following in section 10.1.1: "...For any single Edison instrument, reject QC if either level is greater than 2 SD or if either level falls on the same side of the mean for 10 consecutive days."	D5481		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 37 b. Section 11.1.1 of CL SOP-15026 Revision A further stated that "Daily QC automatically expires 24 hours after use." c. The general supervisor stated that when the QC was unacceptable, the TPS device locked out patient testing for 24 hours or until the QC was acceptable and if the QC was unacceptable another device would be used for testing. d. QC records for Sex Hormone Binding Globulin (SHBG) showed that on Device E001025 QC Level 2's (QC2) 24 hour expiration was on 8/14/14 at 18:54 and was not run again until 8/15/14 at 00:05. Patient data showed that patient Accession #94389 was run on 8/14/14 at 19:09. e. QC records for SHBG showed that on Device E001025 QC Level 1's (QC1) 24 hour expiration was on 8/20/14 at 17:43 and was not run again until 8/21/14 at 17:50. Patient data showed that patient Accession #95403 was run on 8/20/14 at 19:08. f. QC records for SHBG showed that on Device E001036 QC1 was not run again until 11/1/14 at 22:15. Patient data showed that patient Accession #112807 was run on 11/1/14 at 00:02. g. QC records for Vitamin B12 (VB12) showed that on Device E000027 QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48. h. QC records for VB12 showed that on Device	D5481		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 38 E000027 QC1 was run on 8/16/14 at 06:16 and failed. QC1 was next run 8/17/14 at 09:10 and passed. QC2 was not run on 8/15/14 or 8/16/14. Patient data showed that patient Accession #94598 was run on 8/16/14 at 00:48. i. QC records for VB12 showed that on Device E000027 QC2 24 hour expiration was on 8/19/14 at 08:00 and was not run again until 8/20/14 at 21:05. Patient data showed that 3 patients (Accession #s 95411, 95462, 95543) were run on 8/20/14 between 12:33 and 17:52. j. QC records for VB12 showed that on Device E000027 QC2 24 hour expiration was on 8/22/14 at 17:38 and was not run again until 8/23/14 at 21:05. Patient data showed that 2 patients (Accession #s 95984, 96106) were run on 8/22/14 at 18:56 and 21:21. k. QC records for VB12 showed that on Device E000027 QC1's 24 hour expiration was on 8/24/14 at 16:43 and was not run again until 8/25/14 at 07:59. QC2 24 hour expiration was on 8/24/14 at 21:05 and was not run again until 8/25/14 at 12:23. Patient data showed that 3 patients (Accession #s 96327, 96250, 96371) were run on 8/24/14 between 17:15 and 21:36. l. QC records for VB12 showed that on Device E000037 QC1 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 20:29 and again on 2/26/15 at 20:22. QC2 had a "10x warning" message in the QC Pass/Fail Status column on 2/25/15 at 22:11 and again on 2/26/15 at 22:04. QC1 passed on 2/27/15 at 22:54 and QC2 was run and passed on 2/28/15 at 00:27. Patient data showed that 7 patients (Accession #s 146275, 146391, 146651, 146852,	D5481		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 39 147149, 146596, 146898) were run between 2/26/15 and 2/27/15 during the time the laboratory had a 10x warning. m. QC records for VB12 showed that on Device E001000 QC1's 24 hour expiration was on 1/25/15 at 21:58 and was not run again until 1/28/15 at 2140. QC2 24 hour expiration was on 1/26/15 at 02:22 and was not run again until 1/28/15 at 23:19. Patient data showed that 5 patients (Accession #s 136351, 136139,136386, 136897, 135548) were run between 1/27/15 at 1359 and 1/28/15 at 11:50. n. QC records for Vitamin D, 25-OH (VitD) showed that on Device E001059 QC1's 24 hour expiration was on 7/6/14 at 14:11 and was not run again until 7/7/15 at 08:04. Patient data showed that Accession #88699 was run on 7/6/14 at 14:31. o. Levey-Jennings charts revealed that SHBG Device E000026 QC1 had 13 consecutive days and QC2 had 15 consecutive days that the results were at least 2 standard deviations (SDs) below the mean from 9/30/14 through 10/29/14. p. Levey-Jennings charts revealed that SHBG Device E001007 QC1 had 19 consecutive days that the results were at least 2 SDs below the mean from 3/31/15 through 4/29/15. q. Levey-Jennings charts revealed that VitD Device E001059 QC1 had 15 consecutive days that the results were at least 2 SDs above the mean from 6/30/15 through 7/25/14. r. Levey-Jennings charts revealed that Total T3 (TT3) Device E000195 QC1 had 11 consecutive	D5481		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5481	Continued From page 40 days that the results were at least 2 SDs above the mean from 1/3/15 through 1/29/15. s. Levey-Jennings charts revealed that TT3 Device E001032 QC1 had 113 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 7/9/14 through 7/25/14. t. Levey-Jennings charts revealed that VB12 Device E000187 QC1 had 14 consecutive days and QC2 had 12 consecutive days that the results were at least 2 SDs above the mean from 2/10/14 through 2/27/14.	D5481		
D5775 400B	493.1281(a)(c) COMPARISON OF TEST RESULTS (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:	D5775		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5775	Continued From page 41	D5775		

2. Based on review of documentation, the laboratory failed to have a system that twice a year evaluated and defined the relationship between the Theranos Proprietary System (TPS) to a predicate instrument. Findings include:

a. Undated documentation provided by the laboratory revealed a comparison study between the Theranos Proprietary System (TPS) (i.e., Edison) and a predicate device (Immulite, Centaur, or Liaison) for Sex Hormone Binding Globulin (SHBG), Total T3 (TT3), Vitamin D (VitD) and Vitamin B12 (VB12).

b. The method comparison documentation showed that the following devices (i.e., readers) E000026, E001025 and E001036 were used for SHBG comparison testing. SHBG testing occurred from 7/28/14 through 6/25/15.

c. Quality control (QC) monthly reports revealed that seven devices were used for SHBG from February 2015 through June 2015 but only three devices were included in the comparison study.

d. QC and patient result documentation for SHBG also revealed that devices E000040, E001007 and E001035 were used for patient

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5775	Continued From page 42 testing and were not included in the comparison study. e. The method comparison documentation showed that the following devices E000162, E000187, E00195, E001011, E001032, and E001049 were used for TT3 testing. TT3 testing occurred from 2/2/14 through 2/4/15. f. The method comparison documentation showed that the following devices E000053, E000072, E00101, E0001157, E001007, E001043, and E001059 were used for VitD testing. VitD testing occurred from 11/6/13 through 3/10/15. g. Quality control (QC) monthly reports revealed that twelve devices were used for VitD in February 2015 and eighteen devices were used from March 2015 through April 2015 but only seven devices were included in the comparison study. h. QC and patient result documentation for VitD also revealed that device E001059 was used for patient testing and was not included in the comparison study. i. The method comparison documentation showed that the following devices E000053, E000072, E00101, E0001157, E001007, E001043, and E001059 were used for VB12 testing. VB12 testing occurred from 8/12/14 through 3/6/15. j. Quality control (QC) monthly reports revealed that twelve devices were used for VB12 in October 2014 and February 2015 through April 2015 but only eleven devices were included in the	D5775		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5775	Continued From page 43 comparison study.	D5775		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	493.1289(a)(c) ANALYTIC SYSTEMS QUALITY ASSESSMENT (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in	D5791		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	Continued From page 47 §§493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by:	D5791		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791		D5791		

2. Based on review of Quality Control (QC) data and Monthly QC Reports, the laboratory failed to have a quality assessment (QA) procedure to identify and correct problem with the QC values for the Theranos Proprietary System (TPS) when precision did not meet the laboratory's requirement for precision. Findings include:

a. CL PLN-14003 Revision A, "Master Validation Plan for Routine Chemistry Assays on Theranos

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	Continued From page 49 Devices" in section 13.4.5 requires the %CV of replicates to be not more than 15% (20% at the lower and upper limits of detection). b. QC results were reviewed from June 2014 through November 2014 and January through February 2015 for Vitamin B12 (VB12), Vitamin D (VitD), and Sex Hormone Binding Globuin (SHBG) which were used for patient testing on the TPS devices. c. VB12 QC Level 1 and Level 3 (QC1 and QC3) on Device E000110 revealed the following %CV (coefficient of variation): 34.3% and 48.5%, respectively, from 1/5/15 through 1/30/15. d. VB12 QC1 and QC3 on Device E001085 revealed the following %CVs: 52.5% and 35.2%, respectively, from 1/5/15 through 1/30/15. e. VB12 QC1 and QC3 on Device E001102 revealed the following %CVs: 39.0% and 20.0%, respectively, from 2/10/15 through 2/27/15. f. VB12 QC1 and QC3 on Device E001000 revealed the following %CVs: 34.7% and 39.9%, respectively, from 1/2/15 through 1/31/15. g. VB12 QC1 and QC3 on Device E001102 revealed the following %CVs: 39.0% and 20.0%, respectively, from 2/10/15 through 2/27/15. h. VitD QC Level 1 and Level 2 (QC1 and QC2) on Device E000053 revealed the following %CVs: 63.8% and 26.4%, respectively, from 8/21/14 through 8/30/14. i. VitD QC1 and QC2 on Device E001059 revealed the following %CVs: 18.7% and 18.7%,	D5791		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	Continued From page 50 respectively, from 6/29/14 through 7/24/14. j. VitD QC1 and QC2 on Device E001043 revealed the following %CVs: 25.2% and 31.9%, respectively, from 6/29/14 through 7/25/14. k. SHBG QC1 on Device E001026 revealed the following %CV: 18.9% from 9/30/14 through 11/5/14. l. SHBG QC1 on Device E001025 revealed the following %CV: 21.2% from 7/31/14 through 8/28/14. 3. Based on review of Quality Assessment (QA) documentation and QA procedures, the laboratory failed to have a quality assessment (QA) procedure established to identify and correct problems with the Quality Control (QC) program for the Theranos Proprietary System (TPS) . Findings include: a. Monthly QC reports were reviewed for July 2014, October 2014, and February through June 2015. b. All reports were signed by the laboratory director (LD) on 9/19/15, except the March 2015 report was signed by the LD on 11/19/15. c. The total percentage of QC values greater than 2 standard deviations (SDs) was reviewed by the surveyor. d. The July 2014 report indicated in the summary that 2179 controls had been run on the "Edison**" devices; however, the specific report on the "Edison**" device showed that only 1618 were run on all tests and all devices.	D5791		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	Continued From page 51 e. In July 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: Testosterone (TST) (28%), Total T4 (TT4) (21%), VitD (28%). Overall 16% of QC samples on all tests on all devices had values greater than 2 SDs. f. In October 2014, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: Estradiol (EST) (33%), Free T4 (FT4) (19%), Prolactin (PRLN) (47%), SHBG (45%), Thyroid Stimulating Hormone (TSH) (26%), TST (45%), Total T3 (TT3) (32%), TT4 (28%), VitD (19%), VB12 (46%). Overall 29% of QC samples on all tests on all devices had values greater than 2 SDs. g. In February 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: FT4 (26%), SHBG (87%), TT3 (33%), VitD (24%), VB12 (20%). Overall 24% of QC samples on all tests on all devices had values greater than 2 SDs. h. In March 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (42%), TSH (20%). Overall 20% of QC samples on all tests on all devices had values greater than 2 SDs. i. In April 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (16%), total Prostate Specific Antigen	D5791		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	05D2025714	A. BUILDING _____ B. WING _____	11/20/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
THERANOS INC	7333 GATEWAY BLVD NEWARK, CA 94560

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	Continued From page 52 (tPSA) (22%), VB12 (60%). Overall 21% of QC samples on all tests on all devices had values greater than 2 SDs. j. In May 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (34%), tPSA (22%). Overall 26% of QC samples on all tests on all devices had values greater than 2 SDs. k. In June 2015, the data revealed the following tests showed percentage of QC samples with more than 15% of values greater than 2 SD: SHBG (23%). Overall 14% of QC samples on all tests on all devices had values greater than 2 SDs.	D5791		