PRINTED: 01/25/2016 DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED CENTERS FOR MEDICARE & MEDICAID SERVICES OMB NO. 0938-0391 STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER; (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY COMPLETED A. BUILDING \_ 05D2025714 B. WING 11/20/2015 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD THERANOS INC NEWARK, CA 94560 PROVIDER'S PLAN OF CORRECTION SUMMARY STATEMENT OF DEFICIENCIES (X5) COMPLETION ID (X4) ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE DATE TAG TAG DEFICIENCY) 493.841(e) ROUTINE CHEMISTRY D2094 D2094 D2094 2/12/16 The lab has investigated this ungraded (1) For any unsatisfactory analyte or test PT event for ALP and has documented performance or testing event for reasons other than a failure to participate, the laboratory must its investigation and conclusions. undertake appropriate training and employ the technical assistance necessary to correct The new lab director has approved problems associated with a proficiency testing enhanced procedures for proficiency failure. testing, which reinforce the lab's (2) For any unacceptable analyte or testing event systems for the investigation of score, remedial action must be taken and documented, and the documentation must be ungraded PT results. The lab's maintained by the laboratory for two years from technical supervisors will be the date of participation in the proficiency testing responsible for ensuring that these event. procedures are implemented and This STANDARD is not met as evidenced by: followed. Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to The lab will provide oversight through investigate and document the investation of monthly QA meetings by reviewing ungraded alkaline phosphatase (ALP) PT results investigations and corrective action for the 3rd event of 2014. Findings include: for ungraded proficiency tests with outcomes of less than 100%. In The laboratory was enrolled with the College addition, the lab will monitor of American Pathologists (CAP) PT program for ALP for the 3rd event 2014. compliance through its improved occurrence management, and audit b. The CAP results showed that five of five procedures. samples (CHM-06 through CHM-10) were ungraded with a code [20].

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

that an investigation was not done or

e. The QC/QA Manger confirmed on 11/18/15

c. There was no documenation that the ungraded ALP results had been investigated.

 d. The general supervisor stated that the Quality Control/Quality Assurance (QC/QA) Manager was responsible for investigating ungraded PT results.

Kingshuk Das

Digitally signed by Kingshuk Das Date: 2016.02.12 10:18:05 -08'00' TITLE
Lab Director

(X6) DATE 2/12/16

Any deficiency statement ending with an asterisk (\*) denotes a deficiency which the institution may be excused from correcting providing it is determined that of a safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days ling the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

FORM CMS-2567 (02-99) Previous Versions Obsolete \*

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION  A. BUILDING			(X3) DATE SURVEY COMPLETED	
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			7333 GATEWAY BLVD			
(EACH DEFICIENC)	/ MUST BE PRECEDED BY FULL	ID PREFIX TAG	(EACH CORRECTIVE ACTION SHOULD	BE	(X5) COMPLETION DATE	
documented. 493.851(e) HEMAT  (1) For any unsatist performance or test than a failure to part undertake appropri technical assistance	factory analyte or test ting event for reasons other ticipate, the laboratory must ate training and employ the e necessary to correct		D2128 Two out of two challenges for "Cell ID (Educational)" were "No Graded" for the second API every 2014. The lab has investigated to ungraded PT event and documents.	ot nt of his	2/12/16	
than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.  (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.  This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investigation of ungraded blood cell identification PT results and failed to investigate and document the investigation of an unsatisfactory blood cell identification PT result for the 2nd event of 2014. Findings include:  a. The laboratory was enrolled with the American Proficiency Institute (API) PT program for blood cell identification for the 2nd event 2014.  b. The API results showed that two of five samples (BCI-13, BCI-14) were ungraded.			investigation and conclusions.  Four out of five challenges for "Cell Identification" were acceptated for the second API event of 2014 meaning that the PT event received passing grade. The lab has investigated the one unacceptable challenge and documented its investigation and conclusions.  The new lab director has approven thanced procedures for proficion testing, which reinforce the lab's systems for investigation of ung PT results and any challenges the receive an unacceptable grade. The lab's technical supervisors are responsible for ensuring that the procedures are implemented and followed.  The lab will provide oversight the control of the lab will provide oversight the lab will provide o	Blood able 4, ved a le ed ency s raded at The se		
				_		
	SUMMARY STA (EACH DEFICIENCY REGULATORY OR L  4 Continued From pa documented. 4 493.851(e) HEMAT  (1) For any unsatist performance or tes than a failure to par undertake appropri technical assistanc problems associate failure. (2) For any unacce score, remedial act documented, and th maintained by the la the date of participa event. This STANDARD is Based on review or documentation and Supervisor (GS), th investigate and documentation and Supervisor (GS), th investigate investigate investigation of an undertake investigate inves	OF CORRECTION  DENTIFICATION NUMBER:  05D2025714  FOROVIDER OR SUPPLIER  NOS INC  SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 1 documented.  4 493.851(e) HEMATOLOGY  (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.  (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.  This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investigation of ungraded blood cell identification PT results and failed to investigate and document the investigation of an unsatisfactory blood cell identification PT result for the 2nd event of 2014. Findings include:  a. The laboratory was enrolled with the American Proficiency Institute (API) PT program for blood cell identification for the 2nd event 2014.  b. The API results showed that two of five samples (BCI-13, BCI-14) were ungraded.  c. The API results showed that BCI-11 was graded as "unacceptable."	OF CORRECTION  IDENTIFICATION NUMBER:  05D2025714  B. WING  PROVIDER OR SUPPLIER  NOS INC  SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 1 documented. 493.851(e) HEMATOLOGY  (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.  This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documentation and interview with the General Supervisor (GS), the laboratory failed to investigate and document the investigation of ungraded blood cell identification PT results and failed to investigate and document the investigation of ungraded blood cell identification PT result for the 2nd event of 2014. Findings include:  a. The laboratory was enrolled with the American Proficiency Institute (API) PT program for blood cell identification for the 2nd event 2014.  b. The API results showed that two of five samples (BCI-13, BCI-14) were ungraded.  c. The API results showed that BCI-11 was graded as "unacceptable."	OF CORRECTION    DENTIFICATION NUMBER:   DSD2025714   B. WING   STREET ADDRESS, CITY, STATE, ZIP CODE   T333 GATEWAY BLVD   NEWARK, CA 94560   NEW	OF CORRECTION    DENTIFICATION NUMBER:   A BUILDING	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			(X3) DATE SURVEY COMPLETED	
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NAME OF I	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE		
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	0.11.11.1			NEWARK, CA 94560		<u> </u>
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D2128		_	D212	B D2128 (continued)		
	investigated.	tisfactory results had been		for proficiency tests with outcom less than 100% or challenges than		
		pervisor stated that the Quality		ungraded. In addition, the lab w	ill	
		urance (QC/QA) Manager was estigating ungraded PT results.		monitor compliance through its improved occurrence manageme	ent and	
				audit procedures.	iii aiia	
	f.    The QC/QA Ma that an investigatior	nger confirmed on 11/18/15 n was not done or		_		
D5004	documented.	1.007	D.500			
D5024	493.1215 HEMATO	LOGY	D502	D5024		2/12/16
	of Hematology, the requirements speci-	vides services in the specialty laboratory must meet the fied in §§493.1230 through 69, and §§493.1281 through		The laboratory has completed assessments to identify any patie affected or having the potential t affected by the issues identified observation, and has taken correand preventative action. Among	to be in this ctive	<b>2</b> , 12, 10
	Based on the number deficiencies cited had have a procedure in corrective action to counts (CBC) calibrations (See Designations) acceptability (See Designations) controls (See Designations) (See Designat	s not met as evidenced by: ber and severity of the erein, the Condition: but met. The laboratory failed to nanual which included the take when complete blood ration and quality control (QC) et the laboratory's criteria for 15403); document CBC 15403); include two QC ring white blood cell (WBC) of testing (see D5447); verify mmercially assayed CBC 19); ensure QC for PT/INR was reporting patient test results recorrective action policies and ressary to maintain the refor testing patient CBC mer that ensured accurate		things, the lab has hired a new ladirector and established improve quality systems and procedures addressing the issues identified i observation. (D5403, D5437, DD5469, D5481, D5779, D5801).	nb ed n this 5447,	

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714	A. BUILDING  B. WING	E CONSTRUCTION	сом	E SURVEY PLETED 20/2015
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D5024	and reliable patient D5779); have an a assessment mech the effectiveness of processes and taken to resolve prensure that the cal Normalized Ratio (prior to reporting fit 493.1236(c)(1) EV. TESTING PERFORMATION At least twice annuate accuracy of an that is not included This STANDARD Based on review of and interview with laboratory failed to investigation of unitesting (PT) results Findings include:  a. The laboratory testing for troponing Institute (API) for the control of the contr	t test results and reports (see nalytic systems quality anism that included a review of the laboratory's CBC corrective actions oblems (see D5779); and culated International (INR) results were accurate nal patient results (see D5801).  ALUATION OF PROFICIENCY	D5024	2015	to ges. graded  red ency s raded  re hrough ving tion	2/12/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPL A. BUILDING	The state of the s	B) DATE SURVEY COMPLETED
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D5217  D5311  110H 120H 140H 210B 220B 310B 320M 330B 340B 400B 510M	e. The QC/QA I that an investigat documented. 493.1242(a) SPE HANDLING, AND The laboratory m policies and process and specimen sources (4) Specimen stores (5) Conditions for (6) Specimen process and process and process and process and process and process and procedures and	Manger confirmed on 11/18/15 ion was not done or CIMEN SUBMISSION, D'REFERRAL ust establish and follow written edures for each of the following, ration.  Ilection.  In specimen transportation.  In specimen transportation.  Ilection.  Ilection.  Ilection.  In specimen transportation.  In specimen transportation.  Ilection.  In specimen transportation.  Ilection.  Ilection	D5217	D5217 (continued) occurrence management and audit procedures.  D5311 As noted in the findings, it was the practice of the lab to label all patie specimens with lab-generated bar codes issued at the point of collect. Those bar codes and related software properly tracked patient specimens.  The new lab director has approved written policies and procedures addressing patient specimen labeling. The lab's supervisors, quality systedirector, and lab director will be responsible for ensuring that these procedures are implemented and followed.  The lab will provide oversight of accessioning through monthly QA meetings. In addition, the lab will monitor compliance through its improved occurrence management and audit procedures, both of whice address preanalytic activities.	2/12/16 nt ion. are s. ems

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D5391  110H 120H 140H 210B 220B 310B 320M 330B 340B 400B 510M	ASSESSMENT  The laboratory mpolicies and procemechanism to mindicated, correct preanalytic system through 493.1242  This STANDARD  1. Based on lab pre-analytic remes September 23, 2 establish written ongoing mechaniwhen indicated, claboratory's preapatient specimen criteria for acceptant as to why the specimen was relaboratory's criteria sto why the specimen would corrective actions electronically not personnel would corrective actions electronically not captured for qual b. The laboratory on the laboratory of	ust establish and follow written edures for an ongoing onitor, assess, and when problems identified in the ms specified at §§493.1241 2.  is not met as evidenced by:  oratory personnel interviews and edial action record review on 2015, the laboratory failed to policies and procedures for an ism to monitor, assess, and correct problems identified in the nalytic systems when received s did not meet the laboratory's tability. Findings included:  laboratory personnel, during the patient specimens, if a patient ceived that did not meet the ria for acceptability, a description ecimen did not meet the ria for acceptability would be ed, applicable laboratory be notified, appropriate is would be taken and ed, and the incident would be ity assessment review.  Ty maintained no written policies detailing this quality assessment	D5391	D5391 #1 As noted in the findings, if a specimen did not meet the la acceptance criteria, the lab's was to describe the issue in electronic system, to notify lab personnel, and to take, a electronically note, appropricorrective action. Patient sp that did not meet the lab's a criteria were not used for terms as the specimen rejection procedures, which require the lab personnel to further more assess received patient specimen specimen specimen as need procedures also require a surreview and approve daily a requested redraws. The lab conducted training on these procedures.  During monthly QA meeting will review, among other the specimen rejection rates and associated issues. In addition will monitor compliance the improved occurrence manage and audit procedures, both of address preanalytic activities.  The new lab director is respective in the specimen respective in the spec	ab's s practice its relevant and iate ecimens cceptance sting.  proved an he relevant aitor and imens and ed. These pervisor to list of has  gs, the lab ings, any any the lab rough its gement, of which es.	2/12/16

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NAME OF	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
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D5393 110H 120H 140H 210B 310B 310B 330M 330B 400B 510M	patient tests annua  2. Based on labor patient specimen record review on Scilaboratory failed to procedures for an omnitor, assess, ar problems identified systems for patient laboratories for testing to la patient specimens for testing was revireceipt and reporting by the other laboratory and procedures deprocess.  493.1249(b)(c) PRI QUALITY ASSESS  The preanalytic systems with appropriate stadocument all preanalytic systems with appropriate stadocument all preanalsticms assessment activitics.	atory personnel interviews and eferral policies and procedures eptember 23, 2015, the establish written policies and ongoing mechanism to ad when indicated, correct in the laboratory's preanalytic specimens referred to other ing. Findings included:  boratory personnel, a log of referred to other laboratories ewed daily to ensure the timely go of the test results performed tories.  maintained no written policies tailing this quality assessment established the effectiveness of corrective solve problems, revision of lures necessary to prevent ems, and discussion of a quality assessment reviews aff. The laboratory must alytic systems quality	D539	the lab's QA program, and has a appointed a Quality Director wh provide additional oversight.  D5391 #2  As noted in the findings, the lab's practice was to review its log of patient specimens referred to oth labs to ensure the timely receipt reporting of the test results perforby the other labs.  The new lab director has approvenhanced procedures for referral testing, which require, among ot things, the lab to document its reformed tests, including the lab's referral tests, including the lab's	o will  's  ner and ormed  ed her eview log of ner  g the toring hese ded. g of abs ly QA , and	2/12/16	

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D5393 110H 120H 140H 210B 220B 310B 320M 330B 340B 400B 510M	patient specimen record review on Selaboratory failed to procedures for an omnitor, assess, ar problems identified systems for patient laboratories for testing was reviered and reporting by the other laboratory and procedures defined process.  493.1249(b)(c) PREQUALITY ASSESS  The preanalytic systems with appropriate standocument all prean	ratory personnel interviews and eferral policies and procedures eptember 23, 2015, the establish written policies and ongoing mechanism to ad when indicated, correct in the laboratory's preanalytic specimens referred to other ting. Findings included:  boratory personnel, a log of referred to other laboratories ewed daily to ensure the timely go of the test results performed tories.  maintained no written policies tailing this quality assessment  EANALYTIC SYSTEMS  MENT  Stems assessment must the effectiveness of corrective solve problems, revision of lures necessary to prevent ems, and discussion of a quality assessment reviews aff. The laboratory must alytic systems quality	D53	393	(Continued)  D5393  As noted in the findings, the lab' practice was to review its log of patient specimens referred to oth labs to ensure the timely receipt reporting of the test results perfo by other labs.  The new lab director has approve enhanced procedures for referral testing, which require, among other labs.	er and rmed	2/12/16	
OTOW	assessment activities.  This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and patient specimen referral policies and procedures record review on September 23, 2015, the				things, that review of referral tes logs will be documented.			

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NAME OF F	PROVIDER OR SUPPLIER  OS INC			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
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D5393	laboratory failed to document all preanalytic systems quality assessment activities, specifically for patient specimens referred to other laboratories for testing. Findings included:  a. According to laboratory personnel, a log of patient specimens referred to other laboratories for testing was reviewed daily to ensure the timely receipt and reporting of the test results performed by the other laboratories.  b. The laboratory maintained no documentation indicating that the patient specimen referral log was reviewed daily.		D5393 (continued) The lab's management, including lab director and quality systems director, is responsible for over compliance with these procedure. The lab also requires monitoring turnaround times for reference and related issues during month meetings, through regular audit through its improved occurrence management.  D5400 The laboratory has completed		eeing es. of lbs y QA , and	
				assessments to identify any patie affected or having the potential to affected by the issues identified is observation, and has taken correct and preventative action. Among things, the lab has hired a new ladirector and established improve quality systems and procedures addressing the issues identified is observation. (D5403, D5407, D5421, D5423, D5429, D5437, D5447, D5449, D5469, D5477, D5481, D5775, D5779, D5787, D5791, D5793).	o be in this ective other b d	

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D5400	performance spee (see D5421); failed specification who system was mod perform weekly in D5429); failed to calibration (see Equality control may WBC differentials failed to include peach day patient D5449); failed to acceptability of quent hematology and check blood againg growth (see D54 results met the late acceptability for Normalized Ratio presults (see D54 twice per year ever lationship for V (see D5775); failed to documented the patient bacteriological failed to follow quand procedures (monitor the effect and revise policie recurrence of procedures of	the D5413); failed to verify specifications on the Advia XPT and to establish performance on the alkaline phosphatase test iffied (see D5423); failed to maintenance on the Evolis (see document hematology D5437); failed to include two atterials at least once each day as were performed (see D5447); positive quality control materials specimens were assayed (see verify the criteria for uality control materials for chemistry (see D5469); failed to a plates for its ability to support 77); failed to ensure that QC test aboratory's criteria for Prothrombin Time/International	D5400	D5403 #1:	2/12/16	
400M		nanual must include the following to the test procedure:		testing on the Advia 2120i during the survey. The lab has completed an	The second second	

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NAME OF I	PROVIDER OR SUPPLIE		7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560	11/2	20/2015
(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 CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	ILD BE	(X5) COMPLETION DATE
D5403	(1) Requirements specimen collection preservation, trar referral; and crite and rejection as (2) Microscopic edetection of inade (3) Step-by-step including test calc results. (4) Preparation of controls, reagent used in testing. (5) Calibration and procedures. (6) The reportabletest system as es §493.1253. (7) Control proce (8) Corrective act control results fair for acceptability. (9) Limitations in interfering substate (10) Reference in (11) Imminently lippanic or alert valid (12) Pertinent lite (13) The laborate in the patient recoincluding, when a reporting immine panic, or alert valid (14) Description of test system becoming the state of the	is for patient preparation; ion, labeling, storage, isportation, processing, and ria for specimen acceptability described in §493.1242. Examination, including the equately prepared slides. Performance of the procedure, culations and interpretation of slides, solutions, calibrators, is, stains, and other materials and calibration verification are range for test results for the etablished or verified in dures. It to meet the laboratory's criteria the test methodology, including ances. Intervals (normal values). If the etablished in the test methodology, including ances. Intervals (normal values). If the etablished in the test methodology, including ances. Intervals (normal values). If the etablished in the test methodology, including ances. Intervals (normal values). If the etablished in the etablished in the test methodology, including ances. Intervals (normal values). If the etablished in the etabli	D5403	D5403 #1 (continued) assessment to identify any pata affected or having the potentia affected by this issue.  The new lab director has appreenhanced QC procedures that the corrective actions to take v fails to meet the lab's acceptal criteria, and the lab has conductraining on those procedures. lab director has also approved enhanced SOP for CBC on the Siemens Advia 2120i that add the corrective actions to take v calibration or QC fail to meet acceptability criteria  Before the lab resumes any test the Siemens Advia 2120i, it w conduct training on those proced In addition, lab staff will be re to demonstrate competency to that practice is consistent with procedures. In addition, prior resuming any test on this instr the lab will re-verified the test accordance with its improved verification procedures.  Lab management, including the director, technical supervisors quality director, is responsible compliance with these procedures	oved address when QC oility cted The new an eresses when the lab's sts on ill redures. quired ensure these to ument, in method re lab , and for	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION				Co	ATE SURVEY DMPLETED
NAME OF I	PROVIDER OR SUPPLIE		7	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	1/20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R 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
D5403	the laboratory fail that included the calibration or qual the laboratory's concluded:  a. It was the prapatient venous or specimens using instrument.  b. In the laborate Advia 2120i Open was no written probe taken when caresults failed to nacceptability.  c. Between Feb 2015, the laborate patient CB 2120i.  2. Based on reverse procedure for the and documentation the laboratory fail prior to 5/15/2014.  a. CL SOP-150 an effective date  b. A chart provint that	review on November 19, 2015, led to have a procedure manual corrective action to take when ality control results failed to meet riteria for acceptability. Findings actice of the laboratory to test emplete blood counts (CBC) a Siemens Advia 2120i a Siemens Advia C test results using the Advia a siemens Adv	D5403	D5403 #1 (continued) The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures.  D5403 #2 The lab performed QC for the  both before and after May 15, 2014. The lab has complete an assessment to identify any patients affected or having the potential to be affected by this issue.  The new lab director has approved	2/12/16 d
	to 5/15/2014. The	e initial use dates of the from 11/6/2013 through		enhanced QC procedures that address the corrective actions to take when O	

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		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPE DEFICIENCY)	BE	(X5) COMPLETION DATE
D5403	5/9/2014. 493.1251(d) PROC Procedures and chapproved, signed, a laboratory director In This STANDARD in Based on review of with the technical suboratory director of approve procedures include:  a. The current LD b. Eight procedures of prior to putting into signed by the current c. CL SOP-09161 showed an effective not signed by a technical The procedure was approved by any LE d. CL SOP-10001 Prothrombin Time-IBCS XP Instrument 12/5/2014, but was 9/19/2015. The procedure designed by any LE c. CL SOP-06060 Monitor) showed an end approved by any LE	EDURE MANUAL  anges in procedures must be and dated by the current before use. In some the series and interview upervisor, the current (LD) failed to sign, date and its prior to use. Findings  start date was 2/10/2015. In ses were reviewed. Seven of did not include a LD signature use and one of one was not	D54		D5403 #2 (continued) fails to meet the lab's acceptabilic criteria, and the lab has conducte training on those procedures.  Lab management, including tech supervisors, the lab director, and quality director, will be responsifor ensuring compliance with the procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and autoprocedures.	nical the ble ese	

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		05D2025714	B. WING		11/2	20/2015
NAME OF I	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	NTEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE	(X5) COMPLETION DATE
D5407	5/9/2014. 493.1251(d) PROC Procedures and chapproved, signed, a laboratory director This STANDARD i Based on review of with the technical selaboratory director approve procedure include:  a. The current LD b. Eight procedure include:  a. The current LD b. Eight procedure prior to putting into signed by the current c. CL SOP-09161 showed an effective not signed by a technical The procedure was approved by any LI d. CL SOP-10001 Prothrombin Time-BCS XP Instrument 12/5/2014, but was 9/19/2015. The procedure described by any and approved by any e. CL SOP-06060 Monitor) showed an error and approved approved and approved approved and approved and approved and approved and approved approved approved approved and approved a	anges in procedures must be and dated by the current before use. s not met as evidenced by: if procedures and interview upervisor, the current (LD) failed to sign, date and s prior to use. Findings  e start date was 2/10/2015.  es were reviewed. Seven of did not include a LD signature use and one of one was not	D540		hold ew lab te  ed cies e or  ng been r. ent new ures to ved, efore	2/12/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (2		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/20/2015	
THERAN	PROVIDER OR SUPPLIE	R				
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD B CROSS-REFERENCED TO THE APPROPRIA DEFICIENCY)		
D5407	an effective date by the LD until 9/not signed, dated to 9/19/2015.  g. CL PLN-1400 Chemistry Assays an effective date by the LD until 9/not signed, dated to 9/19/2015.  h. Three of three Carbon Dioxide (Phosphatase/CL December 2014. phosphatase propand approved by glucose procedur approved by the 493.1252(b) TES INSTRUMENTS,  The laboratory moditions that ar reagents and spetest system operatives that and, if applicable (1) Water quality. (2) Temperature. (3) Humidity.	Daily QC Procedure) showed of 12/5/2014, but was not signed 19/2015. The procedure was and approved by any LD prior 03, Revision A (Master Validation on ) showed of 11/4/2011, but was not signed 19/2015. The procedure was and approved by any LD prior e procedures for the (Glucose/CL SOP-09118, CO2)/CL SOP-09111, Alkaline SOP-81102) were put into use in The CO2 and alkaline cedures were not signed, dated the LD until 9/19/2015. The re was not signed, dated and LD. T SYSTEMS, EQUIPMENT, REAGENT ust define criteria for those re essential for proper storage of ecimens, accurate and reliable ation, and test result reporting. be consistent with the estructions, if provided. These per monitored and documented include the following:	D5407	QA meetings, and will monitor compliance through its new audit procedures.	or net red. ed il to so fy	

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THERAN	PROVIDER OR SUPPLIE	3		STREET ADDRESS, CITY, STATE, ZIP CO 7333 GATEWAY BLVD NEWARK, CA 94560	DDE		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
D5413	fluctuations and in that adversely affereports. This STANDARD 1. Based on obsithe laboratory failuranges that were manufacturer's instored reference is specimens. Finding a. A tour of the lawere kept showed labeled with the latemperature range.  b. Four of four statemperature range. C. Six of six -20 temperature range.  d. Review of two samples stored in the samples be keen.  e. Review of 3 in samples stored in the samples be keen.  f. The supervisor confirmangeroximately 11 labeled with the aranges did not meaninstructions.	is not met as evidenced by: is not met as evidenced by: is revation and document review, ed to define freezer temperature consistent with the structions for freezers which materials and patient ings include: aboratory where the freezers if that the freezer doors were aboratory's acceptable es.  BO C freezers were marked with inge of -60 to -90 C.  C freezers were marked with a	D5413	D5413 #1 (continued) The new lab director has a enhanced temperature man procedures to reinforce more temperature and environment conditions and storage of according to the manufact temperature range. The lab conducted training on those procedures.  The lab's management, independent of the manufact of the manufact of the manufact of temperature range. The lab conducted training on those procedures.  The lab's management, independent of the manufact of the ma	nagement onitoring of ental materials urer's o has se cluding the ty systems liance with g by making rm their ly. The lab t through d will gh its		

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		05D2025714	B. WING			11/20/2015	
NAME OF F	PROVIDER OR SUPPLIER  OS INC			73	REET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD EWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES 'MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	ĸ	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPE DEFICIENCY)	BE	(X5) COMPLETION DATE
D5413	observation, the late manufacturer instruction in the late manufacturer in the late m	coratory failed to follow the actions for expiration date of astin) used for Prothrombin Normalized Ratio (PT/INR) clude:  thromboplastin) lot number to use by the laboratory at the pervisor stated that the re usually white.  Sert for lot number 539280 cated that the manufacturer al instructions for the specific in.  Pl revealed an "important note" number was only stable for 2 days after reconstitution when to find Innovin reagent was C refrigerator with a 5 day  Revision A, "Measuring." stated on page 10, section age insert for a new lot must or changes before use."  pervisor confirmed on 9/23/15 storage and stability of the dinot been identified from the September 2015.	D54	13	D5413 #2 This PT/INR issue related to one The lab paused testing on the Sie BCS XP, including PT/INR, dur the survey. The lab has complet assessment to identify any patier affected or having the potential traffected by this issue.  The new lab director has approve enhanced reagent qualification a management procedures that rein the lab's practice of ensuring that manufacturer inserts and notificate are reviewed and followed. The has conducted training on those procedures.  Before the lab resumes PT/INR testing, the lab will reinforce with relevant testing personnel the importance of reviewing and following instructions on manufacturer inserts and notificational including instructions concerning expiration dates. The same type training will occur for personnel conducting other tests. These trainings, along with competency testing, will ensure that practice consistent with these procedures.	emens ing ed an its o be  ed ind inforce it intions lab  h	2/12/16
D5421	493.1253(b)(1) EST VERIFICATION OF	FABLISHMENT AND PERFORMANCE	D54	_	lab director, technical supervisor		

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			7	333 GATEWAY BLVD		
(EACH DEFICIENCY	/ MUST BE PRECEDED BY FULL			(EACH CORRECTIVE ACTION SHOULD	BE	(X5) COMPLETION DATE
observation, the late manufacturer instruction of the late manufacturer instruction of the late of the	coratory failed to follow the actions for expiration date of astin) used for Prothrombin Normalized Ratio (PT/INR) clude:  chromboplastin) lot number to use by the laboratory at the ere usually white.  pervisor stated that the ere usually white.  Insert for lot number 539280 cated that the manufacturer al instructions for the specific rin.  PI revealed an "important note" number was only stable for 2 days after reconstitution when  I of Innovin reagent was a C refrigerator with a 5 day  Revision A, "Measuring ." stated on page 10, section age insert for a new lot must by changes before use."  pervisor confirmed on 9/23/15 storage and stability of the dinot been identified from the September 2015.			ensuring that these procedures at followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved	re l	
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	Continued From particles of the string of th	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 14 observation, the laboratory failed to follow the manufacturer instructions for expiration date of Innovin (thromboplastin) used for Prothrombin Time/International Normalized Ratio (PT/INR) testing. Findings include:  a. Dade Innovin (thromboplastin) lot number 539280 was put into use by the laboratory at the end of March 2015.  b. The general supervisor stated that the package inserts were usually white.  c. The package insert for lot number 539280 was pink which indicated that the manufacturer had included special instructions for the specific lot number of Innovin.  d. Review of the PI revealed an "important note" that this specific lot number was only stable for 2 days instead of 10 days after reconstitution when stored at 2-8 C.  e. The current vial of Innovin reagent was observed in the 2-8 C refrigerator with a 5 day expiration date.  f. CL SOP-10001 Revision A, "Measuring Prothrombin Time" stated on page 10, section 12.1 that "the package insert for a new lot must be reviewed for any changes before use."  g. The general supervisor confirmed on 9/23/15 that the change in storage and stability of the Innovin reagent had not been identified from March 2015 through September 2015.	PROVIDER OR SUPPLIER  OS INC  SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 14  observation, the laboratory failed to follow the manufacturer instructions for expiration date of Innovin (thromboplastin) used for Prothrombin Time/International Normalized Ratio (PT/INR) testing. Findings include:  a. Dade Innovin (thromboplastin) lot number 539280 was put into use by the laboratory at the end of March 2015.  b. 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The general supervisor confirmed on 9/23/15 that the change in storage and stability of the Innovin reagent had not been identified from March 2015 through September 2015. 493.1253(b)(1) ESTABLISHMENT AND	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 14 observation, the laboratory failed to follow the manufacturer instructions for expiration date of Innovin (thromboplastin) used for Prothrombin Time/International Normalized Ratio (PT/INR) testing. Findings include:  a. Dade Innovin (thromboplastin) lot number 539280 was put into use by the laboratory at the end of March 2015.  b. The general supervisor stated that the package inserts were usually white.  c. The package insert for lot number 539280 was pink which indicated that the manufacturer had included special instructions for the specific lot number of Innovin.  d. 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Introduced special instructions for the specific lot number of Innovin and Induced special instructions for the specific lot number of Innovin inspecial instructions for the specific lot number of Innovin.  d. Review of the PI revealed an "important note" that this specific lot number was only stable for 2 days instead of 10 days after reconstitution when stored at 2-8 C.  e. The current vial of Innovin reagent was observed in the 2-8 C refrigerator with a 5 day expiration date.  f. CL SOP-10001 Revision A, "Measuring Prothrombin Time" stated on page 10, section 12.1 that "the package insert for a new lot must be reviewed for any changes before use."  g. The general supervisor confirmed on 9/23/16 that the change in storage and stability of the Innovin reagent had not been identified from March 2015 through September 2015.  D5413  D	PROVIDER OR SUPPLIER  OSTINC  STREET ADDRESS, CITY, STATE, ZIP CODE  TAGGED A STATEM, SIT OF CORRECTION  PROVIDER OF A STATEM, STATE, ZIP CODE  TAGGED A STATEM, STATEM, STATEM, STATE, ZIP CODE  TAGGED A STATEM, S

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NAME OF	PROVIDER OR SUPPLIE	R	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COI (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
D5421	FDA-cleared or a following before r (1)(i) Demonstrat specifications con the manufacturer characteristics: (1)(i)(A) Accuracy (1)(i)(B) Precision (1)(i)(C) Reportatest system. (1)(ii) Verify that tintervals (normal laboratory's patie This STANDARD 1. Based on revisite system with the technical supervision with the technical supervision maintain any doc had participated if the performance Findings include:  a. The general supervisor stated performed all of twerification activition.  b. They further were available to and gathering parmanufacturer reporting that the manufacturer had manufacturer h	hat introduces an unmodified, pproved test system must do the eporting patient test results: e that it can obtain performance mparable to those established by for the following performance.  I. ble range of test results for the he manufacturer's reference values) are appropriate for the	D5421	D5421 #1: The lab proactively pause the Advia XPT during the The lab has completed an to identify any patients af having the potential to be this issue.  Before the lab resumes an Advia XPT, the lab will e the test has been re-verification procedures the approved by the new lab of These improved procedure that the lab's testing person required to actively partice method verification and detheir participation.  Before any verification steperformed, these improved require the lab director's approval of a detailed metverification plan containing acceptance criteria. The lab must also review and approverification report before testing begins.  The lab has conducted trathese procedures to ensure practice is consistent with	assessment fected or affected or affected by a sy test on the nsure that ed pursuant hod at have been director. The reinforce onnel are ipate in ocument and procedures review and thod and defined ab director rove the any patient iming on e that	2/12/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPL A. BUILDING	E CONSTRUCTION		E SURVEY PLETED	
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NAME OF	PROVIDER OR SUPPLIE	R	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560				
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO THI DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE	
D5421	Each laboratory to FDA-cleared or a following before recommended in the manufacturer characteristics:  (1)(i)(A) Accuracy (1)(i)(B) Precision (1)(i)(C) Reportation test system.  (1)(ii) Verify that to intervals (normal laboratory's patient This STANDARD 1. Based on revision specification verification verification and participated in the performance Findings include:  a. The general supervisor stated performed all of the verification activity b. They further were available to and gathering parmanufacturer reporting that the performance forms and gathering parmanufacturer reporting that the performed all of the verification.	hat introduces an unmodified, pproved test system must do the eporting patient test results: e that it can obtain performance mparable to those established by for the following performance //.  I. ble range of test results for the he manufacturer's reference values) are appropriate for the	D5421	D5421 #1 (continued) Lab management, included lab director, technical sugguality systems director, for ensuring compliance procedures. The lab will oversight through month meetings, and will monit compliance through its in occurrence management procedures.	pervisors, and is responsible with these provide ly QA or nproved	2/12/16	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		` ′	TIPLE CONSTRUCTION  NG		(X3) DATE SURVEY COMPLETED	
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NAME OF I	PROVIDER OR SUPPLIER  OS INC			STREET ADDRESS, CITY, STATE, ZIF 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES 'MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIVE CROSS-REFERENCED TO THE DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE
D5421	2. Based on revieverification docume general supervisor laboratory failed to and/or reportable rapolipoprotein, trigliglucose. In addition the reference intervidioxide. Findings in a. CL QOP-00022 Revision A", effectiv V.B.1.a. in order to 20 samples of various compared between methodif a secon onsite, compare 20 method used by a compared between method used by a compared determine was acceptable.  b. CL QOP-00022 Revision A", effectiv V.B.1.b. that "a repidetermine precision stated that "at least reactivity's are rundompared. Duplicated days or by different procedure also requiprecision for acception.", effectiv V.B.1.c. that the results of the compared of t	w of verification procedures, entation and interivew with and technical supervisor, the verify accuracy, precision, ange for calcium, albumin, yceride, carbon dioxide, and n, the laboratory failed to verify ral (normal range) for carbon clude:  2, "Verification of Procedures of 8/12/14, stated in Section determine accuracy "at least ous reactivity's should be the method and the old different laboratory." The red that the validation plan of that the validation plan of the procedures of accuracy is accuracy is accuracy in the procedure further and the percentage of accuracy is a samples of various are runs may be on different microbiologists" The cuired that the percentage of tability must be determined.  2, "Verification of Procedures of the that the percentage of tability must be determined.  2, "Verification of Procedures of tability must be determined.  2, "Verification of Procedures of tability must be determined.  2, "Verification of Procedures of tability must be determined.  2, "Verification of Procedures of tability must be determined.	D542	D5421 #2 The lab proactively paus the Advia XPT during the The lab has completed at to identify any patients a having the potential to be this issue.  Before the lab resumes a Advia XPT, the lab will the test has been re-verification procedures approved by the new lab These enhanced procedures approved by the new lab These enhanced procedures approved that must be foll accuracy, precision, repeand reference intervals be put into use.  Before any verification performed, these improved in the lab director's approval of a detailed moverification plan contain acceptance criteria. The must also review and approved begins.  The lab has conducted the lab director's approved by the new lab director's approval of a detailed moverification plan contain acceptance criteria. The must also review and approved begins.	the survey. In assessment affected or be affected or be affected by any test on the ensure that fied pursuant ethod that have been to director. It is reinforce acceptance to owed to verify ortable range, before a test is estudies are reved procedures as review and the thod aning defined lab director oprove the enany patient.	2/12/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		PLE CONSTRUCTION  G		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING _		11	11/20/2015	
54,000	PROVIDER OR SUPPLIE	R	STREET ADDRESS, CITY, STATE, ZIP CO 7333 GATEWAY BLVD NEWARK, CA 94560				
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
D5421	d. CL QOP-000 Revision A," effect V.B.1.d. required approved by the latesting begins."  e. The general supervisor stated use 12/18/14.  Calcium  i. Standard Op- SOP-09107, "Cal- plasma or urine of indicate serum and plasm  ii. The manufact of performance serum and plasm  iii. The manufact of performance serum and plasm  iii. The accuracy ranged from 4.58  iv. The accuracy across the entire  v. The accuracy across the entire  v. The accuracy across the entire  v. The accuracy acceptable perceived.	22, "Verification of Procedures ative 8/12/14, stated in Section that the validation plan be aboratory director "before supervisor and techincal that the Advia XPT was put into that the Advia XPT was put into erating Procedure (SOP) CL cium (CA, CA_2) in serum, on the difference of the control of the cont	D542	D5421 #2 (continued) these procedures to ensure practice is consistent with the laboratory's manage including the new lab distection and the supervisors, and systems director, is respensuring compliance with procedures. The lab will oversight through month meetings, and will monit compliance through its in occurrence management procedures.	th them.  ement, rector, ad quality onsible for th these provide aly QA tor mproved		

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION  A. BUILDING  B. WING		ONSTRUCTION	(X3) DATE SURVEY COMPLETED	
NAME OF	PROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560				20/2013
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG		PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	JLD BE	(X5) COMPLETION DATE
D5421	ix. The precision precision and did run-to-run, or diffex. The summary showed that the recalcium was 0.5-1 the calcium SOP.  xi. The reportable samples from 1.0-the entire reportable samples from 1.0-the entire reportable serum or plasmal indicated that the plasma samples we ffective 7/31/15.  ii. The manufact of performance speciplasma samples.  iii. The accuracy ranged from 2.0-4	study did not include samples eportable range.  study only included within run not include day-to-day, rent operators.  report from the manufacturer eportable range for serum 6.0 mg/dL which differed from e range data showed included 13.4 mg/dL which did not cover alle range stated in the SOP.  rating Procedure (SOP) CL ion A, "Albumin BCP (ALP) in reportable range for serum and vas 0.6-8.0 g/dL. The SOP was curer performed the verification recifications for serum on vas no documentation that the ifications had been verified for study included samples which 4 g/dL.  study did not include samples	D543	21 (0	Continued; see above)		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		(X2) MULTIP A. BUILDING B. WING			(X3) DATE SURVEY COMPLETED	
NAME OF I	PROVIDER OR SUPPLIER		1 8	STREET ADDRESS, CITY, STATE, ZIP CO 2333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF CORF (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AID DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE
D5421	v. The accuracy comparison study procedure. vi. The accuracy acceptable percervii. The precision ranged from 0.5-5 viii. The precision across the entire vix. The SOP states ample 2 times peleast 20 days. x. The precision and did runs per day, for a xi. The summary showed that the realbumin was 0.8-8 SOP. xii. The reportable samples from 0.4 the entire reportable serum or plasmathat the reportable samples was 15-(stated that the reference of the stated that t	study did not include a as required by the laboratory's study did not indicate an intage for accuracy.  study included samples which i.5 g/dL.  study did not include samples reportable range.  ed that for precision each er run, 2 runs per day, for at study only included within run not include 2 times per run, 2	D5421	(Continued; see above)		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIP A. BUILDING B. WING	LE CONSTRUCTION	COM	(X3) DATE SURVEY COMPLETED	
NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP C 7333 GATEWAY BLVD NEWARK, CA 94560		20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
D5421	ii. of performance sy 11/6/14. There we performance special plasma samples.  iii. The accuracy ranged from 88.6 iv. The accuracy across the entire v. The accuracy comparison study procedure.  vi. The accuracy acceptable perceivii. The precision ranged from 100. viii. The precision ranged from 100. viii. The precision across the entire ix. The precision and did run-to-run, or differ x. The summary showed that the restriction of	performed the verification pecifications for serum on as no documentation that the cifications had been verified for a study included samples which 412.0mg/dL.  I study did not include samples reportable range.  I study did not include a required by the laboratory's study did not indicate an intage for accuracy.  I study included samples which 9-314.7 mg/dL.  I study did not include samples reportable range.  I study did not include samples reportable range.  I study did not include samples reportable range.  I study only included within run not include day-to-day,	D5421	(Continued; see above)			

PRINTED: 01/25/2016 FORM APPROVED OMB NO. 0938-0391

	TOF DEFICIENCIES OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  (X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED			
		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER			73	REET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD EWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL .SC IDENTIFYING INFORMATION)	ID PREFI TAG	x	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE	(X5) COMPLETION DATE
D5421	reportable range we manufacturer sum interval (normal rational rat	mary report showed that the ras 0-500 mg/dL. The mary report revealed reference nge) was 0-300 mg/dL.  study included samples which 259 mg/dL.  study did not include samples eportable range.  tudy did not include a as required by the laboratory's study did not indicate an tage for accuracy.  study included samples which 237.3 mg/dL.  study did not include samples eportable range.  study did not include samples eportable range.	D54	21	(Continued; see above)		

FORM CMS-2567(02-99) Previous Versions Obsolete

Event ID: W34211

Facility ID: CA22046272

If continuation sheet Page 22 of 121

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPI A. BUILDING	E CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11	20/2015	
NAME OF	PROVIDER OR SUPPLIE	R	7	STREET ADDRESS, CITY, STATE, ZIP CO 2333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
D5421	plasma, urine or indicate serum and plasma.  ii. The manufact of performance is 10/23/14. There performance spendisma samples.  iii. The accuracy ranged from 47.2 iv. The accuracy across the entire v. The accuracy comparison study procedure.  vi. The accuracy acceptable perceivi. The precision ranged from 57.9 viii. The precision across the entire ix. The precision and did runs per day, for x. The reportables amples from 10	sion A, "Glucose in serum, CSF on the ed that the reportable range for a samples was 4-700 mg/dL. Sturer performed the verification pecifications for serum on was no documentation that the cifications had been verified for study included samples which -384.0 mg/dL.  If study did not include samples reportable range.  If study did not include a y as required by the laboratory's study did not indicate an intage for accuracy.  In study did not include samples which 1-356.2 mg/dL.  In study did not include samples reportable range.  In study did not include samples reportable range.  In study only included within run not include 2 times per run, 2	D5421	(Continued; see above)			

	T OF DEFICIENCIES DE CORRECTION				CO	TE SURVEY MPLETED
NAME OF	PROVIDER OR SUPPLIE		- 40	STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTIO CROSS-REFERENCED TO THE DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE
D5421	sop-09111 Revison the the reportable rar 40 mEq/L.  ii. The manufact of performance s 10/23/14. There performance speplasma samples.  iii. The accuracy ranged from 12.9  iv. The accuracy across the entire  v. The accuracy comparison study procedure.  vi. The accuracy acceptable percevii. The precision ranged from 14.3  viii. The precision ranged from 14.3  viii. The precision across the entirevix. The precision and did runs per day, for x. The manufactors.	erating Procedure (SOP) CL sion B, "CO2 in serum or plasma indicated that age for serum or plasma was 10-cturer performed the verification pecifications for serum on was no documentation that the cifications had been verified for y study included samples which 1-34.3 mEq/L.  If y study did not include samples reportable range.  If y study did not include a y as required by the laboratory's y study did not indicate an entage for accuracy.  In study included samples which 1-23.0 mEq/L.  In study did not include samples reportable range.  In study did not include samples reportable range.  In study only included within run not include 2 times per run, 2	D542	(Continued; see above)		

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTI A. BUILDIN B. WING	PLE CONSTRUCTION  G	СОМ	E SURVEY PLETED 20/2015
NAME OF F	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP CO 7333 GATEWAY BLVD NEWARK, CA 94560		20/2010
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
D5423	xii. The laborator verification study began on 12/18/1493.1253(b)(2) EVERIFICATION Control of the provided standardized met procedures), or uperformance specific manufacturer test results, estable performance characteristics (2)(ii) Accuracy. (2)(iii) Precision. (2)(iii) Analytical substances. (2)(v) Reportable system. (2)(vi) Reference (2)(vii) Any other required for test particular	cumentation verifying the was presented to the surveyor. The veryor of the continuous presented to the surveyor. The veryor of the continuous presented to the surveyor. The veryor of the continuous presented or stem, or introduces a test system. The continuous presented or stem, or introduces a test system. The continuous presented to t	D542	D5422	survey. assessment ected or affected by  y test on that sure that the arsuant to a that have been irector. The explanation of the properties of the explanation of th	2/12/16

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	A. BUILDING  B. WING	LE CONSTRUCTION		SURVEY LETED
NAME OF I	PROVIDER OR SUPPLIER		1	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPR DEFICIENCY)	ULD BE	(X5) COMPLETION DATE
D5423	a. Standard Oper SOP-09102 Revisi (ALP) in serum or indicated serum and plasma b. The reportable range w SOP was incorrect of performance spot 10/23/14. There w performance speciplasma samples.  d. The accuracy ranged from 23.70 e. The accuracy ranged from 23.70 e. The accuracy across the entire ref. The accuracy across the entire ref. The accuracy acceptable percent.  g. The accuracy acceptable percent.  h. The precision ranged from 30.9-3 i. The precision across the entire references the entire refe	rating Procedure (SOP) CL on B, "Alkaline Phosphatase plasma on the I that the reportable range for samples was 0-1100 IU/L.  stated that the ras 10-1100 IU/L and that the ras 10-1100 IU/L and that the ras 10-1100 IU/L and that the ras no documentation that the fications had been verified for study included samples which as required by the laboratory's study did not include a required by the laboratory's study included samples which rating for accuracy.  study did not indicate an tage for accuracy.	D5423	D5423 (continued) require the lab director's revie approval of a detailed method verification plan containing dacceptance criteria. The lab dimust also review and approve verification report before any testing begins.  The lab has conducted training these procedures to ensure the practice is consistent with the them. The lab's management, including new lab director, technical supervisors, and quality system director, is responsible for ensure the lab will provide oversight monthly QA meetings, and will monitor compliance through it improved occurrence manage audit procedures.	efined irector the patient g on at m. ding the ms suring ures. t through till	

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		A. BUILDIN	PLE CONSTRUCTION  3	(X3) DATE SURVEY COMPLETED		
NAME OF I	PROVIDER OR SUPPLIE		B. WING	STREET ADDRESS, CITY, STATE, ZIP CODE	11/3	20/2015
THERAN				7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	DBE	(X5) COMPLETION DATE
D5429 220M	precision, but did run-to-run, or differ k. The summary showed that the run was 0-1100 IU/L.  I. The reportable samples from 12-entire reportable in m. The sensitivity and an established 493.1254(a)(1) M CHECKS  For unmodified minstruments, or teperform and docuby the manufacture frequency specific This STANDARD Based on technic Evolis maintenant November 17, 20 perform weekly Ethe manufacturer a. In general imit the laboratory to to quantiferon using b. In August 201 weeks in which pathe laboratory maintenant or the laboratory main	not include day-to-day, erent operators.  report from the manufacturer eportable range for serum ALP e range data showed included 914 IU/L which did not cover the	D542	D5429	or ed by 7, lis has rector ares nce, ns for l has ce is v lab and or	2/12/16

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A BUILDIN	(X2) MULTIPLE CONSTRUCTION A BUILDING  B. WING		SURVEY PLETED
NAME OF I	PROVIDER OR SUPPLIE		D, 11,110_	STREET ADDRESS, CITY, STATE, 7333 GATEWAY BLVD NEWARK, CA 94560		20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN O (EACH CORRECTIVE AC CROSS-REFERENCED TO DEFICIEN	CTION SHOULD BE THE APPROPRIATE	(X5) COMPLETION DATE
D5429 D5437	reported patient patient the Evolis system	5, the laboratory performed and ent HIV Ag/Ab test results using	D542	oversight of required through monthly QA will monitor complian	maintenance meetings, and ace through its	
400M	each applicable to perform and docu (1) Following the instructions, using or specified, and recommended by (2) Using the crite laboratory as spe (2)(i) Using calibration the test system as reference method value; and (2)(ii) Including the concentration of cacceptable limits calibration; and (3) Whenever cal	specified in this subpart, for est system the laboratory must ament calibration procedures-manufacturer's test system g calibration materials provided with at least the frequency the manufacturer; eria verified or established by the cified in §493.1253(b)(3)ation materials appropriate for and, if possible, traceable to a difference material of known enumber, type, and calibration materials, as well as for and the frequency of ibration verification fails to meet occeptable limits for calibration				
	Based on lab complete blood of documentation re 2015, the laborate instrument calibra	is not met as evidenced by: oratory personnel interviews and ounts (CBC) calibration cord reviews on September 23, ory failed to document all CBC ations performed using the indings included:		(D5437#1 begins on r	next page)	
	a. It was the pra	actice of the laboratory to test				

STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED			
		05D2025714	B. WING _		11/	20/2015	
THERAN	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D5429 D5437 400M	c. In August 201 reported patie the Evolis system. 493.1255(a) CALII VERIFICATION  Unless otherwise each applicable te perform and docur (1) Following the r instructions, using or specified, and v recommended by (2) Using the crite laboratory as spec (2)(i) Using calibra the test system an reference method value; and (2)(ii) Including the concentration of cacceptable limits f calibration; and (3) Whenever calif the laboratory's ac verification.  This STANDARD 1. Based on laboratory	5, the laboratory performed and ent HIV Ag/Ab test results using BRATION AND CALIBRATION specified in this subpart, for st system the laboratory must ment calibration procedures-nanufacturer's test system calibration materials provided with at least the frequency	D542		oved ag g that at be alab has ice and the sused t. we lab and for are	2/12/16	
	documentation red 2015, the laborato instrument calibra Fir	cord reviews on September 23, by failed to document all CBC tions performed using the addings included:					

AND PLAN OF CORRECTION IDENTIFICAT		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A, BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/20/2015	
THERAN	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
D5437	information record the was and information re that the 2015.  b. The laboratory of the August 24, 2 calibrations of the instruments.  c. According to la August 24, 2015 a laboratory perform CBC specimens uninstruments.  2. Based on laboratory perform CBC specimens uninstrument calibrate 2015, the laboratory instrument calibrate 2120i instrument.  a. It was the practical instrument.  a. It was the practical instrument.  b. For Advia 212 in documentation September 21, 20 laboratory maintain calibrations performance.	aboratory designated as On September 23, 2015, ed on "Drew #2" indicated that calibrated on August 24, 2015, corded on september 23, 2015, indicated was calibrated on August 31, 2015 and August 31, 2015 laboratory's two CBC aboratory's two CBC aboratory personnel, between and September 23, 2015, the ed and reported patient sing the two sord reviews on November 19, ry failed to document all CBC ions performed using a Advia Findings included:  Stice of the laboratory to test C specimens using two 20i instruments, designated as 20 #1, the laboratory maintained of any calibrations prior to 15. For Advia 21201 #2, the ned no documentation of any	D543	D5437 #1 (continued) oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and audit procedures.  D5437 #2 The laboratory proactively paused testing on the Advia 2120i during th survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The new lab director has approved enhanced procedures addressing equipment systems, reinforcing that calibration documentation must be organized and maintained. The lab h conducted training on those procedures.		

AND PLAN OF CORRECTION IDENTIFICATION NUMBER:		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIF A. BUILDING	PLE CONSTRUCTION  G		E SURVEY PLETED	
		05D2025714	B. WING			11/20/2015	
NAME OF S	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPR DEFICIENCY)	ULD BE	(X5) COMPLETION DATE	
D5437	patient CBC 19, 2015, the laborator patient CBC 2120i #1. From No 19, 2015, the laborator patient CBC tes #2.	age 29 ry performed and reported test results using the Advia evember 6, 2015 to November ratory performed and reported st results using the Advia 2120I	D543	approved specific calibration procedures for CBC on the Ac 2120i. Before the lab resumes tests on the Advia 2120i, it we conduct training on those pro-	any ill cedures.		
400H	Appendix C of the (CMS Pub. 7), that testing, the laborate At least once a day assayed or examine Each quantitative procedures performed for this STANDARD Based on laborate WBC differential quantitative procedures performed for the state of the state o	y patient specimens are ned perform the following for procedure, include two control and concentrations;  must document all control med.  is not met as evidenced by: pry personnel interviews and uality control record review on 5, the laboratory failed to control materials with differing atterns at least once each day rential specimens were e Cellavision instrument.  etice of the laboratory to use the nent to aid in the examination attent WBC differentials		required to demonstrate compto ensure that practice is conswith those procedures.  Lab management, including the lab director, technical superviquality director, is responsible ensuring that these procedures followed. The lab will provide oversight through monthly Quincetings, and will monitor compliance through its improvedures.	ne new sors, and e for s are le A		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1		IDENTIFICATION NUMBER: A. E		PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
MANEOE	DOMES OF SUSSIE		B. WING_	OTDEET ADDRESS OFFV STATE 710 CODE		20/2015
THERAN	PROVIDER OR SUPPLIE		- 4	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D5437	patient CBC te #2.	page 29 ory performed and reported C test results using the Advia November 6, 2015 to November oratory performed and reported est results using the Advia 2120I	D543			
400H	Unless CMS Approaches Appendix C of the (CMS Pub. 7), that testing, the laborate At least once a dassayed or examinaterials of differ (g) The laboratory procedures performed from several testing to the control of the	roves a procedure, specified in a State Operations Manual at provides equivalent quality atory must—  ay patient specimens are med perform the following for—  procedure, include two control ent concentrations;  must document all control med.  is not met as evidenced by:  tory personnel interviews and quality control record review on 15, the laboratory failed to a control materials with differing patterns at least once each day the cellavision instrument.  ctice of the laboratory to use the ment to aid in the examination patient WBC differentials		The lab proactively paused to the Cellavision during the sur The lab has completed an ass to identify any patients affect having the potential to be aff this issue.  The new lab director has appenhanced QC procedures that reinforce the need to perform at least two levels of control, otherwise specified, and the conducted training on those procedures.  The new lab director has also approved enhanced procedure Cellavision instrument to rein that the daily WBC different include two QC materials with differing WBC patterns. Befoliab resumes any tests on the Cellavision, it will conduct that competency testing on the procedures to ensure that praconsistent with them.	rvey. sessment ted or sected by roved t a QC with unless lab has  es for the inforce ial must th ore the raining iose	2/12/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPL A. BUILDING	and the state of t	(X3) DATE SURVEY COMPLETED 11/20/2015	
	05D202		B. WING			
NAME OF F	PROVIDER OR SUPPLIE	R	7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPR DEFICIENCY)	BE	(X5) COMPLETION DATE
D5447	examine patient so not examine two differing WBC differing WBC differential slides. Laborator Cellavision examitesting personnel before the examited However, the Cellavision examitesting personnel before the examited However, the Cellavisides.  c. According to February 2015, the standard slides.	page 30  If the Cellavision was used to stained slides, the laboratory did quality control materials with ferential patterns each day the used to examine patient stained ry personnel also stated that all inations were reviewed by and revised, if necessary, nation was release for reporting. Ilavision did perform the primary screening of patient stained laboratory personnel, since the laboratory examined and tent WBC differentials using the	D5447	D5447 (continued) Lab management, including tech supervisors, will be responsible frensuring that these procedures ar followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management, and aud procedures.	for re	
D5449 110H 220H	Unless CMS App Appendix C of the (CMS Pub. 7), the testing, the laborate At least once a desayed or exame Each qualitative and positive context (g) The laborator procedures perform this STANDARD Based on technic CT/NG quality context November 17, 20 specimens were	ay patient specimens are nined perform the following for procedure, include a negative rol material;  y must document all control	D5449	Prior to the survey, the lab follow the procedures for QC identified manufacturer's package insert for FDA cleared device.  The lab has completed an assess to identify any patients affected of having the potential to be affected this issue.  The new lab director has approve enhanced QC procedures that reinforce the need to perform QC at least two levels of control, unlotherwise specified, and the lab be conducted training on those procedures.	ment or ed by	2/12/16

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		05D2025714	B. WING	11/20/2015	
NAME OF F	PROVIDER OR SUPPLIE	R	7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560	
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	BE COMPLETION
D5449	a. It was the praperform and reported and results of this "ported and results of this "ported as positive result, the manuficulity control manufacture and results of this "ported as positive result, the manuficulity control manuficul	actice of the laboratory to our patient CT/NG testing using a scords indicated that on positive introl material in the assay. The properties of the laboratory performed sting without including a positive introl material in the assay. The led as a "positive" CT/NG aterial in the assay, the test is stive" CT/NG quality control and to calculate the assay cutoff is whether patient test results a or negative for CT/NG. As a acturer's "positive" CT/NG aterial was considered a to quality control material. The end no other positive CT/NG	D5449	D5449 (continued) The new lab director has also approved enhanced procedures of CT/NG to require the use of a per CT/NG control material that is realso used as a calibrator.  Lab management, including tech supervisors, will be responsible ensuring that these procedures a followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improve occurrence management and aud procedures.	ositive not mical for re
D5469 400H	d. Pursuant to 4 using calibration laboratory must a from a different locut-off value. 493.1256(d)(10)( Unless CMS App Appendix C of the	42 C.F.R. 493.1256(d)(9), when material as control material, the at least use calibration material of than that used to establish a g) CONTROL PROCEDURES roves a procedure, specified in a State Operations Manual at provides equivalent quality	D5469	(D5469 #1 begins on next page)	2/12/16

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	(X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION A BUILDING			СОМ	E SURVEY IPLETED 20/2015		
		PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		20/2013
PR	4) ID REFIX 'AG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	N SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE
D	5469	Establish or verify all control materials are used, example, mean a batch and lot num defined and availa (ii) The laboratory commercially ass the stated value is instrumentation everified by the lab (iii) Statistical paramaterials must be laboratory through materials having parameters.  (g) The laboratory procedures perform This STANDARD  1. Based on laboratory procedures perform the stated on laboratory failed to complete blood or record review on alaboratory failed to commercially assimaterials in use a Findings included  a. It was the pracommercially assimaterials to monition two instruments.	the criteria for acceptability of als.  materials providing quantitative statistical parameters (for and standard deviation) for each aber of control materials must be able.  may use the stated value of a ayed control material provided for the methodology and is coratory.  maneters for unassayed control established over time by the an concurrent testing of control previously determined statistical of must document all control previously determined statistical of must document all control previously determined statistical of the stated values of the ayed CBC quality control september 23, 2015, the coverify the stated values of the ayed CBC quality control at the time of the survey.  Contice of the laboratory to use ayed CBC quality control to patient CBC testing using ments.  BC quality control records June 27, 2015 the laboratory for quality control material from lot	D546	The lab has completed at to identify any patients a having the potential to be this issue.  The new lab director has enhanced procedures to a practice of parallel testing lot of control material with control material in use, a establishing a range base manufacturer's range. To conducted training on the procedures.  Lab management, include supervisors and the quality will be responsible for enthese procedures are followed by the provide oversight monthly QA meetings, a monitor compliance throe improved occurrence manuality procedures.	approved reinforce the g each new ith the lot of and on the he lab has ose ing technical ity director, asuring that owed. The at through and will ugh its	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		A BUILDIN	PLE CONSTRUCTION  IG	COMPLETED		
NAME OF C	PROVIDER OR SUPPLIER	05D2025714	B. WING_	OTDEST ADDRESS SITV PLATE ZID CODE	11/	20/2015
THERAN			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUI CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D5469	to indicate that the control material lo verified by the lab.  d. According to I June 27, 2015 and laboratory used on 30 different days to CBC specimens, instrument on 87 report patient CBC.  2. Based on intersupervisor and characteristic and characteristic and characteristic and the commercially assistant in the commercial into and Advia X justic and A	y maintained no documentation a stated values of CBC quality to number EX075 had been oratory.  aboratory personnel, between a September 24, 2015, the instruments on a perform and report patient and used the other different days to perform and cospecimens.  Inview with the general emistry quality control (QC) inber 17, 2015, the laboratory stated values of the layed QC material. Findings  Insupervior stated that when a new was started, the QC ranges the chemistry analyzers PT) from the prior to use.  Insupervisor further stated that the form QC was run one time prior to those that MultiQual lot number to use in 2014 and discontinued		D5469 #2 The lab has completed assessmidentify any patients affected of having the potential to be affect this issue.  The new lab director has approximate of parallel testing each lot of control material with the control material in use, and establishing a range based on the manufacturer's range. The lab conducted training on those procedures.  Lab management, including testing that these procedures director, will be responsible for ensuring that these procedures followed. The lab will provide	reted by  ved ree the new lot of he has	2/12/16

AND PLAN OF CORRECTION IDENTIFICATION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTII A. BUILDING B. WING	PLE CONSTRUCTION  G	COI	TE SURVEY MPLETED //20/2015
NAME OF I	PROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			720/2013
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES  CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE
D5469	c. The laboratory to indicate that the control material lo verified by the laboratory used or 30 different days to CBC specimens, a instrument on 87 report patient CBC.  Based on intersupervisor and chrecords on Novemfailed to verify the commercially assistinclude:  a. The general solot number of QC were entered into and Advia X	y maintained no documentation a stated values of CBC quality to number EX075 had been oratory.  aboratory personnel, between despetember 24, 2015, the me of the maintained instruments on the perform and report patient and used the other different days to perform and composition of specimens.  Inview with the general emistry quality control (QC) in the 17, 2015, the laboratory stated values of the layed QC material. Findings supervior stated that when a new was started, the QC ranges the chemistry analyzers	D546	D5469 #2 (continued) oversight through month meetings, and will moni compliance through its i occurrence management procedures.	tor mproved	
	new lot number of patient testing.  c. QC records si	tupervisor further stated that the fQC was run one time prior to how that MultiQual lot number o use in 2014 and discontinued				
	manufacturer's Q	supervisor and supervisor and on 11/17/15 at 9:40 am that C ranges for new lot numbers of swere not verified.				

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	FOF DEFICIENCIES DEFICIENCIES	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION  A. BUILDING		1.	(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD E CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)		(X5) COMPLETION DATE
D5477	(e) For reagent, me laboratory must do  (e)(4) Before, or co (e)(4)(i) Check each sterility is required for the support growth a inhibit specific orgation biochemical responsion (e)(4)(iii) Document the media when condeterioration in the laboratory of the media when condeterioration in the laboratory of the standard on the laboratory of l	ncurrent with the initial use h batch of media for sterility if for testing; h batch of media for its ability nd, as appropriate, select or nisms or produce a se; and the physical characteristics of mpromised and report any media to the manufacturer.  must document all control ned. s not met as evidenced by: I supervisor interview and quality control record review 015, the laboratory failed to of media for its ability to ore or concurrent with initial	D54	177	The lab has completed an assessment to identify any patients affected on having the potential to be affected this issue.  The new lab director has approve enhanced QC procedures for microbiology.  Lab management, including techn supervisors, will be responsible for ensuring that these procedures are followed. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improved occurrence management and audit procedures.	r d by d nical or	2/12/16

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		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP A. BUILDING B, WING	- Factorial and a second secon	(X3) DATE SURVEY COMPLETED	
	PROVIDER OR SUPPLIER	05D2025714	- 11	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD	11/20/2015	
THERAN	OS INC			NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATI DEFICIENCY)	COMPLETION DATE	
D5477	c. From Novembre 2015, the laborator specimen cultures 15300, expiration of	er 15, 2015 to November 18, y performed patient using Hardy BAP, lot number late 01/25/2016.	D5477			
D5481	(f) Results of control laboratory's and, as manufacturer's test acceptability before (g) The laboratory procedures perform This STANDARD 1. Based on reviet time/international in procedure, quality results and interviet the laboratory faile PT/INR was accepted the laboratory faile PT	t system criteria for e reporting patient test results.	D5481	D5481 #1 The laboratory paused testing on the Siemens BCS XP, including PT/INI during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue. The new lab director has approved enhanced QC procedures, which reinforce and detail the required investigation and corrective action to must occur to address QC issues before patient tests are performed at clarify which employees are responsible for performing and documenting these activities. The lab has conducted training and competency on those procedures to ensure that practice is consistent withem.  Lab management, including technic supervisors and the quality systems director, is responsible for ensuring compliance with these procedures. The lab will also provide oversight	R, / hat nd th	

AND PLAN OF CORRECTION IDENTIFICATION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIF A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED 11/20/2015	
NAME OF	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATI DEFICIENCY)	COMPLETION DATE	
D5481	e. On 9/8/15, Citr without obtaining a f. On 25 of 32 da when the QC value g. On 5/15/15, 8/Citrol 3 was run tw unacceptable.  h. The Rule Chec QC values in April 7 in June 2015, 13 August, and 24 of 2015 showed rule Citrol 3.  i. patients we through 9/16/15.  2. Based on revie procedure, QC rec patient test runs ar supervisor, the lab QC was acceptable prio results: Findings in a. CL SOP-15020 the following in second instrument greater than 2 SD	rol 3 was run seven times in acceptable QC value.  rol 3 was run twelve times in acceptable QC value.  ays, Citrol 3 was not rerun in was greater than - 2 SD.  13/15, 8/21/15 and 9/10/15, ide. All QC results were  ack report revealed that 13 of 13 2015, 2 of 17 in May 2015, 7 of of 13 in July 2015, 16 of 16 in 24 during September 1-16, violation messages related to are reported from 4/1/15  aw of the quality control (QC) cords, and raw data from and interview with the general oratory failed to ensure that the efor the control of the control of the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efor the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure that the efort the control oratory failed to ensure the control oratory failed to	D548	D5481 #1 (continued) through monthly QA meetings, and will monitor compliance through its improved occurrence management a audit procedures.  D5481 #2 The lab has completed an assessment to identify any patients affected or having the potential to be affected bithis issue.  The new lab director has approved enhanced QC procedures, which reinforce that QC results must be acceptable before patient tests are performed, and detail the steps to take the performed of the steps to take the steps to t	and 2/12/16	

AND PLAN OF CORRECTION IDENTIFICAT		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/20/2015		
THERAN	PROVIDER OR SUPPLIEI	R		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROP DEFICIENCY)	DBE	(X5) COMPLETION DATE	
D5481	b. Section 11.1. further stated that expires 24 hours  c. The general so QC was unaccept patient testing for acceptable and if another device word.  d. QC records for Globulin (SHBG) QC Level 2's (QC 8/14/14 at 18:54 at 8/15/14 at 00:05. patient Accession 19:09.  e. QC records for QC Level was on 8/20/14 at 17 patient Accession 19:08.  f. QC records for QC1 was 22:15. Patient da Accession #11280 g. QC records for that on Device at 06:16 and failed 09:10 and passed or 8/16/14. Patien Accession #9459.	1 of CL SOP-15026 Revision A	D548*	D5481 #2 (continued) when QC results are not accepta The lab has conducted training a competency on those procedure ensure that practice is consistent them.  Lab management, including tech supervisors and the quality syste director, is responsible for ensur that these procedures are follow. The lab will also provide oversi through monthly QA meetings, will monitor compliance throug improved occurrence managem audit procedures.	and s to t with hnical ems ring red. ght and h its		

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	, ,		LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING	B. WING		11/20/2015	
NAME OF	PROVIDER OR SUPPLIER			7	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	1	
(X4) ID PREFIX TAG	(EACH DEFICIENC)	TEMENT OF DEFICIENCIES / MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	BE	(X5) COMPLETION DATE
D5481	failed. QC1 was ne passed. QC2 was Patient data showe #94598 was run on i. QC records for QC2 24 h at 08:00 and was n 21:05. Patient data (Accession #s 954'8/20/14 between 12 j. QC records for QC2 24 h at 17:38 and was n 21:05. Patient data (Accession #s 9598/22/14 at 18:56 ar k. QC records for QC1's 24/8/24/14 at 16:43 ar 8/25/14 at 07:59. Q8/24/14 at 21:05 ar 8/25/14 at 12:23. P patients (Accession were run on 8/24/14. I. QC records for QC1 had the QC Pass/Fail S 20:29 and again on "10x warning" mess Status column on 2/26/15 at 22:04. Q2:54 and QC2 war at 00:27. Patient data data do:27. Patient data data data do:27. Patient data data do:27. Patient data data data data data data data da	run on 8/16/14 at 06:16 and xt run 8/17/14 at 09:10 and not run on 8/15/14 or 8/16/14. d that patient Accession 8/16/14 at 00:48.  VB12 showed that on Device our expiration was on 8/19/14 ot run again until 8/20/14 at showed that 3 patients 11, 95462, 95543) were run on 2:33 and 17:52.  VB12 showed that on Device our expiration was on 8/22/14 ot run again until 8/23/14 at showed that 2 patients 34, 96106) were run on	D54	481			

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		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER			7	STREET ADDRESS, CITY, STATE, ZIP CODE 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 PREF TAG		PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	BE	(X5) COMPLETION DATE
D5481	2/26/15 and 2/27/1. laboratory had a 10 m. QC records for QC1's 24 1/25/15 at 21:58 ar 1/28/15 at 21:40. Qt 1/26/15 at 02:22 ar 1/28/15 at 23:19. Ppatients (Accession 136897, 135548) wt 1359 and 1/28/15 at n. QC records for showed that on De expiration was on 7 again until 7/7/15 at that Accession #88 14:31.  o. Levey-Jenning: Device Quand QC2 had 15 coresults were at least below the mean from p. Levey-Jenning: Device Quand QC2 had 15 coresults were at least below the mean from 3/31/15 q. Levey-Jenning: Device Quand QC2 had 15 coresults were at least below the mean from 3/31/15 q. Levey-Jenning: Device Quand QC2 had 15 coresults were at least below the mean from 3/31/15 q. Levey-Jenning: Device Quand QC2 had 15 coresults were mean from 3/31/15 q. Levey-Jenning: Device Quand QC2 had 15 coresults were mean from 6/30/15	46898) were run between 5 during the time the 1x warning.  VB12 showed that on Device hour expiration was on 1x dwas not run again until 1x dient data showed that 5 may 1x dient data showed 1x dient data showed 1x dient data dient data dient data showed 1x dient data showed 1x dient data dient data showed 1x dient data data dient dat	D54	481			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714		A. BUILDING  B. WING	3	ATE SURVEY OMPLETED		
NAME OF F	PROVIDER OR SUPPLIE		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		11/20/2015	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
D5481 D5775 400B	the mean from 1/s. Levey-Jennin Device and QC2 had 12 results were at let 7/9/14 through 7/s.  t. Levey-Jennin Device and QC2 had 12 results were at let 2/10/14 through 2493.1281(a)(c) CRESULTS  (a) If a laboratory different methodoperforms the sample the laboratory multiple testing production of	ults were at least 2 SDs above 3/15 through 1/29/15.  gs charts revealed that TT3 QC1 had 113 consecutive days consecutive days that the ast 2 SDs above the mean from 25/14.  gs charts revealed that VB12 QC1 had 14 consecutive days consecutive days that the ast 2 SDs above the mean from 2/27/14.  OMPARISON OF TEST  performs the same test using alogies or instruments, or the test at multiple testing sites, and defines the relationship alts using the different estruments, or testing sites.  In must document all test result ties.  Is not met as evidenced by: oratory personnel interview and derential record review on 15, the laboratory failed to have be a year evaluated and defined etween WBC differential test by multiple testing personnel.	D548		t	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714		LE CONSTRUCTION	СОМ	E SURVEY PLETED
NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP COD 7333 GATEWAY BLVD NEWARK, CA 94560		20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SE CROSS-REFERENCED TO THE AP DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE
D5775	b. The laborator year evaluated ar between WBC dif by multiple testing the distribution of laboratory had no whether testing processed the stained slides and differential similar.  2. Based on revelaboratory failed to year evaluated are and a precedent and a precedent processed and a precedent processed by the method of showed that the formal seven devices february 2015 the devices were inclined.	y had no system that twice a and defined the relationship ferential test results examined a personnel. Other than through proficiency testing samples, the documentation to indicate ersonnel were examining patient direporting patient manual WBC dy, accurately, and reliably. The object of the relationship defined the relationship frindings include:  Trindings includ	D5775	D5775 #1 (continued) approved enhanced procedu Cellavision instrument to enthe lab evaluates and define relationship between WBC test results examined by mutesting personnel at least twiyear. Before the lab resume on the Cellavision, it will contraining and competency test those procedures to ensure the practice is consistent with the The lab's technical supervisionality systems director will responsible for ensuring that procedures are followed. The provide oversight through its improcedures through its improcedures.	sure that s the differential ltiple ice each s any tests orduct ting on hat nem.  ors and the l be t these e lab will nonthly itor roved	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIP  A. BUILDING  B. WING	S	OMPLETED
NAME OF F	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL 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	year evaluated and between WBC diff by multiple testing the distribution of plaboratory had no whether testing pestained slides and differential similarly.  2. Based on revision and a predict of the second state of the second	whad no system that twice a didefined the relationship perential test results examined personnel. Other than through personnel of the personnel of the personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient reporting patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manual WBC by, accurately, and reliably.  The personnel were examining patient manua	D5775	D5775 #2  The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The new lab director has approved enhanced method comparison procedures, which reinforce that the lab will compare the results of any instruments running the same test(s) least twice each year, to ensure that their results are comparable and with defined acceptance criteria. The lab has conducted training on those procedures.  The lab's technical supervisors and the quality systems director will be responsible for ensuring that these procedures are followed. The lab with provide oversight through monthly QA meetings, and will monitor	at in

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIF A. BUILDING B. WING	LE CONSTRUCTION	CO	TE SURVEY MPLETED  /20/2015
NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP C 7333 GATEWAY BLVD NEWARK, CA 94560		120/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COP (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
D5775	testing and were study.  e. The method of showed that the following showed that twelve devices February 2015 are from March 2015 seven devices we study.  h. QC and patienals or everalled that patient testing and comparison study is. The method of showed that the following showed showed that the following showed showed that the following showed showe	comparison documentation collowing devices and through 2/4/15.  In the comparison documentation collowing devices are used for VitD and coursed from 11/6/13  In the comparison documentation collowing devices are used for VitD and eighteen devices were used through April 2015 but only the included in the comparison and result documentation for VitD and the comparison documentation for VitD and the comparison documentation for VitD and was not included in the comparison documentation for VitD and was not included in the comparison documentation for VitD and was not included in the comparison documentation for VitD and was not included in the comparison documentation	D5778	D5775 #2 (continued) compliance through its im occurrence management, a procedures.	The second secon	

OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDING		СОМ	DATE SURVEY COMPLETED	
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(EACH DEFICIENC	CY MUST BE PRECEDED BY FULL	ID PREFIX TAG	(EACH CORRECTIVE ACTION	SHOULD BE	(X5) COMPLETION DATE	
comparison study 493.1282(a) COR  Corrective action to available and formaintain the labor patient speciments accurate and relia reports.  This STANDARD Based on laborate complete blood correcord review on Staboratory failed to policies and proceed the laboratory's or specimens in a more reliable patient test laboratory's criterion quality control materials are to use the stated of quality control materials are	RECTIVE ACTIONS  policies and procedures must ollowed as necessary to ratory's operation for testing in a manner that ensures able patient test results and  is not met as evidenced by: ory personnel interviews and ounts (CBC) quality control September 23, 2015, the ofollow corrective action edures as necessary to maintain peration for testing patient CBC anner that ensure accurate and st results and reports when the afor acceptability of CBC terial test results were not met.  ctice of the laboratory to test normal, and high) of quality each day of patient testing and values of commercially assayed terials to monitor patient CBC instruments. In the results desired assay values, nel were to follow the procedure stocol titled "Quality Control er CL QOP-00013, revision F)."	333,101	The lab has completed an to identify any patients af having the potential to be this issue.  The new lab director has enhanced QC procedures, reinforce and detail the reinvestigation and correcti must occur to address QC before patient tests are pe addition, the procedures cemployees are responsible performing and document activities, and require reg supervisor review and anaresults. The lab has conditraining and competency those procedures to ensur practice is consistent with Lab management, includi supervisors and the quality	approved which quired ve action that issues rformed. In clarify which e for ting these ular technical alysis of QC ucted testing on e that them.	2/12/16	
	PROVIDER OR SUPPLIES  SUMMARY ST  (EACH DEFICIENT REGULATORY OR  Continued From properties and properties and reliance and properties.  This STANDARD Based on laborate complete blood or record review on a laboratory failed to policies and proceed the laboratory failed to policies and proceed the laboratory and reliable patient test laboratory's criteric quality control materials and the stated of the stated	DENTIFICATION NUMBER:  05D2025714  PROVIDER OR SUPPLIER  OS INC  SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 43 comparison study. 493.1282(a) CORRECTIVE ACTIONS  Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.  This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and complete blood counts (CBC) quality control record review on September 23, 2015, the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory's operation for testing patient CBC specimens in a manner that ensure accurate and reliable patient test results and reports when the laboratory's criteria for acceptability of CBC quality control material test results were not met. Findings included:  a. It was the practice of the laboratory to test three levels (low, normal, and high) of quality control materials each day of patient testing and to use the stated values of commercially assayed quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control material test results did not fall within the stated assay values, laboratory personnel were to follow the procedure detailed in the protocol titled "Quality Control (document number CL QOP-00013, revision F)."	DENTIFICATION NUMBER:  OS INC  SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 43 comparison study. 493.1282(a) CORRECTIVE ACTIONS  Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.  This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and complete blood counts (CBC) quality control record review on September 23, 2015, the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory's operation for testing patient CBC specimens in a manner that ensure accurate and reliable patient test results and reports when the laboratory's criteria for acceptability of CBC quality control material test results were not met. Findings included:  a. It was the practice of the laboratory to test three levels (low, normal, and high) of quality control materials each day of patient testing and to use the stated values of commercially assayed quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control material test results did not fall within the stated assay values, laboratory personnel were to follow the procedure detailed in the protocol titled "Quality Control (document number CL QOP-00013, revision F)."  i. "Step 1" of the procedure was to "rerun the	PROVIDER OR SUPPLIER  OS INC  SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY PULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 43  comparison study.  493.1282(a) CORRECTIVE ACTIONS  Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.  This STANDARD is not met as evidenced by: Based on laboratory personnel interviews and complete blood counts (CBC) quality control policies and procedures as necessary to maintain the laboratory's operation for testing patient CBC specimens in a manner that ensure accurate and reliable patient test results and reports when the laboratory's operation for testing patient CBC specimens in a manner that ensure accurate and reliable patient test results and reports when the laboratory's criteria for acceptability of CBC quality control materials test results were not met. Findings included:  a. It was the practice of the laboratory to test three levels (low, normal, and high) of quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control materials to monitor patient CBC testing using the instruments. In the event any CBC quality control material test results did not fall within the stated assay values, laboratory personnel were to follow the procedure detailed in the protocol titled "Quality Control document number CL QOP-00013, revision F)."  i. "Step 1" of the procedure was to "rerun the	DEFORMED TO SUPPLIER  OSTINC  SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY PULL REGULATORY OR LSC IDENTIFYING INFORMATION)  Continued From page 43  Comparison study.  493.1282(a) CORRECTIVE ACTIONS  Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and complete blood counts (CBC) quality control record review on September 23, 2015, the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory failed to follow corrective action policies and procedures as necessary to maintain the laboratory follow the procedure sand required investigation and corrective action that must occur to address QC issues before patient tests are performed. In addition, the procedures clarify which employees are responsible for performing and documenting these activities, and require regular technical supervisor review and analysis of QC results. The lab has conducted training and competency testing on those procedures to ensure that practice is consistent with them.  Lab management, including technical supervisors and the quality systems director, is responsible for ensuring director, is responsible for ensuring did not fall within the stated assay values, laboratory personnel were to follow the procedure detailed in the protocol title of "Quality Control (document number CL QOP-00013, revision F)."  i. "Step 1" of the procedure was to "rerun the"	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPL A. BUILDING	E CONSTRUCTION		SURVEY PLETED
		05D2025714	B. WING		11/2	20/2015
NAME OF I	PROVIDER OR SUPPLIE	R	7	TREET ADDRESS, CITY, STATE, ZIP C 333 GATEWAY BLVD IEWARK, CA 94560	ODE	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COF (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
D5779	ii. "Step 2" of the fresh controls" "iff iii. "Step 3" of the operation of the incontrols failed."  iv. "Step 4" of the using a new reaged quality control test the laboratory's control test the laboratory's control test the laboratory's control test the laboratory of the laboratory	e procedure was to "repeat with the rerun of controls failed."  e procedure was to "check the estrument" "if the rerun of [fresh]  e procedure was to "repeat ent kit" and "recalibrate" if st results continued to fall outside riteria for acceptability.  e procedure was to "call outside riteria for acceptability.  e procedure was to "call outside riteria for acceptability.  cords for the supervisor" if st results continued to fall outside riteria for acceptability.  cords for the supervisor instrument signated as indicated 2, 14, and 16, 2015 CBC quality est results failed to meet stated the laboratory's documentation of trol failures indicated that the lifty Control" protocol was not control failures indicated that the laboratory's criteria for exific CBC analyte not thing of the high quality control eated three times before being a "new QC tube." "Step 1" was mes before the laboratory	D5779	D5779 (continued) compliance with these pro The lab will also provide of through monthly QA mee will monitor compliance to improved occurrence man audit procedures.	oversight tings, and hrough its	

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER OS INC			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPE DEFICIENCY)	BE	(X5) COMPLETION DATE
D5779	acceptability (specidesignated). Testir material was repea acceptable on a thir repeated two times iii. On July 17, 20′ indicated that the halled to meet the la acceptability (specidesignated). Testir material was repea acceptable on a thir repeated two times [NOTE: On July 11 records also indicated material failed to macceptability (specidesignated). Testir acceptable. "Step [NOTE: On July 14 indicated that the nation failed to meet the la acceptability (specidesignated). Testir acceptable. "Step construment the labor was used to testing specimens on July specime	fic CBC analyte not ag of the high quality control ted two times before being rd repeat. "Step 1" was without following "Step 2."  15, laboratory records igh quality control material aboratory's criteria for fic CBC analyte not ag of the high quality control ted two times before being rd repeat. "Step 1" was without following "Step 2."  and 14, 2015, laboratory ted that the high quality control ted that the high quality control ted that the high quality control ted that the laboratory's criteria for fic CBC analyte not ag was repeated and was 1" was followed.]  2015, laboratory records also formal quality control material aboratory's criteria for fic CBC analyte not ag was repeated and was 1" was followed.]  ords indicated that the gratory designated as a set and report patient CBC 11, 2015, patient CBC 12, 2015, patient CBC 14, 2015, and patient CBC 16, 2015. It is unknown how specimens were tested using	D5	7779			

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				SURVEY PLETED
l		05D2025714	B. WING		11/2	20/2015
NAME OF F	PROVIDER OR SUPPLIER  OS INC		7	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPROPROPROPROPROPROPROPROPROPROPROPRO	BE	(X5) COMPLETION DATE
D5787 D5787	The laboratory mus	RECORDS et maintain an information or	D5787 D5787	The lab is keeping records that the media used to test any given		2/12/16
	(a)(1) The positive (a)(2) The date and the laboratory. (a)(3) The condition that do not meet the specimen acceptable (a)(4) The records a testing, including the performed the test( This STANDARD is Based on technical bacteriology media on November 18, 2 have an information	and dates of all specimen e identity of the personnel who s). s not met as evidenced by: I supervisor interview and quality control record review 015, the laboratory failed to n or record system that s of all bacteriology patient		The lab has completed an assess to identify any patients affected having the potential to be affected this issue.  The new lab director has approvenhanced procedures regarding documentation of the bacteriolog media used to test patient specin.  The lab will ensure these procedures followed through audits perfipursuant to the lab's new audit.	or ed by ed gy nens. ures formed	
D5791	bacteriology media bacteriology specim controlled by the malaboratory maintain of media used to te bacteriology specim maintained no such 493.1289(a)(c) ANA ASSESSMENT  (a) The laboratory r written policies and mechanism to mon	ndicate that all lots of used to test patient mens had been quality anufacturer or laboratory, the ed no documentation of the lot st any given patient men. The laboratory information or record system. ALYTIC SYSTEMS QUALITY must establish and follow procedures for an ongoing itor, assess, and when roblems identified in the	D5791	D5791 #1 A review of hourly data demons that average hourly temperature nearly all of the freezers at issue the manufacturer temperature requirements for the materials st	trated for met	2/12/16

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714		PLE CONSTRUCTION	СОМ	E SURVEY PLETED 20/2015
NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		20/2013
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPR DEFICIENCY)	ULD BE	(X5) COMPLETION DATE
D5791	This STANDARD  1. Based on the Audit Node Reportable to identify a when ten of ten fromeet the manufar requirements. Firm a. The Audit Not September 2015  b. Six -20 C free Freezer Sanyo JF 7063 -20 Freezer 3JP.  c. Four -80 C freezer 1 Nuair, 7113 -80 Freezer 1 Muair, 7113 -80 Freezer 7120 -80 Fr	regin 493.1283.  If must document all analytic ment activities.  It is not met as evidenced by: It is sensoScientific Monitoring and intervew, the laboratory and perform corrective action reezer temperatures did not acturer temperature adings include:  It de Reports for July 2015 and were reviewed.  It is received.  It is recei	D579*	The lab has identified and disany materials that had the pothave been affected. The lab has completed an assessment to it any patients affected or having potential to be affected by this. The new lab director has apprenhanced temperature manage procedures to reinforce monit temperature and environment conditions and storage of mataccording to the manufacturer temperature range. The lab has conducted training on those procedures.  The lab's management, including the director, will ensure compliant these procedures, including by sure that supervisors perform respective duties effectively. Will also provide oversight the monthly QA meetings, and we monitor compliance through it improved occurrence manage audit procedures.	ential to as also dentify g the s issue.  Foved ement oring of al erials c's as ding the ystems are with y making their The lab rough ill	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDIN	G	TE SURVEY MPLETED
NAME OF	DOWNER OF GUEST ISS	05D2025714	B. WING_		/20/2015
THERAN	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D5791	9/24/15 revealed to that the freezers of acceptable tempe equal to -20 C or grows of the control	the following number of days id not meet the required rature range of greater than or greater that or equal to -80 C:  Sanyo JP Lab 12/24 days reezer 4 12/24 days Accessioning 11/24 days 9/24 days 2 JP 6/24 days 3JP 5/24 days 3JP 5/24 days 2 Thermo 3/24 days 2 Thermo 3/24 days 2 Thermo 3/24 days 1 12/24	D579	D5791 #2 The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue. The new lab director is responsible for the lab's QA program and has	2/12/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIP  A. BUILDING  B. WING	LE CONSTRUCTION	СОМ	TE SURVEY MPLETED  /20/2015	
NAME OF	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP COI 7333 GATEWAY BLVD NEWARK, CA 94560	DE		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES OF MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SI CROSS-REFERENCED TO THE AF DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE	
D5791	replicates to be no lower and upper line.  b. QC results we through November February 2015 for which were the devices.  c. QC Leve QC3) on Device %CV (coefficient or respectively, from d. QC1 and revealed the follow respectively, from f. QC1 and revealed the follow respectively, from g. QC1 and revealed the follow respectively, from g. QC1 and revealed the follow respectively, from g. QC1 and revealed the follow respectively, from h. QC Level on Device and through 8/30/14.	in 13.4.5 requires the %CV of the more than 15% (20% at the mits of detection).  The reviewed from June 2014 of 2014 and January through  The used for patient testing on the land Level 3 (QC1 and revealed the following of variation):  The detection of the land revealed the following of variation):  The land Level 3 (QC1 and revealed the following of variation):  The land Level 3 (QC1 and land land land land land land land	D5791	approved enhanced quality and related procedures. The also appointed a Quality Di will provide additional over These improved systems improcedures to reinforce that effectively reviewed to identification that is inconsistent lab's CV requirements and documented investigations corrective action occur. In a the procedures clarify which employees are responsible for performing and documenting activities, and require regulativities, and require regulativities. The lab has conduct and competency testing on procedures to ensure that procedures to ensure that procedures to ensure that procedures to ensure that procedures and the quality are responsible for compliant these procedures. The lab was provide oversight through the QA meetings, and will more compliance through its improcedures.	e lab has rector who reight.  clude QC QC is attify t with the that and addition, h for ag these ar technical vsis of QC ted training those ractice is g technical director, ace with will also anonthly itor roved		

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	T OF DEFICIENCIES DF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	W	G	ATE SURVEY DMPLETED
NAME OF	PROVIDER OR SUPPLIE		STREET ADDRESS, CITY, STATE, ZIP CODE  7333 GATEWAY BLVD  NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R 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	j. QC1 and revealed the following spectively, from k. QC1 of following %CV: 11/5/14.  I. QC1 of following %CV: 8/28/14.  3. Based on revealed to the ground occumentation a laboratory failed to (QA) procedure of problems with the for the Findings include:  a. Monthly QC in 2014, October 2015.  b. All reports we director (LD) on streport was signed to by the surveyor.  d. The July 201 summary that 21 device on the	d QC2 on Device and and and an anomal of 6/29/14 through 7/25/14.  on Device revealed the from 9/30/14 through  on Device revealed the from 7/31/14 through  view of Quality Assessment (QA) and QA procedures, the to have a quality assessment established to identify and correct to Quality Control (QC) program	D579	D5791 #3  The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director wh will provide additional oversight.  These improved systems include enhanced QC procedures, which reinforce and detail the required investigation and corrective action the must occur to address QC issues before patient tests are performed. In addition, they clarify which employed are responsible for performing	or o

	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTI A. BUILDIN B. WING	PLE CONSTRUCTION  G	СОМ	E SURVEY PLETED
NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		20/2013
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D5791	tests showed per more than 15% of (28%). Ove tests on all device SDs.  f. In October 26 following tests sh samples with mothan 2 SD: (19%), (45%), (19%), (46%) on all tests on all 2 SDs.  g. In February 2 following tests sh samples with mothan 2 SD: (24%), samples on all tegreater than 2 SI: (24%), samples on all tegreater than 2 SI: (24%), samples with mothan 2 SD: (24%), samples with mothan 2 SD: (20% of QC sampl	the data revealed the following centage of QC samples with of values greater than 2 SD:  (28%), (21%), rall 16% of QC samples on all es had values greater than 2  (21%), rall 16% of QC samples on all es had values greater than 2  (21%), (21%), (21%), rall 16% of QC re than 15% of values greater  (33%), (26%),	D579	D5791 #3 (continued) and documenting these a require regular technical review and analysis of Q lab has conducted training competency testing on the procedures to ensure that consistent with them.  Lab management, include supervisors and the qualities responsible for compliane procedures. The lab will oversight through month meetings, and will monit compliance through its in occurrence management procedures.	supervisor C results. The g and lose t practice is  ing technical ity director, is ce with these also provide ly QA or mproved	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULT A. BUILDIN B. WING_	IPLE CONSTRUCTION  NG	COM	E SURVEY MPLETED	
NAME OF	PROVIDER OR SUPPLIE		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560				
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D5791	j. In May 2015, tests showed peromore than 15% of (34%) samples on all test greater than 2 SD k. In June 2015, tests showed peromore than 15% of (23%). Over tests on all devices SDs.  4. Based on reverse Assessment (QA) with the QA/Quality laboratory failed to with drawing patient specific staff earlier or corrective actions. The QA prese 2014 showed that patient speciments (293).  c. The QA prese 2015 showed that	(60%). Overall 21% of QC sts on all devices had values is.  the data revealed the following centage of QC samples with f values greater than 2 SD:  (22%). Overall 26% of QC sts on all devices had values	D579	D5791 #4 As noted by CMS above, if specimen did not meet the la acceptance criteria, the lab's was to describe the issue in electronic system, to notify lab personnel, and to take, a electronically note, appropri corrective action. Patient spethat did not meet the lab's a criteria were not used for test. The new lab director is respethe lab's QA program and happroved enhanced quality and related procedures. The also appointed a Quality Dirwill provide additional over	ab's s practice its relevant nd iate ecimens eceptance sting. onsible for as systems lab has rector who	2/12/16	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION  A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING _		11/	20/2015	
NAME OF I	PROVIDER OR SUPPLIER OS INC			STREET ADDRESS, CITY, STATE, ZIP O 7333 GATEWAY BLVD NEWARK, CA 94560			
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D5791	d. The QA presen 2015 showed that t patient specimens (116).  e. There was no c that the lab had ide redraws due to clot	ge 53 tation from the 2nd quarter he number 1 reason that had to be redrawn was clots documentation which showed ntified the large number of s or that any action had been number of redraws due to	D579	D5791 #4 (continued) The new lab director has enhanced specimen reject procedures, which require lab personnel to further massess received patient sp to correct problem as nee	tion e the relevant nonitor and ecimens and ded.		
D5793 400B	493.1289(b)(c) ANA ASSESSMENT  (b) The analytic system include a review of actions taken to respolicies and procedure recurrence of problem analytic systems quappropriate staff. (c) The laboratory resystems assessment assessment assessment assessment review of the effect CBC processes. Fig. The laboratory procedure failed to to be taken when coresults failed to me acceptability. See	s not met as evidenced by: atory personnel interviews and ints (CBC) quality control and eview on September 23, 2015, d to have an analytic systems mechanism that included a iveness of the laboratory's inding included: s Siemens Advia 2120i include the corrective actions alibration or quality control et the laboratory's criteria for	D57	will review, among other specimen rejection rates a associated issues. In addi will monitor compliance improved occurrence manaudit procedures, both of address preanalytic activities.	things, and any tion, the lab through its nagement and which		

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:					SURVEY PLETED	
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NAME OF F	PROVIDER OR SUPPLIER  OS INC		1	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD E CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)		(X5) COMPLETION DATE
D5791 D5793 400B	d. The QA present 2015 showed that the patient specimens (116).  e. There was no of that the lab had ideredraws due to clot taken to correct the clots.  493.1289(b)(c) ANA ASSESSMENT  (b) The analytic systems and proced recurrence of problanalytic systems quappropriate staff. (c) The laboratory resystems assessment This STANDARD in 1. Based on labor complete blood could calibration record rethe laboratory failed quality assessment review of the effect CBC processes. Failed the systems assessment review of the effect CBC processes.	tation from the 2nd quarter he number 1 reason that had to be redrawn was clots documentation which showed ntified the large number of s or that any action had been number of redraws due to ALYTIC SYSTEMS QUALITY stems quality assessment must the effectiveness of corrective solve problems, revision of lures necessary to prevent ems, and discussion of lurity assessment reviews with must document all analytic nt activities. In some that any personnel interviews and lunts (CBC) quality control and eview on September 23, 2015, at to have an analytic systems a mechanism that included a liveness of the laboratory's inding included:		D5793 #1 The laboratory proactively paused testing on the Advia 2120i during survey. The lab has completed ar assessment to identify any patient affected or having the potential to affected by this issue.  The new lab director is responsible the lab's QA program and has approved enhanced quality system and related procedures. The lab halso appointed a Quality Director will provide additional oversight.  The new lab director has approve enhanced QC procedures that add among other things, parallel testing verify QC values; review of QC of the strength of the procedure of QC of the strength of the stre	the notes that the no	2/12/16
	to be taken when c results failed to me acceptability. See	include the corrective actions alibration or quality control et the laboratory's criteria for D5403.  s quality assessment		including regular review by techn supervisors; and investigation and correction action to take when QQ fails to meet the lab's criteria for	d	

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NAME OF	PROVIDER OR SUPPLIE	05D2025714 R	7	STREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD NEWARK, CA 94560	11/2	0/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	BE	(X5) COMPLETION DATE
D5793	mechanism failed calibration docum D5437.  c. The laborator mechanism failed of commercially a materials were very d. The laborator mechanism failed personnel follows action protocol wresults failed to macceptability every maintained documented CBC actions had been assessment audithe laboratory maintained documented CBC actions had been assessment audithe laboratory maintained documented CBC actions had been assessment audithe laboratory maintained documented CBC actions had been assessment audithe laboratory failed aproblems with the being used as it haboratory's criter testing for 5 of 7 from July 11, 201  2. Based on lab WBC differential report record revisaboratory failed aquality assessment audithe experies of the effect or practice of the laboratory failed and protocological for protocological failed for prot	d to ensure that all CBC nentation was maintained. See by a quality assessment of to ensure that the stated values assayed CBC quality control erified. See D5469.  The quality assessment of the established corrective then CBC quality control test neet the laboratory's criteria for an though the laboratory mentation to indicate that the quality control corrective reviewed during a quality to naugust 6, 2015. In addition, aintained no documentation it and investigated possible thing the high quality control material and failed to meet the ria for acceptability upon initial days of patient specimen testing 5 to July 17, 2015. See D5779.  The proposed of the propose	D5793	D5793 #1 (continued) acceptability. The lab has conductraining on those procedures.  The new lab director has also approved enhanced procedures addressing equipment systems a reinforcing that calibration documentation must be organize maintained. The lab has conduct training on those procedures.  The new lab director has also approved an enhanced SOP for on the Advia 2120i that addresse corrective actions to take when calibration or QC fail to meet the criteria for acceptability. Before lab resumes any tests on the Advia 2120i, it will conduct training or procedures. In addition, lab staff be required to demonstrate competency to ensure that practice consistent with these procedures.  Lab management, including tech supervisors and the quality direct responsible for compliance with procedures. The lab will provide oversight through monthly QA meetings, and will monitor compliance through its improve occurrence management, and au procedures.	red and ted  CBC es the e lab's e the via n those f will ice is s. mical etor, is these e	

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	ATEMENT OF DEFICIENCIES D PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		(X2) MULT A. BUILDIN B. WING	IPLE CONSTRUCTION IG	(X3) DATE SURVEY COMPLETED	
NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP COD 7333 GATEWAY BLVD NEWARK, CA 94560		120/2015
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D5793	mechanism failed calibration docum D5437.  c. The laborator mechanism failed of commercially a materials were very description. The laborator mechanism failed personnel follows action protocol were sults failed to macceptability every maintained documented CBC actions had been assessment audithe laboratory maintained documented CBC actions had been assessment audithe laboratory maintained documented CBC actions had been assessment audithe laboratory maintained documented CBC actions with the laboratory failed appropries of the laboratory failed quality assessment audithe laboratory failed quality assessment audithe laboratory failed quality assessment audithe laboratory failed appropries of the effect or practice of the laboratory failed appropries. Findings included as a for patient or practice of the laboratory failed appropries actions findings included as a for patient or practice of the laboratory failed appropries.	d to ensure that all CBC nentation was maintained. See by a quality assessment of to ensure that the stated values assayed CBC quality control erified. See D5469.  The quality assessment of the established corrective then CBC quality control test neet the laboratory's criteria for an though the laboratory mentation to indicate that the quality control corrective reviewed during a quality to naugust 6, 2015. In addition, aintained no documentation it and investigated possible thing a puality control material and failed to meet the ria for acceptability upon initial days of patient specimen testing 5 to July 17, 2015. See D5779.  The proposition of the	D579	D5793 #2 The lab proactively paused t	sessment	2/12/16

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NAME OF I	PROVIDER OR SUPPLIE	A STATE OF THE STA	7	STREET ADDRESS, CITY, STATE, ZIP COI 333 GATEWAY BLVD NEWARK, CA 94560		20/20/13
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SI CROSS-REFERENCED TO THE AF DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE
D5793	b. On August 23 was us WBC differentials  perperformance cheefailed at 10:18. A documentation in performance cheefailed to indicate that the 2015 to "pass" the check had been in the actions under assessment media  3. Based on tech human chorionic control record rev laboratory failed to quality assessme review of the effectorrective actions Findings included a. It was the practical patient quality of laboratory's criterical patient quantitative patient quantitative	ed to perform and report patient, laboratory indicated that at 09:30 the efformance check failed. The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory to use the properties of the laboratory to use the commercial to 12:49, laboratory to use the chapter of the laboratory to use sayed quality control materials lues of the commercially ontrol materials as the laboratory materials as the laboratory to monitor in the commercial to 12:49, laboratory to materials as the laboratory to monitor in the commercial to 13:40, laboratory to materials as the laboratory to monitor in the commercial to 13:40, laboratory to 13:	D5793	D5793 #2 (continued) The new lab director is resp the lab's QA program and h approved enhanced quality and related procedures. The also appointed a Quality Di will provide additional over The new lab director has ap enhanced procedures to rein practice of addressing a per check fail through documen investigations and corrective The lab has conducted train those procedures.  Lab management, including supervisors and the quality are responsible for complian these procedures. The lab w oversight through monthly meetings, and will monitor compliance through its imp occurrence management, ar procedures.	systems lab has rector who reight.  proved aforce the formance ated e action. ing on g technical director, ace with vill provide QA roved	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	A. BUILDING  B. WING		ATE SURVEY DMPLETED  1/20/2015
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D5793	b. On August 23 was us WBC differentials  perperformance check failed at 10:18. A documentation incomperformance check c. The laborator to indicate that the 2015 to "pass" the check had been re the actions under assessment med  3. Based on tech human chorionic secontrol record rev laboratory failed to quality assessme review of the effectorrective actions Findings included a. It was the practical process and the stated va assayed quality of laboratory's criteri patient quantitative	de to perform and report patient, laboratory indicated that at 09:30 the rformance check failed. The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck was repeated and again to 12:49, laboratory dicated that the ck passed.  The ck passed in the effective performance eviewed for the effective performance eviewed for the effective performance eviewed for the effective performance in the laboratory's quality performance in the laboratory in the performance in the laboratory in the performance in the performanc	D5793	D5793 #3 The lab proactively paused testing on the Siemens Immulite 2000 XPi during the survey.  The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.	

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	l ' '		E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
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NAME OF	PROVIDER OR SUPPLIER			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
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D5793	three quality contronumber 40310, expuse on November level 1 quality contracceptability used was 9.38 - 14.4 ml control material's comonitor patient HC mlU/mL, and the lecriteria for accepta HCG testing was 2 c. According to thinsert, the assayed control materials in monitor patient HC mlU/mL for level 1, 2, and 306 - 460 mlu/mL for level 1, 2, and 306 - 460 mlu/mL for level 1, 2, and 306 - 460 mlu/mL for level 1, 2, and 306 - 460 mlu/mL for level 1, 2, and 306 - 460 mlu/mL for level 1, 2, and 306 - 460 mlu/mL for level 1, 201 acceptability that we 2015. According to the criter on September 11, 201 acceptability that we 2015. According to the criter on September 11, apparent "shift" in the materials test result in the criter on the september 11 apparent "shift" in the control materials reacceptability for the control materials reacceptability outside e. The laboratory acceptability outside e.	all materials (Bio-Rad, lot biration date 12/31/2017) in 19, 2015 indicated that for the rol material the criteria for to monitor patient HCG testing U/mL, the level 2 quality riteria for acceptability used to G testing was 20.6 - 32.4 evel 3 quality control material's bility used to monitor patient 64 - 376.  The manufacturer's package values of the three quality use on November 19, 2015 to G testing was 8.66 - 18.2 21.6 - 40.6 mIU/mL for level 1U/mL for level 3.  The three quality control November 19, 2015 to G testing was changed on 5 to the criteria for as used until November 19, 2015 to G testing was changed on 5 to the criteria for as used until November 19, 2015 because there was an the laboratory's quality control lts. The laboratory conducted ation or review prior to ia for acceptability for the three	D57	793	D5793 #3 (continued) These new procedures reinforce need to document investigations the reasons for corrective action QC fails to meet the lab's criteri acceptability, including the reason any changes to QC parameters. Iab has conducted training on the procedures.  These procedures require the tect supervisors to regularly review and to initiate investigations and corrective action when QC fails meet the lab's acceptability crite addition, oversight of QC review investigations and corrective act occurs through monthly QA meet the lab will also monitor complethrough its improved occurrence management, and audit procedure.  Before the lab resumes any test of Siemens Immulite 2000 XPi, the will ensure that the test has been re-verified pursuant to the lab's improved method verification procedures that have been approby the new lab director. The lab also ensure that testing personne been trained and demonstrated competency to ensure that testing testing the other procedures for that testing the other procedures for the other procedures for the other procedures for the other procedures fo	and when a for ons for The ose chnical QC to cria. In vs, ion etings. iance cres. on the e lab a ved will be have the ist and	

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NAME OF	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	20/2010
(X4) ID PREFIX TAG	(EACH DEFICIENC	TATEMENT OF DEFICIENCIES  CY MUST BE PRECEDED BY FULL  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
D5793	mechanism to ass corrective action.  f. From Septem 2015, the laborator patient quantitative 4. Based on tech hepatitis B survey control record revilaboratory failed to quality assessment review of the effect control corrective problems. Finding a. It was the praimmulite 2000 XP report patient HBs practice of the lab assayed quality or values of the commontrol materials a acceptability to more than the positive quality control material's monitor patient HI and the po	ber 11, 2015 to November 19, bry performed and reported ve HCG tests.  Innical supervisor interviews and antibody (HBsAb) quality lew on November 19, 2015, the phave an analytic systems at mechanism that included a ctiveness of HBsAb quality actions taken to resolve gos included:  It was also the oratory to use the right instrument to perform and sAb test results. It was also the oratory to use three levels of control materials and the stated mercially assayed quality as the laboratory's criteria for conitor patient HBsAb testing.  The criteria for acceptability for the rol materials (Siemens, lot britation date 11/2016) in use on 15 indicated that for the control material the criteria for acceptability used to BsAb testing was 10.3 - 19.6, uality control material's criteria sed to monitor patient HBsAb	D579	D5793 #4 The lab proactively paused testing on the Siemens Immulite 2000 XPi during the survey. The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has also appointed a Quality Director who will provide additional oversight.  The new lab director has approved enhanced QC procedures to reinforce the need to document investigations and the reasons for corrective action when QC fails to meet the lab's acceptability criteria, including the reasons for any changes to QC parameters. The lab has conducted training on those procedures.  These procedures require the technical	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIP  A. BUILDING  B. WING	LE CONSTRUCTION	СОМ	E SURVEY PLETED 20/2015
NAME OF	PROVIDER OR SUPPLIER		(f) :	STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		
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D5793	control materials in monitor patient HE the negative quality the low positive quality and for the positive d. According to for acceptability for materials in use of monitor patient HE September 11, 20 acceptability that v. 2015. According to change to the crite on September 11, apparent "shift" in materials test resund further investig changing the crite quality control materials test resundent for the quality control materials test resundent for the quality control materials test resundent for the patient for the quality control materials test resundent for the quality control materials test resundent for the quality control materials to control materials to associate the manufacturer. The mechanism to associate the laboratory patient HBsAb test.  5. Based on technical patient HBsAb test.  5. Based on technical patient HBsAb test.  6. Based on technical patient HBsAb test.	d values of the three quality in use on November 19, 2015 to 3sAb testing was 0.0 - 4.0 for ty control material, 11 - 21 for pality control material, and 226 - 4 e quality control material.  Aboratory records, the criteria for two of the three quality control in November 19, 2015 to 3sAb testing was changed on 15 to the criteria for was used until November 19, 2015 to 18 laboratory personnel, the peria for acceptability was made 2015 because there was an the laboratory's quality control ults. The laboratory conducted ation or review prior to ria for acceptability for the three terials.  It is change of the criteria for the two of the three HBsAb terials resulted in criteria for de the criteria established by The laboratory maintained no sess the effectiveness of this for the three than 11, 2015 to November 19, any performed and reported	D5793	D5793 #4 (continued) supervisors to regularly and to initiate investigat corrective action when (meet the lab's acceptable addition, oversight of Quinvestigations and corrective action when the lab will also monitor through its improved occurs through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through its improved occurs and audit provided in the lab will also monitor through the lab wi	ions and QC fails to lity criteria. In C reviews, ctive action QA meetings. or compliance currence	

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		05D2025714	B. WING		11/20/2015	
NAME OF	PROVIDER OR SUPPLIER		7	STREET ADDRESS, CITY, STATE, ZIP CODE 3333 GATEWAY BLVD NEWARK, CA 94560		
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D5793	actions taken to resincluded:  a. It was the pract Siemens Advia Cer System instrument LH test results. It valaboratory to use the control materials are commercially assay the laboratory's critic patient LH testing.  b. A review of the three quality control number 50980, expuse on November acceptability used the was 2.86 - 4.18 ml control material's committed material's committed material for acceptability used the criteria for acceptability used the criteria for acceptability of the control materials in monitor patient LH mlU/mL, and the lection of the control materials in monitor patient LH mlU/mL for level 1, 2, and 57.6 - 84.8 red. According to la for acceptability for materials in use on monitor patient LH mlumited in the control materials in use on monitor patient LH	f LH quality control corrective solve problems. Findings  dice of the laboratory to use the staur XP Immunoassay to perform and report patient was also the practice of the ree levels of assayed quality and the stated values of the red quality control materials as eria for acceptability to monitor criteria for acceptability to monitor criteria for acceptability for the lamaterials (Bio-Rad, lot biration date 11/30/2016) in 19, 2015 indicated that for the rol material the criteria for comonitor patient LH testing J/mL, the level 2 quality riteria for acceptability used to testing was 16.98 - 25.48 yel 3 quality control material's collity used to monitor patient 6 - 84.8 mIU/mL.  The manufacturer's package values of the three quality use on November 19, 2015 to testing was 2.86 - 4.18 16.6 - 23.9 mIU/mL for level	D5793	D5793 #5 The lab proactively paused testing the Siemens Advia Centaur XP Immunoassay System during the survey.  The lab has completed an assess to identify any patients affected having the potential to be affected this issue.  The new lab director is responsified the lab's QA program and has approved enhanced quality system and related procedures. The lab also appointed a Quality Director will provide additional oversight.  These new procedure reinforce to need to document investigations the reasons for corrective action QC fails to meet the lab's acceptoriteria, including the reasons for changes to QC parameters. The has conducted training on those procedures.  These procedures require the test supervisors to regularly review and to initiate investigations and corrective action when QC fails meet the lab's criteria for acceptability. In addition, oversity QC reviews, investigations and corrective action occurs through corrective action occurs through	ment or ed by ble for ems has or who t. the and when tability r any lab chnical QC to ght of	2/12/16

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP A. BUILDING	des printers proprie de con-	(X3) DATE SURVEY COMPLETED	
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D5793	until November 1 personnel, the ch acceptability was there was an app quality control ma laboratory condu- review prior to ch acceptability for t materials.  e. The laborator acceptability for t control materials acceptability outs the manufacturer mechanism to as corrective action.  f. From July 9,	9, 2015. According to laboratory range to the criteria for made on July 9, 2015 because parent "shift" in the laboratory's aterials test results. The cted no further investigation or ranging the criteria for the three quality control by schange of the criteria for the one of the three LH quality resulted in criteria for cide the criteria established by the Iaboratory maintained no seess the effectiveness of this	D5793	D5793 #5 monthly QA meetings. The lab will also monitor compliance through it improved occurrence management audit procedures.	ts	
	CA-125 quality or November 19, 20 an analytic system mechanism that is effectiveness of 0 actions taken to rincluded:  a. It was the pralmmulite 2000 XI report patient CA practice of the lal assayed quality ovalues of the concontrol materials	chnical supervisor interviews and control record review on 115, the laboratory failed to have ms quality assessment included a review of the CA-125 quality control corrective resolve problems. Findings actice of the laboratory to use the Pi instrument to perform and 125 test results. It was also the coratory to use three levels of control materials and the stated mercially assayed quality as the laboratory's criteria for conitor patient CA-125 testing.		D5783 #6 This finding appears to have a typographical error because CA-12 was tested on the Siemens Advia Centaur XP Immunoassay System during this period, not the Siemens Immulite 2000 XPi.  The lab proactively paused testing the Siemens Advia Centaur XP Immunoassay System during the survey.  The lab has completed an assessment	on	

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D5793	b. A review of the three quality control number 19980, expuse on November level 1 quality control acceptability used testing was 18.6 - 2 control material's comonitor patient CAU/mL, and the lever criteria for accepta CA-125 testing was c. According to thinsert for quality conumber 19980, the the three quality control material's in the criteria for accepta quality control material was and was told by the criteria for accepta quality control material was and was told by the criteria for accepta quality control material was and was told by the criteria for accepta quality control material was criteria for accepta quality control material for acceptability from the acceptability for used by the laborar monitor patient CA	criteria for acceptability for the of materials (Bio-Rad, lot biration date 09/30/2016) in 19, 2015 indicated that for the rol material the criteria for to monitor patient CA-125 28.7 U/mL, the level 2 quality riteria for acceptability used to -125 testing was 53.5 - 82.2 If 3 quality control material's bility used to monitor patient as 92.5 - 141 U/mL.  The manufacturer's package entrol materials Bio-Rad, lot are were no assayed values for entrol materials in use on 5 to monitor patient CA-125. The quality hanufacturer could not publish estability at the time the quality is received by the laboratory, as manufacturer to use the bility from the previous lot of erials. The laboratory umentation to support the tructions for the use of the bility from the previous lot of erials.  The manufacturer's criteria for the previous lot of erials.  The laboratory umentation to support the tructions for the use of the bility from the previous lot of erials.  The quality control materials to on November 19, 2015 to 125 testing did not match the bility from the previous lot of of 125 testing did not match the bility from the previous lot of of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not match the bility from the previous lot of 125 testing did not	D5793	D5793 #6 (continued) to identify any patients affected having the potential to be affected this issue.  The new lab director is responsithe lab's QA program and has approved enhanced quality system and related procedures. The lab also appointed a Quality Director will provide additional oversight.  The new lab director has approventanced QC procedures to rein the need to document investigate and the reasons for corrective as when QC fails to meet the lab's acceptability criteria, including reasons for any changes to QC parameters. The lab has conduct training on those procedures.  These procedures require the test supervisors to regularly review and to initiate investigations and corrective action when QC fails meet the lab's criteria for acceptability. In addition, oversity QC reviews, investigations and corrective action occurs through monthly QA meetings. The lab also monitor compliance through improved occurrence management and audit procedures.	ble for  ems has or who t.  red force ions etion  the  ded chnical QC to ight of will h its	

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D5793	e. Upon further the criteria for accompany and a company a	review, it was discovered that ceptability for the quality control of the laboratory on November for patient CA-125 testing was ceptability established by the Bio-Rad, lot number 19980, for a instrument and not the entaur XP Immunoassay not.  The quality control materials for 19980 to November 19, for performed and reported for a state of the entaur XP Immunoassay not.  The quality control materials for 19980 to November 19, for performed and reported for a state of the control materials for the control personnel interviews and for a state of the control materials and the control personnel interviews and for a state of the control materials and the control personnel interviews and control personnel pers	D579	D5793 #7 The lab directors during covered by the survey no any position with the lab director was hired after the survey had been complet.  The new lab director is rethe lab's QA program an approved enhanced quality and related procedures. The also appointed a Quality will provide additional of the new lab director has enhanced procedures required alternative assessments in subject to timely review as	o longer hold . The new lab he on-site ed. esponsible for d has ty systems The lab has Director who versight. approved uiring that nust be	2/12/16	

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D5793	test results on the XPT. Laboratory review of this AAP November 16, 201 personnel and was director as required.  ii. On May 15, 201 testing for and contest results on the XPT. Laboratory review of this AAP November 15, 201 personnel.  iii. On July 31, 201 testing for and contest results on the XPT. Laboratory review of this AAP November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv. On November 16, 201 personnel and was director as required iv.	ecords indicated that the was not completed analytes using the Advia ecords indicated that the was not completed until 5 by appropriate laboratory on the reviewed by the laboratory of by laboratory protocol.  14, the laboratory completed analytes using analytes using analytes using the Advia ecords indicated that the was not completed until 5 by appropriate laboratory  14, the laboratory completed analytes using analytes using analytes using the Advia ecords indicated that the was not completed until 5 by appropriate laboratory analytes using the Advia ecords indicated that the was not completed until 5 by appropriate laboratory onto reviewed by the laboratory onto reviewed by the laboratory of by laboratory protocol.  20, 2014, the laboratory for and compared of test results on the same Advia XPT. Laboratory that the review of this AAP was all November 15, 2015 by	D5793	D5793 #7 (continued) evaluation by the lab direct technical supervisor.  The lab will provide overs monthly QA meetings, an monitor compliance throu improved occurrence man audit procedures.	sight through d will also gh its	2/12/16	

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D5793	corrective actions of venipuncture laboral consecutive times of Findings include:  a, CL QOP-00013 in Chemistry", state is deemed to have hae not been violat section 6.3.2)."  b. CL QOP-00013 section 6.3.2.5 that on the same side of monitored.  c. The Advia XPT testing on 12/18/14 1800 was used for Albumin  i. Review of the Fast and 2nd events submitted results section -3.3 to -4.9 and ii. Review of Leve 2014 and Septemb MultiQual Level 1 ((MQ2) had at least the mean but within iii. Review of Leve 2015 through April number 45661) had	assessment (QA) laboratory failed to take when chemistry QC in the atory was observed ten on the same side of the mean.  Revision D, "Quality Control d in section 6.3.1.7.2 that QC passed whenWestgard rules ed (see following monthly QC  Revision D also stated in ten consecutive observations f the mean should be  was put into use for chemistry . Prior to 12/18/14, the Advia	D5793	The new lab director is respons the lab's QA program and has approved enhanced quality syst and related procedures. The lab also appointed a Quality Direct will provide additional oversight that regular review of QC data required and that investigations corrective actions must be taken QC fails to meet the lab's criter acceptability. The lab has conditraining on those procedures to that practice is consistent with the These procedures require the te supervisors to regularly review and to initiate investigations and corrective action when QC fails meet the lab's criteria for acceptability. In addition, overse QC reviews, investigations and corrective action occurs through monthly QA meetings. The lab also monitor compliance through improved occurrence managem and audit procedures.	ible for ems has or who int.  ved inforce is and in when ia for acted ensure ihem.  chnical QC d ight of in will gh its

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D5793	)		D5793	(continued; see above)		
	MultiQual Level3 (N	below the mean and MQ3, Lot number 45663) had ults below the mean but within nonths.				
		aled 125 of 125 below the 2015 through April 2015 but				
	v. MQ2 data revealed 126 of 126 below the mean for January 2015 through April 2015 but within 2 SDs.					
		aled 123 of 125 below the 2015 through April 2015 but				
		ey-Jenning reports from May MQ1, MQ2 and MQ3 were 21 of 31 days.				
	5/22/15 to fit the da documentation of a	all three levels was adjusted on ta without investigation or in investigation. After 5/22/15 were above the mean.				
	ix. The manufacturer ranges for MQ1 (Lot number 45661) was 2.03-3.04 g/dL; MQ2 (Lot number 45662) was 3.04-4.56 g/dL; MQ3 (Lot number 45663) was 3.26-4.89 g/dL.					
	5/22/15, the laborate manufacturer's ass	the acceptable ranges on tory's ranges fell outside the ayed ranges and were as 7-2.665 g/dL); MQ2 (2.5-3.74 52 g/dL).				
		ity Assessment PowerPoint the 3rd quarter of 2014				

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D5793	through the 2nd of the negative bias consecutive QC vii. albumin 2015 through Jur Calcium  i. Review of the 2nd events of 20 results showed a to -5.1.  ii. Review of Le 2014 and May 20 25 QC consecutive within 2 SDs.  iii. calcium 2015 through Jur Other Chemistrie Review of Levey-September 2014, Creatinine, Gluco (HDL), Low dens Bilirubin, Chloride Cholesterol, Alka Transaminase has consecutive QC in but within 2 SDs.  9. Based on reviassessment proof from August 2014 laboratory failed in the consecutive QC in the consecut	quarter of 2015 did not identify for albumin or the 10 values above or below the mean. It is were reported from January it is 2015.  PT results for calcium for the 15 revealed that the submitted negative bias ranging from -3.9 is vey-Jenning reports from April 15 revealed 27 of 27 and 25 of we results below the mean but its were reported from January its 2015.	D57	(continued; see above		

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D5793	performed every 6 and reviewed and (LD) in a timely man laboratory's proces in effective. Finding a. CL SOP-0002 testing for section 3.1 that the responsible for enconducted every 6 b. Section 3.3.2 the TS was reports amples results a LD was responsible each testing even c. Review of the FRM-00022-F3) reperformed on 8/18 d. All three result documented evaluations and the result form by the LD.  f. tests  were initial.	was not smonths and was not reviewed approved by the laboratory anner as required by the dures, and therefore, gs include:  O Revision B, "Proficiency  effective 1/1/2014, stated in the technical supervisor (TS) was suring that the AAP was smonths for all analytes.  of the procedures stated that sible for evaluating testing and section 3.4 stated that the lefor reviewing and approving the documentation.  AAP result forms (CL. evealed that the AAP was 3/14, 10/21/14, and 3/13/15.  It forms did not include a function by the TS.  Cuments from 8/18/14 and signed by the LD until 11/15/15 in from 10/12/14 was not signed ally implemented in November ew of patient raw data reports	D5793	The lab directors during the covered by the survey no leany position with the lab. It director was hired after the survey had been completed. The new lab director is rest the lab's QA program. The also appointed a Quality D will provide additional ove. The new lab director has apenhanced quality systems to that the lab's procedures are Among other things, the lab management, including the director and new quality systemetor, will provide overs proficiency testing and AA monthly QA meetings. The also monitor compliance the improved occurrence management and audit procedures.  Before the survey, the lab procedures are the survey and the paused testing on its laborate developed tests. It is not curperforming AAP testing.	onger hold The new lab on-site I.  ponsible for lab has irector who resight.  pproved o ensure re followed. b's e new lab restems sight over IP through e lab will brough its regement, proactively atory	2/12/16

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D5793	laboratory failed to mechanism to ide reference ranges study were accurated at reports. Find a. The validation reference range value in the patient range for the patient range for the patient range of the patient range	o have a quality assessement entify that the laboratory's established from the validation ately reflected on the patient raw dings include: In report for stated that the was 9.3-47.9 ng/mL.  aw data reports revealed that the was "30-100."  ata reports were reviewed from 8/31/14 and from 2/1/15 through ninety-four (94) patient results Insufficiency" on the patient raw the result was normal according a reference range.  In (27) of ninety four (94) patient ged as normal on the patient raw the result was above the normal to the laboratory's reference  T REPORT  ust have an adequate manual or u(s) in place to ensure test patient-specific data are liably sent from the point of data terfaced or entered manually) to ation, in a timely manner. This	D5793	D5801 The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The new lab director is responsible for the lab's QA program and has approved enhanced quality systems and related procedures. The lab has	2/12/16

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THERAN				7333 GATEWAY BLVD NEWARK, CA 94560		
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D5793	laboratory failed to mechanism to ider reference ranges of study were accurated at reports. Find a. The validation reference range with the patient range ference range with the patient range according to range.  4. Thirty (30) of right were flagged as "Indicated a report when the total aboratory's e. Twenty seven results were flagged data report when the range according to range.  4. The laboratory must be results and other part accurately and religional report destination includes the follow (a)(1) Results report (a)(2) Results and other part (a)(2) Results and (a)	have a quality assessement hitry that the laboratory's established from the validation tely reflected on the patient raw ings include:  report for stated that the ras 9.3-47.9 ng/mL.  w data reports revealed that the ras "30-100."  Ita reports were reviewed from (31/14 and from 2/1/15 through hinety-four (94) patient results insufficiency" on the patient raw the result was normal according reference range.  (27) of ninety four (94) patient red as normal on the patient raw the result was above the normal of the laboratory's reference  REPORT  Ist have an adequate manual or is) in place to ensure test patient-specific data are lably sent from the point of data erfaced or entered manually) to ation, in a timely manner. This	D580	also appointed a Quality Dirwill provide additional over  The new lab director has appenhanced procedures for reaqualification and management include procedures to ensure manufacturer inserts are revolved Training on these procedures occurred.  Before PT/INR testing resultab will also prepare a revise assay-specific procedure for to reinforce that the Internat Normalized Ratio (INR) much calculated accurately prior to patient test results. The releatesting personnel will be recodemonstrate competency to that practice is consistent with procedures.	proved agent ent that e riewed. es has mes, the ed r PT/INR tional ast be to reporting evant quired to ensure ith these ents will also a its	

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		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	` ′	PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/20/2015	
NAME OF F	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 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 CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE COMPLETION	
D5801	transmitted results information reporte outside referral lab point-of-care testin This STANDARD is Based on review of manufacturer Internumber, and the lap prothrombin time (I ensure that the rep Ratio (INR) was careporting final patie include:  a. Laboratory quanthat Dade Innovin (539280 was put inf MNPT for this lot n 8.0 seconds and the ISI was 0.89.  b. A review of the through 9/21/15 refinal patient results patient prothrombin	nscribed or electronically and patient-specific d directly or upon receipt from oratories, satellite or	D580	1		
D5805	c. The final repor results by 0.1-0.5 t 493.1291(c) TEST		D580	5 D5805:	2/12/16	
	(c)(1) For positive patient's name and	st indicate the following: patient identification, either the identification number, or a tifier and identification number.		The lab revised its patient report PT/INR during the survey so that interpretive note appears only unthe heading for patients with the	nt the inder	

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		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		TIPLE CONSTRUCTION  NG		E SURVEY PLETED
		05D2025714	B. WING		11/	20/2015
NAME OF F	PROVIDER OR SUPPLIER  OS INC			STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	REFIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL			PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTIO) CROSS-REFERENCED TO THE DEFICIENCY)	N SHOULD BE	(X5) COMPLETION DATE
D5805	(c)(2) The name ar location where the (c)(3) The test report (c)(4) The test perfect) (c)(5) Specimen so (c)(6) The test result of measurement or (c)(7) Any information of special patrices of standard or standa	and address of the laboratory test was performed.  ort date.  ormed.  urce, when appropriate.  Ilt and, if applicable, the units interpretation, or both.  ion regarding the condition and mens that do not meet the for acceptability.  Is not met as evidenced by:  If final reports and interview to President, the laboratory to the intrepretive data for the intrepretive data for the interpretive data on the interpretive da	D586	D5805 (continued): The lab has completed ar to identify any patients at having the potential to be this issue.  The new lab director has enhanced reporting process require the technical superverify that interpretive in accurate and to obtain ap the lab director or clinical before any updates are in The lab will provide over monthly QA meetings, at monitor compliance through improved occurrence may and audit procedures.	approved edures that ervisor to formation is proval from al consultant explanation in the proval from the prov	
D5821	above finding on 9/pm. 493.1291(k) TEST  When errors in the are detected, the lafollowing: (k)(1) Promptly not ordering the test ar using the test resul (k)(2) Issue correct authorized person applicable, the indirect person applicable in the indirect person	22/15 at approximately 4:45	D58	D5821: The new lab director has enhanced procedures to a correcting potential error reports. These procedure the person ordering the termines that a correcting required.	address s in patient es require that est is ne lab	2/12/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		05D2025714	B. WING		11/2	0/2015
THERAN	PROVIDER OR SUPPLIER OS INC		10	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	( (EACH DEFICIENCY MUST BE PRECEDED BY FULL PREFIX (EACH C		PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D5821	Based on review interview with the interview with interview and interview in the interview with the interview interview in the interview inter	ed report. is not met as evidenced by: of patient test reports and technical supervisor, the o notify the authorized person seven weeks after the surveyor control problem with //International Normalized Ratio is include: 3. In final patient reports reviewed reports were faxed between 5/15. In final patient reports reviewed mentation that the authroized d when an error in patient test ed. Itient test results were reported	D582	D5821 (continued): The lab has completed an asse to identify any patients affecte having the potential to be affect this issue.  The lab will provide oversight monthly QA meetings, and will monitor compliance through it improved occurrence manager audit procedures.	through also senent and tients also be din this rective	2/12/16
		is not met as evidenced by: ober and severity of the		things, the lab has hired a new	lab	

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AND BLAN OF CORRECTION IN INDENTIFICATION NUMBER:		(X2) MULTIP A. BUILDING	X3) DATE SURVEY COMPLETED		
		05D2025714	B. WING		11/20/2015
NAME OF I	PROVIDER OR SUPPLIER  OS INC		} ;	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD E CROSS-REFERENCED TO THE APPROPRI DEFICIENCY)	
D6079	Laboratories perfor laboratory director director failed to en personnel were res (QC) and quality as D6079); failed to en temperatures were specimens and refe failed to ensure the provided quality resensure the verificat (see D6086); failed programs (see D60 D6094) are establisensure that the fina appropriate interpre (see D6098); and fapersonnel were app D6102).  493.1445(a)(b) LAERESPONSIBILITIE  The laboratory dire overall operation and laboratory, including who are competent record and report to and proficiently, and the applicable regulary (a) The laboratory operform the duties clinical consultant, personnel, or delegopersonnel meeting 493.1447, 493.145, respectively.	erein, the Condition: ming high complexity testing; was not met. The laboratory sure that appropriate ponsible for the quality control is essment (QA) programs (see issure that the freezer appropriate for storage of erence materials (see D6083); methodologies selected sults (see D6085); failed to ion procedures were adequate to ensure that the QC 193) and QA programs (see shed and maintained; failed to ill patient test reports included etation information for PT/INR ailed to ensure that all propriately trained (see BORATORY DIRECTOR S ctor is responsible for the and administration of the gethe employment of personnel to perform test procedures, est results promptly, accurately defor assuring compliance with	D6079	director and established improved quality systems and related procedudressing the issues identified in observation. (D6079, D6083, D6 D6086, D6093, D6094, D6102).	dures this 085,  d 2/12/16 hold w lesite hent r liby  le for hs

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		05D2025714	B. WING		11/20/2015
NAME OF I	PROVIDER OR SUPPLIER  OS INC		1	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	
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D6079	performance of his she remains responduties are properly This STANDARD is Based on the Plan 12/3/2013 recertific quality control (QC) documentation and Report (CMS-209), failed to ensure tha programs were delesupervisor (TS). Fir a. The POC from recertification surve Manager was hired 12/10/13.  b. The QA/QC Maagain on 11/19/15 to the QA and QC promanager's response.  c. The QA/QC Maagain on 11/15/15 in any caped. The QA/QC Maagain on 11/15/15 in any caped. The laboratory directly sical plant and elaboratory are approperformed. This STANDARD is standard to the properson of the	or her responsibilities, he ornsible for ensuring that all performed. In some the performed is not met as evidenced by: of Correction (POC) from the ation survey and review of and quality assessment (QA) the Laboratory Personnel the laboratory director (LD) the laboratory director (LD) the laboratory's QC and QA egated to a qualified technical andings include:  The laboratory's 12/3/2013 ey stated that a QA/QC and began employment on an ager stated on 9/23/15 and hat evaluating and monitoring grams was solely the QA/QC ibility.  The laboratory by 12/3/15, or lacity.  The laboratory of the laboratory of the laboratory's 12/3/2013 ey stated that a QA/QC and began employment on the laboratory of the QA/QC ibility.  The laboratory of the laboratory's 12/3/2013 ey stated that a QA/QC and began employment on the laboratory of the laboratory's 12/3/2013 ey stated that a QA/QC and began employment on the laboratory of the laboratory's 12/3/2013 ey stated that a QA/QC and began employment on the laboratory of the laboratory's 12/3/2013 ey stated that a QA/QC and began employment on the laboratory of th	D6079	appropriate supervisors are invo in review of quality metrics. The has conducted training on those procedures. The new lab director the technical supervisor for chere hematology, and immunohemated During the survey, CMS determs that Technical Supervisor #3 was qualified in bacteriology, mycol virology, and diagnostic immunometers technical supervisors are responsible for QC assessments their respective specialties.  The lab will ensure that the new director is effective in overseein compliance with these procedures, through audits performed pursuate lab's new audit procedures, through oversight during month meetings, and through use of a ron-site visit log that records the director's time spent physically lab.	lved lee lab  or is mistry, cology. ined lss ogy, cology. now in  lab g es ant to  ly QA new lab in the  2/12/16  lod chold leew

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	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP A. BUILDING	LE CONSTRUCTION		E SURVEY IPLETED
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	PROVIDER OR SUPPLIE	R	,	STREET ADDRESS, CITY, STATE, ZIP COD 2333 GATEWAY BLVD NEWARK, CA 94560	E	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRI (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D6085	and interview with the laboratory direfreezer temperatus storage of referer specimens. Refer 493.1445(e)(3) LARESPONSIBILITY.  The laboratory directory dire	the ector failed to ensure that the eres were appropriate for one materials and patient of to D5413 and D5791.  ABORATORY DIRECTOR ES  Rector must ensure that the test elected have the capability of lity of results required for patient is not met as evidenced by: of validation documents on the their failed to ensure that the quality entering formance specifications ratory's procedures to establish on, reportable range, and/or Findings include:  Reports for were were were the procedure, CL sion A, "Master Validation Plan en surveyor requested their ablishing performance validation reports results without an evidence of the entering performance without an evidence of the entering performance wall dation reports results without an evidence of the entering performance wall dation reports results without an evidence of the entering performance wall dation reports results without an evidence of the entering performance wall dation reports results without an evidence of the entering performance of the	D6083	that average hourly tempera nearly all of the freezers at i the manufacturer temperature requirements for the materia	ture for ssue met re als stored. iscarded otential to has also identifying the his issue. In the lab end of a new the lab ally in the lab all all all all all all all all all	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
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THERAN	PROVIDER OR SUPPLIE	R	7	STREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D6083	and interview with the laboratory dire freezer temperate storage of referer specimens. Refe		D6083	those procedures  D6085		2/12/16
	RESPONSIBILIT The laboratory dimethodologies seproviding the quacare. This STANDARD Based on review laboratory director of results on the establishment of followed the laboraccuracy, precision reference range.  a. Validations R  reviewed.  b. The laborator PLN-14003 Revision when the procedure for est specifications.  c. included explanation as to	rector must ensure that the test elected have the capability of lity of results required for patient is not met as evidenced by: of validation documents on the the refailed to ensure that the quality; failed to ensure the performance specifications ratory's procedures to establish on, reportable range, and/or Findings include:  eports for were the procedure, CL sion A, "Master Validation Plan he surveyor requested their ablishing performance validation reports results without an		covered by the survey no lonary position with the lab. The director was hired after the osurvey had been completed.  The lab has completed an asset to identify any patients affect having the potential to be affectively implementations and validation procedures, incoverification and validation procedures, through audits per pursuant to the lab's new aud procedures, and through use on-site visit log that records director's time spent physical lab.  This improved oversight will that the new lab director important to the lab's enhanced procedure method verification. Before as	sessment ted or fected by hew lab nocedures, nthly QA formed lit of a new the lab lly in the lensure lements es for	

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Event ID: W34211

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e de la constantina della cons	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDING	LE CONSTRUCTION		SURVEY PLETED
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D6085	d. Accuracy for not determined following.  e. Precision for determined following.  f. Reportable randwas not determined following.  g. Percent (%) Relaboratory's accetation.  h. Allowable Biast acceptable criterian.  i. Refer to D6118.493.1445(e)(3)(ii) IRESPONSIBILITIE.  The laboratory directly verification proceed determine the acceptable criterian pertinent performance in the second pertinent performance in the laboratory of the laboratory of the laboratory's Findings included:	was not mg CL PLN-14003.  was not mg CL PLN-14003.  was not mg CL PLN-14003.  ge data for meet the did not meet the laboratory's for meet the labora	D6085	these improved procedures reclab director's review and appredetailed method verification periodication defined acceptance. The lab director must also reveapprove the verification report any patient testing begins. The conducted training on those procedures.  The lab will ensure that the nedirector also implements enhanced validation procedures, which winclude review processes and acceptance criteria similar to timproved method verification.	quire the oval of a lan e criteria. iew and t before e lab has ew lab need will he equired onnel petency that	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIF A. BUILDING	Contract to the contract of th	OATE SURVEY OMPLETED	
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THERAN	PROVIDER OR SUPPLIE	R	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL 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	
D6085	d. Accuracy for not determined for determined follows.  f. Reportable rawas not determined follows.  f. Reportable rawas not determined follows.  g. Percent (%) Reportable criteristic.  i. Refer to D61' 493.1445(e)(3)(ii) RESPONSIBILIT.  The laboratory direction procedetermine the acceptable criteristic performmethod.  This STANDARD 1. Based on labe establishment of specifications reconstruction procedetermine pertined determine pertined determine pertined for specification procedetermine pertined for specification procedetermin	was not ving CL PLN-14003.  was not ving CL PLN-14003.  ange data for etermined following CL  Recovery did not meet the table criteria for each of the e	D6088	D6086 #1 The lab directors during the period covered by the survey no longer hole any position with the lab. The new lab director was hired after the on-sit survey had been completed.  The lab has completed an assessmen to identify any patients affected or having the potential to be affected by this issue.	e t	
	a. A review of th	ne laboratory's vitamin B12				

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPE A. BUILDING B. WING	E CONSTRUCTION	СОМІ	SURVEY PLETED
NAME OF I	PROVIDER OR SUPPLIE		S 7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		20/2015
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D6086	document indica an allowable bias criteria for accept this discrepant relaboratory person error in the writte reviewed. The la corrected data and documents.  b. In spite of the in the vitamin B12 specifications document witamin B12 specifications document between 19, 20 document error.  2. Based on lab establishment of policies and proc September 22, 20 to ensure that veradequate to dete and other pertine of the laboratory's Findings included analytes the laboratory's Findings included analytes the laboratory included	performance specifications ted that the laboratory obtained greater than the laboratory's tability. When asked to explain sult, upon close examination, anel indicated that there was an an information provided and aboratory was able to provided ad appropriate supporting  e erroneous information included appropriate supporting appropriate supporting be erroneous information included appropriate supporting appropriate supporting be erroneous information included appropriate supporting appropriate supporting be erroneous information included appropriate supporti	D6086	D6086 #1 (continued) The lab will ensure that the new director effectively implement monitors lab procedures, incheverification and validation procedures through oversight during more meetings, through audits perfipursuant to the lab's new audiprocedures, and through use consite visit log that records the director's time spent physical lab.  This improved oversight will that the new lab director implete lab's enhanced procedures method verification. Before a verification studies are perfort these improved procedures relab director's review and appropriate detailed method verification procedures approve the verification report any patient testing begins. The conducted training on those procedures.  The lab will ensure that the new director also implements enhanced acceptance criteria similar to improved method verification.	ats and uding ocedures, athly QA formed it of a new he lab lly in the ensure dements is for any med, equire the roval of a plan e criteria. View and at before he lab has ewellab anced will the	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDING	ELE CONSTRUCTION	CON	E SURVEY MPLETED
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THERAN	PROVIDER OR SUPPLIE	R		STREET ADDRESS, CITY, STATE, ZIP CO 7333 GATEWAY BLVD NEWARK, CA 94560	DE	
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D6086	Continued From page 76 establishment of performance specifications document indicated that the laboratory obtained an allowable bias greater than the laboratory's criteria for acceptability. When asked to explain this discrepant result, upon close examination, laboratory personnel indicated that there was an error in the written information provided and reviewed. The laboratory was able to provided corrected data and appropriate supporting documents.  b. In spite of the erroneous information included in the vitamin B12 establishment of performance specifications document provided during this survey for review on September 22, 2015, laboratory records indicated that eleven people from the laboratory's staff approved this document between August 5, 2014 and September 19, 2015 without recognizing the document error.		D6086	D6086 #1 (continued) procedures, along with the required procedures. Relev personnel will receive train competency on those proceensure that practice is consthem.	ant lab ing and dures to	
	establishment of policies and proc September 22, 20 to ensure that veradequate to dete and other pertine of the laboratory's Findings included a. It was the pragardaytes the laboratory included	actice of the laboratory to use the to perform and report patient testing. Examples of ratory tested using the		D6086 #2 The lab directors during the covered by the survey no loany position with the lab. Ilab director was hired after survey had been completed. The lab has completed an a to identify any patients affe having the potential to be a this issue.  The lab will ensure that the	onger hold The new the on-site  sssessment ected or ffected by	
	included	the laboratory's protocol titled		The lab will ensure that the	new lab	

#### PRINTED: 01/25/2016 DEPARTMENT OF HEALTH AND HUMAN SERVICES FORM APPROVED OMB NO. 0938-0391 CENTERS FOR MEDICARE & MEDICAID SERVICES STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA (X2) MULTIPLE CONSTRUCTION (X3) DATE SURVEY AND PLAN OF CORRECTION IDENTIFICATION NUMBER: COMPLETED A. BUILDING 05D2025714 B. WING 11/20/2015 NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD THERANOS INC NEWARK, CA 94560 SUMMARY STATEMENT OF DEFICIENCIES PROVIDER'S PLAN OF CORRECTION (X5) COMPLETION (X4) ID ID (EACH DEFICIENCY MUST BE PRECEDED BY FULL (EACH CORRECTIVE ACTION SHOULD BE PREFIX PREFIX DATE REGULATORY OR LSC IDENTIFYING INFORMATION) CROSS-REFERENCED TO THE APPROPRIATE TAG TAG DEFICIENCY) D6086 #2 (continued) D6086 | Continued From page 77 D6086 director effectively implements and "Master Validation Plan for monitors lab procedures, including Assays on for establishing verification and validation procedures. the trueness or comparability of two procedures. . through oversight during monthly QA at least 50% of samples should be outside the meetings, through audits performed reference interval." pursuant to the lab's new audit c. A review of the test results used by the procedures, and through use of a new laboratory to establish "the trueness or on-site visit log that records the lab comparability of two procedures" for director's time spent physically in the testing using the lab. showed that the laboratory did not follow its established protocol and use "at least 50% of samples. . . outside the reference interval." This improved oversight will ensure that the new lab director implements For a validation document dated April 2, the lab's enhanced procedures for test results used to establish "the method verification. Before any trueness or comparability of two procedures" for

trueness or comparability of two procedures" for tests performed using the 1 of 110 test result used was outside the laboratory's reference interval.

iii. For a validation document dated April 21,

test results used were outside the

ii. For a validation document dated April 21,

trueness or comparability of two procedures" for

test results used to establish "the

test result used was outside the laboratory's

test results used to establish "the

iv. For a validation document dated April 21, test results used to establish "the trueness or comparability of two procedures" for tests performed using the 6 of 110

verification studies are performed, these improved procedures require the lab director's review and approval of a detailed method verification plan containing defined acceptance criteria. The lab director must also review and approve the verification report before

any patient testing begins. The lab has conducted training on those

procedures.

The lab will ensure that the new lab director also implements enhanced validation procedures, which will nclude review processes and acceptance criteria similar to the improved method verification

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tests performed using the

tests performed using the

reference interval.

2015.

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laboratory's reference interval.

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/	20/2015
NAME OF	PROVIDER OR SUPPLIE	R	7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PREFIX (EACH CORRECTIVE ACTION SHOULD BE		(X5) COMPLETION DATE
D6086	test resulaboratory's reference.  v. For a validation 2015, test test resultaboratory's reference test resultaboratory's reference.  3. Based on laboratory directory record review on laboratory directory directory recedures used precision of the laboratory directory recedures used precision of the laboratory directory recedures used precision of the laboratory directory dir	Its used were outside the ence interval.  on document dated April 1, tresults used to establish "the earability of two procedures" for using the ence interval, 1 of 113 trusted was outside the ence interval.  oratory personnel interviews and performance specifications November 17, 2015, the refailed to ensure that ence interval verification were adequate to determine the aboratory's testing	D6086	D6086 #2 (continued) procedures, along with the oth required procedures. Relevant personnel will receive training competency on those procedure ensure that practice is consiste them.  D6086 #3 The lab directors during the perceived by the survey no long any position with the lab. The lab director was hired after the survey had been completed.  The lab has completed an asset to identify any patients affected having the potential to be affect this issue.  The lab will ensure that the net director effectively implement monitors lab procedures, incluverification and validation prothrough oversight during monimeetings, through audits perfect pursuant to the lab's new audit procedures, and through use of on-site visit log that records the director's time spent physicall lab.  This improved oversight will entire the other contents and the lab's new audit procedures, and through use of on-site visit log that records the director's time spent physicall lab.	eriod	2/12/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION  A. BUILDING  B. WING		COM	E SURVEY IPLETED		
NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		20/2015		
(X4) ID PREFIX TAG	FIX (EACH DEFICIENCY MUST BE PRECEDED BY FULL		(EACH DEFICIENCY MUST BE PRECEDED BY FULL		ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIVE ACTION SHOOL CROSS-REFERENCED TO THE APP DEFICIENCY)	ACTION SHOULD BE TO THE APPROPRIATE	
D6086	ii. For had dated April 21, 20  iii. For dated April 21, 20  iv. For dated April 21, 20  v. For dated April 21, 20  c. The laborator explanation/investobtained using greater than these laboratory directly direc	based on a laboratory document of the laboratory determined of the laborat	D6086	that the new lab director import the lab's enhanced procedure method verification. Before verification studies are performant these improved procedures relab director's review and apply detailed method verification containing defined acceptant. The lab director must also reapprove the verification report any patient testing begins. The conducted training on those procedures.  The lab will ensure that the redirector also implements enhanced acceptance criteria similar to improve director method verification procedures, along with the or required procedures. Relevant personnel will receive training competency on those procedures that practice is consist them.  D6086 #4  The lab directors during the procedured by the survey no long any position with the lab. The	es for any rmed, equire the proval of a plan ee criteria. view and rt before he lab has hew lab anced will the her he her her her her her her her he	2/12/16		

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	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		LE CONSTRUCTION		E SURVEY PLETED
		05D2025714	B. WING		11/	20/2015
NAME OF	PROVIDER OR SUPPLIE	R		STREET ADDRESS, CITY, STATE, ZIP COD 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE AP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D6086	used were adequiperformance charange, of the labor methods. Finding a. It was the pranallytes the labor included b. A review of latestablishing performance by the from the reference reports.  i. For the labor method in the reference reports.  ii. For the labor manage on the test reports was a lated April 21, 20, 22.5 mg/dL. How range on the test range	ate to determine pertinent racteristics, such as reference pratory's gradient testing gradient testing gradient to perform and report patient testing. Examples of ratory tested using the performed using the performed using the laboratory's testing differed that the reference range te laboratory's testing differed the range on the laboratory's testing differed the range on the laboratory document 15, the laboratory determined the eference range as 0 - 52 U/L. The poratory's reference range on the	D6086	D6068 #4 (continued) lab director was hired after to survey had been completed.  The lab has completed an asto identify any patients affect having the potential to be afthis issue.  The lab will ensure that the director effectively implement monitors lab procedures, incomplete werification and validation puthrough oversight during momeetings, through audits perpursuant to the lab's new au procedures, and through use on-site visit log that records director's time spent physical lab.  This improved oversight with that the new lab director impute lab's enhanced procedure werification studies are perfet these improved procedures and application defined acceptants.	sessment eted or fected by mew lab ents and eluding procedures, onthly QA formed dit of a new the lab ally in the lab ally in the lab es for any ormed, require the proval of a plan	

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDING	LE CONSTRUCTION	СОМ	E SURVEY PLETED
		05D2025714	B. WING			20/2015
THERAN	PROVIDER OR SUPPLIE	R		STREET ADDRESS, CITY, STATE, ZIP CC 7333 GATEWAY BLVD NEWARK, CA 94560	IDE	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORI (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE
D6086	the 112.3 mg/dL. Hor reference range of mg/dL.  c. The laborator explanation/inves obtained reference ranges Laboratory record documents were director on Septe 5. Based on lab complete blood of method specifical November 19, 20 to ensure that veradequate to deter and other pertine for the two Sieme Findings included a. It was the prapatient venous CI Siemens Advia 20 #1 and #2.  b. Although the verification of test documents for the laboratory maindicate that verification that the reviewed and approportion of the reviewed	reference range as 64.0 - wever, the laboratory's on the test reports was 73 - 99  ry provided no written tigation as to why the laboratory the ranges to different than than the indicated on the test reports. Its indicated that these laboratory papproved by the laboratory mber 19, 2015.  roratory personnel interviews and counts (CBC) verification of tions record review on 15, the laboratory director failed rification procedures used were rmine the accuracy, precision, not performance characteristics was Advia 2120i instruments.	D6086	D6068 #4 (continued) The lab director must also approve the verification repany patient testing begins, conducted training on thos procedures.  Any update to a reference reviewed and approved by director or a clinical consumate the lab has procedures to edata on patient reports are with established reference addition, the lab will ensurnew lab director also impleenhanced validation procedures which will include review and acceptance criteria similar improved method verificat procedures, along with the required procedures. Relev personnel will receive train competency on those procedures that practice is constituen.	range is the lab ltant, and nsure that consistent ranges. In the that the ements dures, processes hilar to the ion other rant lab ning and edures to	

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	T OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDIN		сом	E SURVEY PLETED
NAME OF	PROVIDER OR SUPPLIE	05D2025714 R	B. WING _	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	11/2	20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPR DEFICIENCY)	BE	(X5) COMPLETION DATE
D6086	the 112.3 mg/dL. Horeference range mg/dL.  c. The laborator explanation/invest obtained reference ranges Laboratory record documents were director on Septe 5. Based on lab complete blood of method specifical November 19, 20 to ensure that we adequate to dete and other pertine for the two Siemes Findings included a. It was the prapatient venous C Siemens Advia 2 #1 and #2.  b. Although the verification of test documents for the laboratory maindicate that verifinstruments were evidence that the reviewed and appropriate in the laboratory maindicate the laborat	reference range as 64.0 - wever, the laboratory's on the test reports was 73 - 99  ry provided no written stigation as to why the laboratory ce ranges e different than than the indicated on the test reports ds indicated that these laboratory approved by the laboratory ember 19, 2015.  coratory personnel interviews and counts (CBC) verification of tions record review on 015, the laboratory director failed rification procedures used were rmine the accuracy, precision, ant performance characteristics ens Advia 2120i instruments.	D608	D6086 #5 The lab directors during the period covered by the survey no longer land position with the lab. The nelab director was hired after the or survey had been completed.  The lab has completed an assess to identify any patients affected chaving the potential to be affected this issue.  The lab will ensure that the new ladirector effectively implements a monitors lab procedures, includir verification procedures, through oversight during monthly QA meetings, through audits perform pursuant to the lab's new audit	hold ew n-site ment or d by lab und	2/12/16

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIE A. BUILDING	PLE CONSTRUCTION  G		E SURVEY IPLETED	
		05D2025714	B. WING		11/	20/2015	
THERAN	PROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		DE		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORI (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
D6086	c. Between Febru 2015, the laborator patient CBC 2120i #1. From No. 19, 2015, the labor 67 patient CBC tes #2.  6. Based on revied documentation, ob the general supervialled to ensure that the mean normal pto implementing a (thromboplastin) of Findings include:  a. Dade Innovin (539280 was put into b. The test system seconds) be calculof Innovin.  c. The MNPT spell Innovin was to be ed.  d. The MNPT was approximately 3:25 MNPT was entered e. Review of the MNPT data was perfected to the month of	pary 2015 and September 21, by performed and reported test results using the Advia ovember 6, 2015 to November atory performed and reported at results using the Advia 21201 aw of documentation, lack of servation and interview with isor, the laboratory director at the laboratory determined rothrombin time (MNPT) prior new lot number of Innoving the Siemens BCS XP.  Attromboplastin) lot number to use in March 2015.  The required that the MNPT (in ated for each new lot number of entered into the BCS XP.  Sobserved on 9/23/15 at 5 pm revealed the correct of into the BCS XP.  MNPT data revealed that the enformed on 9/18/15.  Appervisor stated that there and March 2015; however, the	D608	D6068 #5 (continued) procedures, and through us on-site visit log that record director's time spent physi lab.  This improved oversight w that the new lab director in the lab's enhanced procedu method verification. Befor verification studies are per these improved procedures lab director's review and a detailed method verification containing defined accepta The lab director must also approve the verification re any patient testing begins. conducted training on thos procedures.	Is the lab cally in the vill ensure applements ares for re any formed, a require the pproval of a on plan ance criteria. review and port before The lab has		

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTI A. BUILDIN B. WING	G	DATE SURVEY COMPLETED
NAME OF PROVIDER OR SUPPLIER  THERANOS INC			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	11/20/2015	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL 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
D6086	c. Between Feb 2015, the laborate patient CBC 2120i #1. From N 19, 2015, the laborate 67 patient CBC to #2.  6. Based on revidocumentation, of the general superfailed to ensure the mean normal to implementing a (thromboplastin) Findings include:  a. Dade Innovin 539280 was put in b. The test systeseconds) be calcord innovin.  c. The MNPT syllnnovin was to be d. The MNPT was entered.  d. The MNPT was entered.  e. Review of the MNPT data was put in the mean normal to implementing a complete for the model.	ruary 2015 and September 21, bry performed and reported 2 test results using the Advia November 6, 2015 to November oratory performed and reported est results using the Advia 2120 liew of documentation, lack of bservation and interview with visor, the laboratory director at the laboratory determined prothrombin time (MNPT) prior a new lot number of Innovin on the Siemens BCS XP.  (thromboplastin) lot number not use in March 2015.  The performed on 9/23/15 at 25 pm revealed the correct end into the BCS XP.  (MNPT data revealed that the performed on 9/18/15.  Supervisor stated that there om March 2015; however, the bould not be located.	D608	D6068 #6: The lab directors during the period covered by the survey no longer hole any position with the lab. The new ladirector was hired after the on-site survey had been completed.  This PT/INR issue related to one reagent lot. The lab paused testing of the Siemens BCS XP, including PT/INR, during the survey. The lab has also completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The lab will ensure that the new lab director effectively implements and monitors lab procedures, including reagent qualification and manageme procedures, through oversight during monthly QA meetings, through audit performed pursuant to the lab's new audit procedures, and through use	nt g

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		COMPLETED		
		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER	,		7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPE DEFICIENCY)	BE	(X5) COMPLETION DATE
D6093	493.1445(e)(5) LAIRESPONSIBILITIE  The laboratory direquality control programintained to assuservices provided as they occur.  This STANDARD  1. Based on laboratine direct observations reviews, the laboratine direct observations as they occur. The ensure that the laboratory included least once each datassayed (see D544 commercially assawere verified (see was checked for its D5477), results of the laboratory's crit D5481), and the laquality control correduction of the laboratory director D5779).  2. Based on revietime/international reprocedure, quality interview with the glaboratory director PT/INR was accepresults and failed to	BORATORY DIRECTOR	D60		LIJOUAN #N (CONTINUEC)	the lab s a for an PT) lot t d to are	

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		05D2025714	B. WING			11/2	0/2015
NAME OF	PROVIDER OR SUPPLIER		7333 GATE		REET ADDRESS, CITY, STATE, ZIP CODE  133 GATEWAY BLVD  EWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATI DEFICIENCY)	E	(X5) COMPLETION DATE
D6093	493.1445(e)(5) LA RESPONSIBILITII  The laboratory direquality control programintained to assist services provided as they occur. This STANDARD  1. Based on laboratine to the laboratine to be evaluated as they occur. The laboratine that quality control and maintained to services provided as they occur. The ensure that the laboratory included least once each dassayed (see D54 commercially assawere verified (see was checked for it D5477), results of the laboratory's crip5481), and the laboratory in the	BORATORY DIRECTOR	D60	093	D6093 #1 The lab directors during the period covered by the survey no longer hol any position with the lab. The new l director was hired after the on-site survey had been completed.  The lab has completed an assessment to identify any patients affected or having the potential to be affected be this issue.  The lab will ensure that the new lab director effectively implements and monitors lab procedures, including a lab's improved quality systems and related procedures, through oversign during monthly QA meetings, through audits performed pursuant to the lab new audit procedures, and through upon a new on-site visit log that record the lab director's time spent physical in the lab.	nt  by  the ht igh b's use ds	2/12/16
	time/international procedure, quality interview with the laboratory director PT/INR was accepted in the procedure of the proc	ew of the prothrombin normalized ratio (PT/INR) control (QC) records and general supervisor, the failed to ensure that the QC for otable prior to reporting patient to identify that the QC data eater than 2 standard			D6093 #2 The lab directors during the period covered by the survey no longer hol any position with the lab. The new l director was hired after the on-site survey had been completed.	ld	2/12/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION  A. BUILDING			(X3) DATE SURVEY COMPLETED		
		05D2025714	B. WING			11/2	20/2015
NAME OF F	PROVIDER OR SUPPLIER  OS INC			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES / MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE	(X5) COMPLETION DATE
D6093	deviations (SD) from September 2015. For a. CL SOP-10001 Prothrombin Time-IBCS XP Instrument 8.6 that if control varieties determined range, instrument perform that identification at should be document results.  b. QC records for were reviewed from c. The general suracceptable if the varieties.  d. From April 1, 20 2015, 32 of 69 days were greater than 2 e. On 4/7/15, Citro an acceptable QC virial acceptable QC virial for a consideration of the varieties of the	n April 2015 through	D60	093	D6093 #2 (continued) In addition, the lab paused testin the Siemens BCS XP, including PT/INR, during the survey. The has also completed an assessmer identify any patients affected or having the potential to be affected this issue.  The lab will ensure that the new director effectively implements a monitors lab procedures, includi procedures, through oversight dumonthly QA meetings, through a performed pursuant to the lab's a audit procedures, and through us new on-site visit log that records lab director's time spent physical the lab.  This improved oversight will ensure that the new lab director implement the lab's enhanced QC procedure which reinforce and detail the reinvestigation and corrective action must occur to address QC issues before patient tests are performed clarify which employees are responsible for performing and documenting these activities. The has conducted training and competency to ensure that practic consistent with them.	lab nt to ed by lab and ng QC uring nudits new se of a the lly in sure ents es, quired on that d and	

	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIN	, , ,	TE SURVEY MPLETED
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NAME OF I	PROVIDER OR SUPPLIE	R		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R 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
D6093	j. TheRule Che QC values in Apr 7 in June 2015; 1 August and 24 of violation message k. On approximadjusted the accommatch the data. without any invessift in control val. patients without any invessift in control val. patients withough 9/16/15. 493.1445(e)(5) L. RESPONSIBILIT The laboratory diquality assessme maintained to asservices provided as they occur. This STANDARD 1. Based on lab direct observation reviews, the laboratory serviews, the laboratory serviews, the laboratory serviews, the laboratory services in quality director failed to D5391 and D539 D5793) systems were established	eck report revealed that 13 of 13 il 2015, 2 of 17 in May 2015, 7 of 3 of 13 in July 2015, 16 of 16 in 24 9/1-9/16 2015 showed rule es related to Citrol 3.  ately 9/16/15, the labortory eptable range for Citrol 3 to This change was implemented tigation as to the reason for the lues.  were reported from 4/1/15  ABORATORY DIRECTOR	D609		

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPI A. BUILDING	X2) MULTIPLE CONSTRUCTION A. BUILDING		E SURVEY PLETED
		05D2025714 B. WING 11/2		20/2015		
NAME OF I	PROVIDER OR SUPPLIE	R	7	TREET ADDRESS, CITY, STATE, ZIP CODE 1333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D6093	j. TheRule Che QC values in Apr 7 in June 2015; 1 August and 24 of violation message k. On approxim adjusted the acce match the data. without any inves shift in control va	ack report revealed that 13 of 13 il 2015, 2 of 17 in May 2015, 7 of 3 of 13 in July 2015, 16 of 16 in 24 9/1-9/16 2015 showed rule es related to Citrol 3.  ately 9/16/15, the labortory eptable range for Citrol 3 to This change was implemented tigation as to the reason for the	D6093	D6094 #1 (continued) The lab will ensure that the new director effectively implements monitors these procedures thro audits performed pursuant to the new audit procedures, through oversight during monthly QA meetings, and through use of a on-site visit log that records the director's time spent physically lab.	s and ugh ne lab's new e lab	
D6094	RESPONSIBILIT The laboratory diquality assessme maintained to asservices provided as they occur. This STANDARD 1. Based on lab direct observation reviews, the laboratory diaboratory services in quality director failed to 0 D5391 and D539 D5793) systems were established 2. Based on rev	ABORATORY DIRECTOR IES rector must ensure that the ent programs are established and sure the quality of laboratory and to identify failures in quality is not met as evidenced by: coratory personnel interviews, as, and quality control document ratory director failed to ensure esament programs were maintained to assure the quality vices provided and to identify as they occur. The laboratory ensure that preanalytic (see 3) and analytic (see D5791 and quality assessment programs, followed, and effective.	D6094	D 6094 #2: The lab directors during the pe covered by the survey no longe		2/12/16

AND PLAN OF CORRECTION IDENTIF		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDING	PLE CONSTRUCTION		E SURVEY PLETED
		05D2025714	B. WING			20/2015
THERAN	PROVIDER OR SUPPLIE	R		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APP DEFICIENCY)	DULD BE	(X5) COMPLETION DATE
D6094	identify failures in Normalized Ratio the quality of the include:  a. The Dada Ini was used past the D5413.  b. The quality of through 9/16/15 rabove normal we value was lower reported).  c. The target IN therapy was 2-3.  d. Datients we through 9/21/15.  e. Datients we through 9/21/15.  e. Datients we through 9/21/15.  There was no other documental failure had been 493.1445(e)(8) LRESPONSIBILITY.  The laboratory did of test results incorrequired for intering This STANDARD.	Prothrombin Time/International (PT/INR) testing which affected PT/INR patient results. Findings novin (thromboplastin) reagent e expiration date. Refer to control data from 4/1/2015 revealed that patient results are biased low (i.e., reported than it should have been all value for patients on Warfarin were reported from 4/1/15 retained and of the control of the control data from 4/1/15 retained and corrected. The control data from 4/1/15 retained and corrected. ABORATORY DIRECTOR rector must ensure that reports all depertment information	D6094	D6094 #2 (continued) hold any position with the lainew lab director was hired at on-site survey had been completed and assess identify any patients affected having the potential to be affectively implementations. The lab will ensure that the monitors lab procedures, inciprocedures, through oversight monthly QA meetings, through oversight monthly QA meetings, through oversight monthly QA meetings, through oversight will that the new lab director's time spent phythe lab.  This improved oversight will that the new lab director improved oversight will be a lab director improved oversight will	eter the pleted.  sting on ing The lab ment to lor lected by  new lab nts and luding QC at during gh audits o's new th use of a brds the sically in lements dures, e required action that sues ormed,	

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		(X2) MULTIF A. BUILDING B. WING	S	(X3) DATE SURVEY COMPLETED	
NAME OF F	PROVIDER OR SUPPLIE	ER		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	1720/2010
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES NCY MUST BE PRECEDED BY FULL R 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
D6094	Normalized Ratio the quality of the include:  a. The Dada Ini was used past the D5413.  b. The quality of through 9/16/15 is above normal we value was lower reported).  c. The target IN therapy was 2-3.	page 86 a Prothrombin Time/International b (PT/INR) testing which affected PT/INR patient results. Findings  novin (thromboplastin) reagent e expiration date. Refer to  control data from 4/1/2015 revealed that patient results are biased low (i.e., reported than it should have been  IR value for patients on Warfarin were reported from 4/1/15	D6094	D6094 #2 (continued) documenting these activities. The lab has conducted training and competency testing on those procedures to ensure that practice is consistent with them.	
D6098	f. There was nother documental failure had been 493.1445(e)(8) L RESPONSIBILITY The laboratory did of test results increquired for inter This STANDARD Based on review interview with the	than or equal to 3 reported.  o quality assessment (QA) or tion to indicate that the PT/INR identified and corrected.  ABORATORY DIRECTOR TES  rector must ensure that reports clude pertinent information	D6098	D6098 The lab directors during the period covered by the survey no longer hold any position with the lab. The new ladirector was hired after the on-site survey had been completed.  The lab revised its patient reports for PT/INR during the survey so that the	b

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		05D2025714	B. WING			20/2015
THERAN	PROVIDER OR SUPPLIE	R	7	TREET ADDRESS, CITY, STATE, ZIP COD 333 GATEWAY BLVD IEWARK, CA 94560	E	
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE API DEFICIENCY)	IOULD BE	(X5) COMPLETION DATE
D6098	interpretive data of Time/International final reports was Warfarin therapy Refer to D5805.	on the Prothrombin al Normalized Ratio (PT/INR) clear to differentiate between and non-Warfarin therapy.  LABORATORY DIRECTOR	D6098	the heading for patients und The lab has completed an as to identify any patients affect having the potential to be af this issue.	er therapy. ssessment eted or fected by	
	testing patients's the appropriate e receive the appropriate. This STANDARD Based on review interview with the Assurance/Qualit supervisor and te failed to documer on the to patient testing in the vacutainer prior to patient testing ii. Eleven testin iii. Eleven testin iii. Eleven testin iii. Eight of elever any documentation	rector must ensure that prior to specimens, all personnel have ducation and experience, priate training for the type and services offered, and have at they can perform all testing y to provide and report accurate is not met as evidenced by: of training documents and QA/QC (Quality y) Control) Manager, technical sting personnel, the laboratory at training of testing personnel prior and failed to document training laboratory of testing personnel sting. Findings include:  Manager and technical that all training documentation testing personnel files were reviewed. The personnel files did not include on of training on the prior to rting patient test results.		The new lab director has apprevised reporting procedures require the technical superviverify that interpretive infor accurate and to obtain approache lab director or clinical cobefore any updates are impless. The lab will ensure that the director effectively implement monitors these procedures that audits performed pursuant to new audit procedures, throu oversight during monthly Queetings, and through use of on-site visit log that records director's time spent physical lab.  (D6102 begins on next page)	s that isor to mation is oval from onsultant emented.  new lab ents and nrough o the lab's gh A f a new the lab ally in the	

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A BUILDING	LE CONSTRUCTION	СОМ	E SURVEY PLETED
NAME OF	PROVIDER OR SUPPLIE	05D2025714 R		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	1 11/	20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPR DEFICIENCY)	JLD BE	(X5) COMPLETION DATE
D6098	interpretive data of Time/International final reports was Warfarin therapy Refer to D5805. 493.1445(e)(12) RESPONSIBILIT The laboratory ditesting patients' st the appropriate ereceive the appropriate of the demonstrated the assurance/Quality supervisor and testing in the vacutainer prior to patient testing in the vacutainer p	on the Prothrombin al Normalized Ratio (PT/INR) clear to differentiate between and non-Warfarin therapy.  LABORATORY DIRECTOR IES rector must ensure that prior to specimens, all personnel have ducation and experience, opriate training for the type and services offered, and have at they can perform all testing by to provide and report accurate is not met as evidenced by: of training documents and	D6102	D6102 The lab directors during the pe	er hold new lab resite essment ed or cted by oved e that l, have apetent any those has e is	2/12/16

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		05D2025714	B. WING		11/2	20/2015
NAME OF I	PROVIDER OR SUPPLIER  OS INC		7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPROPERTION OF T	D BE	(X5) COMPLETION DATE
D6102	supervisor stated the was kept in each tee.  b. Three testing person not include docume Advia 2120i, Eldon the Centaur, IRIS, Ed.  d. TP6 stated that completed as of 9/2 running and reportin April 2015. TP6 alson the training docusigned off were perhad not occurred.  e. TP6 confirmed at approximately 3:3  f. Testing Person did not include documulite, BC SXP, MacroVu RPR, Mul Liaison.  g. TP6 stated that patient test results the test results the testing Person documentation include and the testing Person documentation include testing Person documentation includ	aboratory  anager and technical nat all training documentation sting person's employee file.  ersonnel files were reviewed.  #6 (TP6) training records did entation for the Siemens XPT, Card, and were incomplete for 3C SXP and Cellavision.  training had not been 23/15; however PT6 had been ng patient test results since so stated that activities listed amentation which were not formed by TP6, but training  the above findings on 9/23/15 30 pm.  #11 (TP11) training records amentation for the Advia, Advia 2120i, Centaur, tispot HIV, and Diasorin  TP11 ran and reported from these systems.  #31 (TP31)'s training uded documents on critical values logsheets. No other	D6102	D6102 (continued) audit procedures, through overs during monthly QA meetings, a through use of a new on-site vis that records the lab director's ti spent physically in the lab.	nd sit log	

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AND PLAN OF CORRECTION IDENTIFIC		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTI A. BUILDIN B. WING	PLE CONSTRUCTION  G	COM	E SURVEY IPLETED 20/2015
NAME OF I	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODI 7333 GATEWAY BLVD NEWARK, CA 94560		20/2015
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D6102	i. The general sibeen running and j. The general sitraining documents for three of three to 11:40 am. 493.1447 LABORA SUPERVISOR  The laboratory must who meets the quasive supervision in accession in	upervisor stated that TP31 had releasing patient test results.  upervisor confirmed that the swere missing or incomplete esting personnel on 11/19/15 at ATORY TECHNICAL  st have a technical supervisor alification requirements of subpart and provides technical ordance with §493.1451 of this is not met as evidenced by the nerein, the Condition: rming high complexity testing; or was not met. Two of three persons failed to meet the training or ement in one or more ecialties (see D6111), and the persons failed to ensure the erformance specifications for were wed the laboratory's procedure CAL SUPERVISOR	D610	D6108 The lab has corrected this issensuring that all of its technical supervisors meet the training experience requirements. The director is the technical superchemistry, hematology, and immunohematology. CMS a qualified the lab's other tech supervisor for microbiology diagnostic immunology.  TS1 and TS2 are no longer to supervisors for the lab. It is noting, however, that CMS of TS1 as a technical supervisor chemistry and found that TS months away from qualifying hematology and immunology.	g and he new lab ervisor for lready mical and echnical worth qualified r for 1 was just g for y. In oring to s former site	2/12/16

		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  (X2) ML A. BUIL		LE CONSTRUCTION	(X3) DATE SU COMPLET	
		05D2025714	B. WING		11/20/2	2015
NAME OF I	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE CO	(X5) MPLETION DATE
D6102	i. The general si been running and j. The general si training documents for three of three to 11:40 am.	upervisor stated that TP31 had releasing patient test results.  upervisor confirmed that the swere missing or incomplete esting personnel on 11/19/15 at	D6102	this issue (see 06111, 06115).  The new lab director has appropriate and procedu governing personnel qualificate defining among other things.	oved res ion and	
D6108	The laboratory mu who meets the qua §493.1449 of this is supervision in accessible and followed by the complete and followed by the complete and followed by the current license issuboratory is locate and (b) The laboratory	st have a technical supervisor alification requirements of subpart and provides technical ordance with §493.1451 of this lis not met as evidenced by the and severity of the nerein, the Condition: rming high complexity testing; or was not met. Two of three ors failed to meet the training or ment in one or more cialties (see D6111), and the ors failed to ensure the erformance specifications for were wed the laboratory's procedure.  CAL SUPERVISOR  supervisor must possess a used by the State in which the ed, if such licensing is required; may perform anatomic and procedures and tests in all	D6108	education and experience requirements for a technical supervisor (see 06111). The notice of the director has also approved enhance of performance specifications (see 06115). The has conducted training on these procedures to ensure that its procedures to ensure that its procedures to ensure that its procedures to the establishment of performance specifications (see 06115).  In addition, the lab has improve quality systems and procedures including quality assurance reconstructions, and audits—to prefere the procedures of the proce	ew lab anced e lab e actice is 1 and ed its s— view, vent	

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AND PLAN OF CORRECTION IDENTIFICATION NUM		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	A. BUILDIN	PLE CONSTRUCTION  G	(X3) DATE SURVEY COMPLETED	
NAME OF I	PROVIDER OR SUPPLIE	05D2025714 R	B. WING	STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	11/2	20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROVIDENCY)	D BE	(X5) COMPLETION DATE
D6102	i. The general speen running and j. The general straining document for three of three 11:40 am.	page 89 supervisor stated that TP31 had releasing patient test results. supervisor confirmed that the ts were missing or incomplete testing personnel on 11/19/15 at	D610			
D6106	The laboratory members the question of the laboratory members the question of the laboratories perfected as the laboratories and the laboratories laboratories and the l	ust have a technical supervisor delification requirements of subpart and provides technical cordance with §493.1451 of this lis not met as evidenced by mber and severity of the herein, the Condition: forming high complexity testing; sor was not met. Two of three sors failed to meet the training or mement in one or more ecialties (see D6111), and the sors failed to ensure the performance specifications for were lowed the laboratory's procedure	D610	8		
D6111	(a) The technical current license is laboratory is local and (b) The laboratory	SUPERVISOR Supervisor must possess a sued by the State in which the ted, if such licensing is required; may perform anatomic and procedures and tests in all	D611	The lab has corrected this issue ensuring that all of its technical supervisors meet the training ar experience requirements. The n director is the technical supervichemistry, hematology, and	l nd new lab	2/12/16

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NAME OF	PROVIDER OR SUPPLIE			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560		20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORREC (EACH CORRECTIVE ACTION SHO CROSS-REFERENCED TO THE APPI DEFICIENCY)	OULD BE	(X5) COMPLETION DATE
D6111	specialties and substocompatibility services provided technical supervise (b)(1) Is a doctor osteopathy licens osteopathy in the located; and (b)(2) Is certified in pathology by the American Ost Possesses qualifit those required for (c) If the requirem section are not matests in the subspindividual function must(c)(1)(i) Be a doctoosteopathy licens osteopathy in the located; and (c)(1)(ii) Be certificated (c)(2)(ii) Be a doctoosteopathy, or do licensed to practic podiatry in the Stalocated; and (c)(2)(ii) Have at I training or experiencesting within the minimum of 6 mo	and clinical cytogenetics the individual functioning as the sor of medicine or doctor of ed to practice medicine or State in which the laboratory is n both anatomic and clinical American Board of Pathology or eopathic Board of Pathology or cations that are equivalent to such certification. The entry of paragraph (b) of this et and the laboratory performs ecialty of bacteriology, the hing as the technical supervisor for of medicine or doctor of ed to practice medicine or State in which the laboratory is ed in clinical pathology by the of Pathology or possess are equivalent to those required	D611	D6111 (continued) immunohematology. CMS al qualified the lab's other techn supervisor for microbiology a diagnostic immunology.  TS1 and TS2 are no longer to supervisors for the lab. It is noting, however, that CMS q TS1 as a technical supervisor chemistry and found that she months away from qualifying hematology and immunology addition, TS2 is still endeavo obtain documents from his for employers to show that he har requisite experience (see 061  The lab has completed an ass to identify any patients affect having the potential to be affethis issue (see 06111, 06115)  The new lab director has apprenhanced policies and proceed governing personnel qualificate defining, among other things education and experience requirements for a technical supervisor (see 06111). The director has also approved en procedures related to the	echnical worth ualified for was just g for v. In ring to ormer s the 11).  essment red or rected by roved dures ation and the new lab	

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	. ,		E CONSTRUCTION		SURVEY PLETED
		05D2025714	B. WING			11/2	20/2015
THERAN				7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  Y MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFI TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPOSITION OF THE PROPOSITION OF THE PR	BE	(X5) COMPLETION DATE
D6111	chemical, physical, science from an ac (c)(3)(ii) Have at lead or experience, or both within the specialty minimum of 6 month complexity testing within the special physical, science or medical institution; and (c)(4)(ii) Have at lead training or experient testing within the special physical, science or medical institution; and (c)(4)(ii) Have at lead training or experient testing within the special physical, medical technology and (c)(5)(ii) Have at lead training or experient testing within the special physical, medical technology and (c)(5)(iii) Have at lead training or experient testing within the special physical phacteriology. (d) If the requirement section are not met tests in the subspecting individual functioning must—(d)(1)(i) Be a doctor osteopathy licensed	ge 91  Immed doctoral degree in a biological or clinical laboratory credited institution; and ast 1 year of laboratory training oth, in high complexity testing of microbiology with a hs experience in high within the subspecialty of  ed a master's degree in a biological or clinical laboratory technology from an accredited  ast 2 years of laboratory ce, or both, in high complexity becialty of microbiology with a hs experience in high within the subspecialty of  ed a bachelor's degree in a or biological science or from an accredited institution; ast 4 years of laboratory ce, or both, in high complexity becialty of microbiology with a hs experience in high within the subspecialty of  must be paragraph (b) of this and the laboratory performs cialty of mycobacteriology, the ng as the technical supervisor  of medicine or doctor of to practice medicine or tate in which the laboratory is	D6	1111	D6111 (continued) establishment of performance specifications (see 06115). The has conducted training on these procedures to ensure that its praconsistent with them (see 06111 06115).  In addition, the lab has improved quality systems and procedures—including quality assurance review monitoring, and audits—to prever recurrence (see 06111 and 06115).	d its	

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	•	05D2025714	B. WING			11/2	20/2015	
NAME OF	PROVIDER OR SUPPLIER		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560					
(X4) ID PREFIX TAG	(EACH DEFICIENC)	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE	(X5) COMPLETION DATE	
D6111	American Board of Osteopathic Board qualifications that a for such certificatio (d)(2)(i) Be a docto osteopathy, or doct licensed to practice podiatry in the State located; and (d)(2)(ii) Have at least or experience, or bowithin the specialty minimum of 6 monto complexity testing of the mical, physical, science from an actification (d)(3)(ii) Have at least or experience, or bowithin the specialty minimum of 6 monto complexity testing of the mical, physical, science or medical institution; and (d)(4)(ii) Have at least institution; and (d)(4)(iii) Have at least institution; and (d)(4)(iiii) Have at least institution; and (d)(4)(iiiii) Have at least institution; and (d)(4)(iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	d in clinical pathology by the Pathology or the American of Pathology or possess are equivalent to those required in; or of medicine, doctor of or or podiatric medicine a medicine, osteopathy, or in which the laboratory training oth, in high complexity testing of microbiology with a thing experience in high within the subspecialty of or arned doctoral degree in a biological or clinical laboratory credited institution; and last 1 year of laboratory training oth, in high complexity testing of microbiology with a thing experience in high within the subspecialty of or ed a master's degree in a biological or clinical laboratory technology from an accredited last 2 years of laboratory technology from an accredited east 2 years of laboratory on both, in high complexity of one content of the possession of the pathology from an accredited last 2 years of laboratory on both, in high complexity of the possession of the possession of the pathology with a the experience in high within the subspecialty of	D6	111	(continued; see above)			

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NAME OF I	PROVIDER OR SUPPLIER		7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULI CROSS-REFERENCED TO THE APPROF DEFICIENCY)	) BE	(X5) COMPLETION DATE
D6111	training or experient testing within the spring minimum of 6 months complexity testing within the spring mycobacteriology.  (e) If the requirement section are not metatests in the subspecial individual functioning mustage.  (e)(1)(i) Be a doctorous osteopathy licensed osteopathy in the Slocated; and (e)(1)(ii) Be certified American Board of Osteopathic Board qualifications that a for such certification (e)(2)(i) Be a doctorous depote to practice podiatry in the State located; and (e)(2)(ii) Have at less or experience, or bowithin the specialty minimum of 6 months complexity testing with mycology; or (e)(3)(i) Have an each chemical, physical, science from an accine (e)(3)(ii) Have at less or experience, or box or expe	ast 4 years of laboratory ce, or both, in high complexity becialty of microbiology with a ths experience in high within the subspecialty of this and the laboratory performs cialty of mycology, the gas the technical supervisor of medicine or doctor of to practice medicine or tate in which the laboratory is d in clinical pathology by the Pathology or the American of Pathology or possess re equivalent to those required	D6111	(continued; see above)		

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		05D2025714	B. WING			11/2	20/2015
NAME OF I	PROVIDER OR SUPPLIER			73	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD EWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	<b>(</b>	PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	BE	(X5) COMPLETION DATE
D6111	complexity testing mycology; or (e)(4)(i) Have earn chemical, physical science or medica institution; and (e)(4)(ii) Have at letraining or experient testing within the sminimum of 6 more complexity testing mycology; or (e)(5)(ii) Have earn chemical, physical medical technolog and (e)(5)(ii) Have at letraining or experient testing within the sminimum of 6 more complexity testing mycology. (f) If the requirement section are not metests in the subspection are not metests in the subspection in the subspection are not metests in the subspec	age 94  Iths experience in high within the subspecialty of ed a master's degree in a biological or clinical laboratory technology from an accredited east 2 years of laboratory pecialty of microbiology with a liths experience in high within the subspecialty of ed a bachelor's degree in a or biological science or y from an accredited institution; east 4 years of laboratory nee, or both, in high complexity pecialty of microbiology with a liths experience in high within the subspecialty of east 4 years of laboratory nee, or both, in high complexity pecialty of microbiology with a liths experience in high within the subspecialty of ents of paragraph (b) of this et and the laboratory performs ecialty of parasitology, the ng as the technical supervisor of medicine or a doctor of ed to practice medicine or State in which the laboratory is d in clinical pathology by the f Pathology or the American	D61	11	(continued; see above)		
	Osteopathic Board qualifications that for such certification	of Pathology or possess are equivalent to those required					

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		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:				(3) DATE SURVEY COMPLETED	
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NAME OF	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUI CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D6111	licensed to practice podiatry in the Stat located; and (f)(2)(ii) Have at least training or experier testing within the siminimum of 6 mon complexity testing parasitology; (f)(3)(ii) Have an each emical, physical, science from an act (f)(3)(ii) Have at least or experience, or by within the specialty minimum of 6 mon complexity testing parasitology; or (f)(4)(ii) Have earned chemical, physical, science or medical institution; and (f)(4)(ii) Have at least training or experier testing within the siminimum of 6 mon complexity testing parasitology; or (f)(5)(ii) Have earned chemical, physical medical technology and (f)(5)(iii) Have at least training or experier testing within the siminimum of 6 mon complexity testing the minimum of 6 mon complexity testing the	age 95 tor of podiatric medicine e medicine, osteopathy, or e in which the laboratory nce, or both, in high complexity pecialty of microbiology with a ths experience in high within the subspecialty of arred doctoral degree in a biological or clinical laboratory credited institution; and ast 1 year of laboratory training oth, in high complexity testing of microbiology with a ths experience in high within the subspecialty of  and a master's degree in a biological or clinical laboratory technology from an accredited ast 2 years of laboratory nce, or both, in high complexity pecialty of microbiology with a ths experience in high within the subspecialty of and a bachelor's degree in a or biological science or or from an accredited institution; ast 4 years of laboratory nce, or both, in high complexity pecialty of microbiology with a ths experience in high within the subspecialty of the da bachelor's degree in a or biological science or or from an accredited institution; ast 4 years of laboratory nce, or both, in high complexity pecialty of microbiology with a ths experience in high within the subspecialty of	D611	(continued; see above)			

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Event ID: W34211

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PROVIDER'S PLAN OF CORRECTION PREFIX (EACH CORRECTIVE ACTION SHOULD TAG CROSS-REFERENCED TO THE APPROPROPRIES OF THE PROPROPROPRIES OF THE PROPROPROPRIES OF THE PROPROPROPRIES OF THE PROPROPROPROPROPROPROPROPROPROPROP		BE	(X5) COMPLETION DATE	
D6111	parasitology. (g) If the requireme section are not met tests in the subspect functioning as the treatment of tests in the subspect functioning as the treatment of tests in the subspect functioning as the treatment of the subspect of the s	ints of paragraph (b) of this and the laboratory performs cialty of virology, the individual echnical supervisor mustar of medicine or doctor of to practice medicine or tate in which the laboratory is d in clinical pathology by the Pathology or the American of Pathology or possess are equivalent to those required	D6	1111	(continued; see above)		

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Event ID: W34211

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION  A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/	20/2015
NAME OF I	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	•	
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D6111	training or experient testing within the sprinimum of 6 mont complexity testing wirology; or (g)(5)(i) Have earned chemical, physical medical technology and (g)(5)(ii) Have at least training or experient testing within the sprinimum of 6 mont complexity testing wirology.  (h) If the requirement section are not met tests in the specialt the individual function supervisor mustich)(1)(i) Be a doctorosteopathy licensed osteopathy licensed osteopathic Board qualifications that a for such certification (h)(2)(i) Be a doctorosteopathy, or doct licensed to practice podiatry in the State located; and (h)(2)(ii) Have at least or experience, or be complexed.	ast 2 years of laboratory ce, or both, in high complexity becialty of microbiology with a chs experience in high within the subspecialty of ed a bachelor's degree in a or biological science or from an accredited institution; ast 4 years of laboratory ce, or both, in high complexity becialty of microbiology with a chs experience in high within the subspecialty of  and the laboratory performs y of diagnostic immunology, oning as the technical  r of medicine or a doctor of d to practice medicine or tate in which the laboratory is d in clinical pathology by the Pathology or possess re equivalent to those required	D6111	(continued; see above)		

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STATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		(X2) MULTII A. BUILDINI B. WING			(X3) DATE SURVEY COMPLETED 11/20/2015	
NAME OF I	PROVIDER OR SUPPLIE	R		STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTIV CROSS-REFERENCED TO TH DEFICIENCY	ON SHOULD BE IE APPROPRIATE	(X5) COMPLETION DATE
D6111	chemical, physical science from an al (h)(3)(ii) Have at I or experience, or within the specialt (h)(4)(i) Have earlichemical, physical science or medical institution; and (h)(4)(ii) Have at I training or experience testing for the special form of the special form o	earned doctoral degree in a al, biological or clinical laboratory accredited institution; and east 1 year of laboratory training both, in high complexity testing by of diagnostic immunology; or ned a master's degree in a al, biological or clinical laboratory al technology from an accredited east 2 years of laboratory ence, or both, in high complexity exialty of diagnostic immunology; and a bachelor's degree in a all or biological science or gy from an accredited institution; east 4 years of laboratory ence, or both, in high complexity exialty of diagnostic immunology, ents of paragraph (b) of this et and the laboratory performs alty of chemistry, the individual atechnical supervisor mustate or of medicine or doctor of ed to practice medicine or State in which the laboratory is add in clinical pathology by the of Pathology or the American dof Pathology or possess are equivalent to those required		(continued; see below)		

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Event ID: W34211

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPI A. BUILDING	E CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
		05D2025714	B. WING		11/	20/2015
NAME OF	PROVIDER OR SUPPLIER		7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560	•	
(X4) ID PREFIX TAG	(EACH DEFICIENC)	TEMENT OF DEFICIENCIES  MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECT (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D6111	or experience, or be for the specialty of (i)(3)(i) Have an ear chemical, physical, science from an ac (i)(3)(ii) Have at leas or experience, or be within the specialty (i)(4)(i) Have earne chemical, physical, science or medical institution; and (i)(4)(ii) Have at least training or experient testing for the spec (i)(5)(i) Have earne chemical, physical medical technology and (i)(5)(ii) Have at least training or experient testing for the spec (j) If the requirement esting for the special functioning as the total content of the special functioning as the total content estimated and (j)(1)(ii) Be certified American Board of Osteopathic Board qualifications that a for such certification	ast 1 year of laboratory training oth, in high complexity testing chemistry; or red doctoral degree in a biological or clinical laboratory credited institution; and ast 1 year of laboratory training oth, in high complexity testing of chemistry; or d a master's degree in a biological or clinical laboratory technology from an accredited ast 2 years of laboratory technology from an accredited ast 2 years of laboratory in the complexity is a bachelor's degree in a correct or from an accredited institution; ast 4 years of laboratory and a bachelor's degree in a correct or from an accredited institution; ast 4 years of laboratory are, or both, in high complexity is and the laboratory performs and the laboratory performs by of hematology, the individual echnical supervisor mustage of medicine or a doctor of a doctor o	D6111	(continued; see above)		

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Event ID: W34211

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		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	IDENTIFICATION NUMBER		2) MULTIPLE CONSTRUCTION BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING			11/3	20/2015	
NAME OF	PROVIDER OR SUPPLIER			7:	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULI CROSS-REFERENCED TO THE APPROF DEFICIENCY)	D BE	(X5) COMPLETION DATE	
D6111	osteopathy, or doc licensed to practic podiatry in the State located; and (j)(2)(ii) Have at letraining or experietesting for the speexample, physicia or hematology and American Board of (j)(3)(ii) Have an exchemical, physical science from an af (j)(3)(ii) Have at letraining or experience, or within the specialt (j)(4)(ii) Have earn chemical, physical science or medical institution; and (j)(4)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience (k)(1) If the requires testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience (k)(1) If the requires testing for the speedical technologiand (j)(5)(ii) Have at letraining or experience (j)(5)(iii) Have at letraining or experience (ji)(5)(iii) Have at letraining or experi	age 100 ctor of podiatric medicine e medicine, osteopathy, or te in which the laboratory is ast one year of laboratory ince, or both, in high complexity cialty of hematology (for ins certified either in hematology if medical oncology by the f Internal Medicine); or arned doctoral degree in a in, biological or clinical laboratory ceredited institution; and ast 1 year of laboratory training both, in high complexity testing y of hematology; or ed a master's degree in a in, biological or clinical laboratory ast 2 years of laboratory ince, or both, in high complexity cialty of hematology; or ed a bachelor's degree in a in or biological science or y from an accredited institution; ast 4 years of laboratory ince, or both, in high complexity cialty of hematology. In the laboratory ince, or both, in high complexity cialty of hematology. In the laboratory ince, or both, in high complexity cialty of hematology. In the laboratory ince, or both, in high complexity cialty of hematology. In the laboratory ince, or both, in high complexity ince, or both, in hi	D6	111	(continued; see above)			

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	1 ' '		E CONSTRUCTION	(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING			11/2	20/2015
NAME OF I	PROVIDER OR SUPPLIER  OS INC			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTIO (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROP DEFICIENCY)	BE	(X5) COMPLETION DATE
D6111	requirements(k)(1)(ii)(A) Be cert the American Board Qualifications that a for such certificatio (k)(1)(ii)(B) Be cert of Cytology to pracqualifications that a for such certificatio (l) If the requirement section are not ment tests in the subspecindividual functionismust(l)(1) Meet one of the (l)(1)(i)(A) Be a docosteopathy licensed osteopathy licensed osteopathy in the Slocated; and (l)(1)(i)(B) Be certification (l)(1)(ii) An individuce such certification (l)(1)(iii) An individuce such certificatio (l)(1)(iii) An individuce such certificatio (l)(1)(iii) An individuce such certification (l)(1)(iii) An individuce such certification (l)(1)(iiii) An individuce such certification (l)(1)(iiiiii) An individuce such certification (l)(1)(iiiiiii) An individuce such certification (l)(1)(iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	ified in anatomic pathology by d of Pathology or the American of Pathology or possess are equivalent to those required in; or ified by the American Society tice cytopathology or possess are equivalent to those required in; or if it is of paragraph (b) of this and the laboratory performs cialty of histopathology, the ing as the technical supervisor the following requirements: stor of medicine or a doctor of it is in which the laboratory is ited in anatomic pathology by d of Pathology or the American of Pathology or possess are equivalent to those required in; all qualified under aragraph (l)(1) of this section individual who is a resident in leading to certification aph (b) or (l)(1)(i)(B) of this sibility for examination and stopathology specimens.	D6	111	(continued; see above)		

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED		
		05D2025714	B. WING			11/2	20/2015
NAME OF	PROVIDER OR SUPPLIER			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES  / MUST BE PRECEDED BY FULL  SC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE	(X5) COMPLETION DATE
D6111	located and (l)(2)(i)(B) I requirements: (l)(2)(i)(B)(1) Be ceil by the American Board American Board of qualifications that a for such certification (l)(2)(i)(B)(3) Be ceil American Board of qualifications that a for such certification (l)(2)(i)(B)(3) Be ceil American Board of qualifications that a for such certification (l)(2)(ii) An individual §493.1449(b) or parany delegate to an a training program specified in paragras section, the responsinterpretation of del (l)(3) For tests one of the following (l)(3)(i)(A) Be a docosteopathy licensed osteopathy in the Slocated and (l)(3)(i)(B) Must me requirements: (l)(3)(i)(B)(1) Be ceil by the American Osteopathy possess qualification required for such ceil	Meet one of the following rtified in anatomic pathology or and of Pathology or the thic Board of Pathology or ons that are equivalent to those ertification; or rtified in dermatopathology by d of Dermatology and the Pathology or possess are equivalent to those required in; or rtified in dermatology by the Dermatology or possess are equivalent to those required in; or all qualified under ragraph (I)(2)(i) of this section individual who is a resident in leading to certification aphs (b) or (I)(2)(i)(B) of this sibility for examination and rmatopathology specimens, in ophthalmic pathology, meet a requirements: stor of medicine or doctor of d to practice medicine or tate in which the laboratory is et one of the following rtified in anatomic pathology or the thic Board of Pathology or ons that are equivalent to those	D6	111	(continued; see above)		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		(X2) MULTIPLE CONSTRUCTION  A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING _		11/	/20/2015
NAME OF	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP ( 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTIOI CROSS-REFERENCED TO THE DEFICIENCY)	N SHOULD BE	(X5) COMPLETION DATE
D6111	of Ophthalmology of are equivalent to the certification and haleast 1 year of form training in ophthalm (I)(3)(ii) An individue §493.1449(b) or paray delegate to an a training program specified in paragrasection, the responsinterpretation of op (m) If the requirem section are not metests in the subspecified in paragrasection are not metests in the subspecification and in the Subspecifica	or possess qualifications that lose required for such live successfully completed at hal post-residency fellowship nic pathology; or al qualified under largraph (1)(3)(i) of this section individual who is a resident in leading to certification laphs (b) or (1)(3)(i)(B) of this lesibility for examination and lithalmic specimens; or lents of paragraph (b) of this late and the laboratory performs leading to certification and lithalmic specimens; or lents of paragraph (b) of this late and the laboratory performs leading of oral pathology, the laboratory is lead in anatomic pathology by the laboratory is lead in anatomic pathology by the laboratory is lead in anatomic pathology by the laboratory is late in which the laboratory is lead in anatomic pathology by the laboratory is late in late laboratory in oral pathology or possess late equivalent to those required late; or late late late late late late late late	D61 <sup>-</sup>	(continued; see above)		

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	l ' '		E CONSTRUCTION		E SURVEY PLETED
		05D2025714	B. WING			11/2	20/2015
NAME OF I	PROVIDER OR SUPPLIER			7	TREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPI DEFICIENCY)	BE	(X5) COMPLETION DATE
D6111	Continued From page	_	D6	111	(continued; see above)		
	individual functioni must (n)(1)(i) Be a doctor osteopathy license osteopathy in the Stocated; and (n)(1)(ii) Be certified American Board of Osteopathic Board qualifications that a for such certification (n)(2)(i) Be a doctor osteopathy, or doctor osteopathy, or doctor podiatry in the Stationary i	or of medicine, doctor of tor of podiatric medicine e medicine, osteopathy, or se in which the laboratory is east 1 year of laboratory training both, in high complexity testing					

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP A. BUILDING	LE CONSTRUCTION		(X3) DATE SURVEY COMPLETED	
NAME OF	PROVIDER OR SUPPLIE	05D2025714	B. WING	STREET ADDRESS, CITY, STATE, ZIP C		/20/2015	
THERAN	3.46.45	n.	7333 GATEWAY BLVD NEWARK, CA 94560				
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PREFIX (EACH CORRECTIVE ACTION SHOULD BE		(X5) COMPLETION DATE	
D6111	testing for the spi (o) If the laborator of histocompatibility (o)(1)(i) Be a doc osteopathy, or do licensed to practipodiatry in the St located; and (o)(1)(ii) Have tracene of the followity (o)(1)(ii)(A) Have experience, or be histocompatibility (o)(1)(ii)(B)(1) Have experience, or immunology; and (o)(1)(ii)(B)(2) Have experience, or histocompatibility (o)(2)(i) Have an biological or clinical accredited institution (o)(2)(ii)(A) Have experience, or be histocompatibility (o)(2)(ii)(B)(1) Have experience, or be histocompatibility (o)(2)(ii)(B)(1) Have experience, or immunology; and (o)(2)(ii)(B)(2) Have experience, or histocompatibility (o)(2)(ii)(B)(2) Have experience, or histocompatibility (o)(1)(ii)(B)(2) Have experience, or histocompatibility (o)(2)(ii)(B)(2) Have experience, or histocompatibility (	ence, or both, in high complexity ecialty of radiobioassay. The specialty of radiobioassay or performs tests in the specialty lity, the individual functioning as ervisor must either—tor of medicine, doctor of podiatric medicine oce medicine, osteopathy, or ate in which the laboratory is sining or experience that meets on requirements:  4 years of laboratory training or oth, within the specialty of general ove 2 years of laboratory training both, in the specialty of general of the specialty of general of training or experience that following requirements:  4 years of laboratory training or oth, within the specialty of general of training or experience that following requirements:  4 years of laboratory training or oth, within the specialty of general of the special of the	D6111	(continued; see above)			

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		1	LE CONSTRUCTION	(X3) DATE SURVEY COMPLETED		
		05D2025714	B. WING		11/:	20/2015
NAME OF I	PROVIDER OR SUPPLIER  OS INC		7	STREET ADDRESS, CITY, STATE, ZIP CODE 333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES Y MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOUL CROSS-REFERENCED TO THE APPRO DEFICIENCY)	D BE	(X5) COMPLETION DATE
D6111	(p)(1)(i) Be a docto osteopathy, or doct licensed to practice podiatry in the State located; and (p)(1)(ii) Have 4 year or both, in genetics clinical cytogenetics (p)(2)(i) Hold an eabiological science, clinical laboratory sinstitution; and (p)(2)(ii) Have 4 year or both, in genetics clinical cytogenetics (q) If the requirement section are not met tests in the specialtindividual functioning must(q)(1)(i) Be a docto osteopathy licensed osteopathy licensed osteopathy in the Stocated; and (q)(1)(ii) Be certified American Board of Osteopathic Board qualifications that a for such certification.  Note: The technica "laboratory training each specialty or siconcurrently in mor subspecialties of seindividual, who has and additionally has	or of medicine, doctor of or of podiatric medicine emedicine, osteopathy, or ein which the laboratory is ars of training or experience, 2 of which have been in si, or rned doctoral degree in a including biochemistry, or cience from an accredited ars of training or experience, 2 of which have been in si, and the laboratory performs by of immunohematology, the ng as the technical supervisor of medicine or a doctor of d to practice medicine or tate in which the laboratory is d in clinical pathology by the Pathology or possess are equivalent to those required		(continued; see above)		

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		05D2025714	B. WING			11/	20/2015
NAME OF I	PROVIDER OR SUPPLIER			73	REET ADDRESS, CITY, STATE, ZIP CODE 33 GATEWAY BLVD EWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFI TAG	x	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE
D6111	high complexity termicrobiology and of work experience in bacteriology, my would qualify as the specialty of chemists bacteriology, mycon This STANDARD Based on review of three technicals required 4 years or both, in a specialty qualify as a technic include:  a. Training docur for three technical by Technical Sup QA/QC Manager's documentation was each employee.  c. TS1 was unably which showed 4 years or hematology or immed. Technical Sup provided documentation was each employee.  d. Technical Sup provided documentation and/or experience in high hematology or immed. Technical Sup provided documentation and/or experience for hematology or immediately and the story of the sto	sting in the specialties of chemistry and 6 months of that included high complexity testing voology, and mycobacteriology, e technical supervisor for the stry and the subspecialties of ology, and mycobacteriology.  is not met as evidenced by: of training documentation, two supervisors failed to have the fraining or experience, or or subspecialty as required to cal supervisor. Findings  ments from the personnel file supervisors were reviewed.  ervisor #1 (TS1) and the stated that all training is kept in the personnel file for one of training and/or complexity testing for nunology.  ervisor #2 (TS2) was unable to station which showed 4 years of perience in high complexity logy, chemistry or immunology.  If on 9/23/2015 at 10:30 am that	D6	111	(continued; see above)		
		n did not show the required nce in immunology and 11.					

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		A. BUILDING		(X3) DATE SURVEY COMPLETED	
NAME OF	PROVIDER OR SUPPLIE	<b>05D2025714</b>	7	STREET ADDRESS, CITY, STATE, ZIP CODE 1333 GATEWAY BLVD NEWARK, CA 94560	1/20/2015
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R 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
D6111	f. TS2 confirme approximately 9:5 did not show the in hematology, ch 493.1451(b)(2) TI RESPONSIBILITY. The technical supverification of the establishment of performance charprecision and accession and accession. This STANDARD Based on review supervisor failed procedures performance specification, reportar range and failed to performance specification, reportar range and failed to performance specification are viewed.  b. The laborator PLN-14003 Revisitor "when the specification of the second se	and on 11/18/2015 at 50 am that the documentation required training or experience remistry or immunology for TS2. ECHNICAL SUPERVISOR IES  Dervisor is responsible for test procedures performed and the laboratory's test racteristics, including the racteristics, including the racteristics, including the racteristics are established to ensure that the validation remed on the restablished confications for accuracy, ble range, and/or reference to ensure establishment of the confications followed the edures. Findings include:	D6111	D6115 The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The lab's management, including the new lab director and newly appointed quality director, is responsible for ensuring that technical supervisors are effective in supervising method verification and validation procedure. The lab will further ensure that these procedures are effective through oversight during monthly QA meetings. In addition, the lab will monitor the implementation of these procedures through audits performed pursuant to the lab's new audit procedures.	d re s.

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AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIF A. BUILDING B. WING	PLE CONSTRUCTION	COM	TE SURVEY MPLETED
NAME OF	PROVIDER OR SUPPLIE	R		STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		20/2010
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CO (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	ON SHOULD BE E APPROPRIATE	(X5) COMPLETION DATE
D6115	included 'explanation as to corrected or which d. The procedulate laboratory directive date of the LD until 9/19/performed on the 6/24/15.  Accuracy  a. The procedulation and the entire reported to the entire reported run in at least 2 rewere to be outsided by indicated that the performed in dup samples were run to the range of 42.8 d. The laborator to perform the act 148 specimens or reference range.	-corrected" results without an how the "Theranos Result" was the result was reported.  The requires in Section 4.1 that ector (LD) ensures that the sare qualified and validated procedure.  The report for the same had an	D6118	(continued; see above)		

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	ATEMENT OF DEFICIENCIES D PLAN OF CORRECTION (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714		(X2) MULTIPLE CONSTRUCTION  A. BUILDING  B. WING		) co	(X3) DATE SURVEY COMPLETED	
NAME OF	PROVIDER OR SUPPLIE	4.74 F. F. C. L.		STREET ADDRESS, CITY, STATE, ZIP 7333 GATEWAY BLVD NEWARK, CA 94560		720/2015	
(X4) ID PREFIX TAG	(EACH DEFICIEN	BTATEMENT OF DEFICIENCIES NCY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF C (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY	ON SHOULD BE HE APPROPRIATE	(X5) COMPLETION DATE	
D6115	a. The procedu samples used to the entire reportation study of control sample, hoperating days, a equal to 15% (less lower and upper b.  that none of the properating days.  c. precision study drange.  d. document that the in the validation relevel of quality controls (15, 33.5 mgreater than 20%)  f. precision levels (15, 33.5 mgreater than 15%)  g. precision greater than 15%  g. precision greater tha	re required in Section 13 that the calculate precision were to cover able range, include data from the ady, include at least 1 quality have study performed over 20 and have a CV% less than or as than or equal to 20% at the level of detection).  The reports revealed brecision studies covered 20  The reports revealed that the identical did not cover the entire reportable report and did not document 1 and and a showed that two of three ag/mL) used showed a CV% and 15% respectively.  The data showed that two of three ag/dL) used showed a CV% and 15% respectively.  The data showed that two of three ag/dL) used showed a CV% and 15% respectively.  The data showed that two of three ag/dL) used showed a CV% and 15% respectively.  The data showed that two of three ag/dL) used showed a CV% and 15% respectively.	D6118	(continued; see above)			

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	PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		(X2) MULTIPE A. BUILDING B. WING	E CONSTRUCTION	COM	(X3) DATE SURVEY COMPLETED 11/20/2015	
NAME OF I	PROVIDER OR SUPPLIE	R	7	TREET ADDRESS, CITY, STATE, ZIP CO 333 GATEWAY BLVD NEWARK, CA 94560		20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COR (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE A DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
D6115	b. The validation reportable range tested covered and c. The validation reportable range tested covered and d. The validation the reportable range tested covered and e. The validation the R2 value for the R2 value for the seven sample percent recovery recovery than the R2 value of the 0.95 acceptant Reference Range and the R2 value of the 0.95 acceptant Reference range minimum of 120 instance, if a reference range minimum of 120 instance.	n report for stated that the was 10-150 ng/mL. Samples range of 14.17-108.25 ng/mL.  In report for stated that the was 47.6-1420 ng/dL. Samples range of less than 40-266 ng/dL.  In report for stated that nge was 2.5-200 nM. Samples range of 2.4-106 nM.  In report for also stated that nge was 2.5-200 nM. Samples range of 2.4-106 nM.  In report for also stated that the dilution linearity should be extended that the dilution linearity should be extended that the optimal and show slighty higher % and show sligh	D6115	(continued; see above)			

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	TEMENT OF DEFICIENCIES PLAN OF CORRECTION  (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		(X2) MULTIPI A. BUILDING B. WING	E CONSTRUCTION	COL	(X3) DATE SURVEY COMPLETED 11/20/2015	
NAME OF	PROVIDER OR SUPPLIE	ER	7	TREET ADDRESS, CITY, STATE, ZIP C 333 GATEWAY BLVD NEWARK, CA 94560		20/2010	
(X4) ID PREFIX TAG	(EACH DEFICIEN	SUMMARY STATEMENT OF DEFICIENCIES ID PROVIDER'S PLAN OF CORRECTION  (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)  TAG CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)		(X5) COMPLETION DATE			
D6115	a. The laborato Recovery Rate of the upper limit art for b. The "Clinical Table 7, for twenty nine (29) greater than +/-2 had a % Recover these 10 sample upper or lower limit c. The "Clinical Table 8, for eighty one (81) signerater than +/-2 samples had a % Of these 28 same eight (28) were not the reportable rand. The "Clinical table, Table 6, for one hundred showed a % Recovery greate samples, 23 of 3 limit of the reportable rand. The "Clinical table, Table 6, for one hundred showed a % Recovery greate samples, 23 of 3 limit of the reportable rand.	ry validation reports required a f 100 +/- 20% (100 +/- 25% at and lower limit of reportable range)  Correlation (Historical)" table, revealed that twelve (12) of samples showed a % Recovery 20%. Ten (10) of the 12 samples ry greater than +/- 25%. Of s, eight of ten were not at the mit of the reportable range.  Correlation (Historical)" table, revealed that twenty eight (28) of amples showed a % Recovery 20%. Twenty (20) of the 28 & Recovery greater than +/- 25%. ples, seventeen (17) of twenty lot at the upper or lower limit of nige.  Correlation and Bias Correction" revealed that thirty six (36) and seven (107) samples covery greater than +/- 20%. of the 36 samples had a % r than +/- 25%. Of these 36 were not at the upper or lower table range.  Linearity" table, Table 21, for that the content of the covery of 131% and (nominal value 2.4 nM) had a % %. The laboratory's reportable	D6115	(continued; see above)			

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AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIPI A. BUILDING B. WING	E CONSTRUCTION	co	E SURVEY MPLETED 20/2015	
NAME OF	PROVIDER OR SUPPLIE		5 7	STREET ADDRESS, CITY, STATE, ZIP C 333 GATEWAY BLVD NEWARK, CA 94560		120/2015	
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES NCY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF COP (EACH CORRECTIVE ACTION CROSS-REFERENCED TO THE DEFICIENCY)	SHOULD BE	(X5) COMPLETION DATE	
D6115	f. The "Summa Reference Range revealed that ten for females and males showed a 20%. Fourteen (samples had a % Of these 24 samupper or lower limals. The Alternation procedure stated predicate method was: Laboratory divided by Predicate value/Females. The reference ramethod and the e. Nine random 68, 73, 92) were correlation study.	ary of normal patient samples for e" table, Table 24, for (10) of fourteen (14) samples on the (9) of ten (10) samples for Recovery greater than +/-14) of the twenty four (24) total Recovery greater than +/-25%. ples, 24 of 24 were not at the mit of the reportable range.  The Assessment Program and that allowable bias between a diand the sease equal to or less than 20%.  The Allowable Error and the minus the Predicate value are value (Laboratory value - Predicate value).  The samples (01, 20, 30, 41, 91, 32, are reviewed from the control of the reportable plas calculation mples ranged from 21-130%.  The allowable bias calculation mples for both the Predicate	D6115	(continued; see above)			

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AND PLAN OF CORRECTION IDENTIFICATION 05D20:		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTII A. BUILDIN B. WING	G	TE SURVEY MPLETED
NAME OF F	PROVIDER OR SUPPLIE	3		STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	720,2010
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL 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
D6115	nine samples rangereference ranges and the were were f. Nine random 76, 131, 145) were clinical correlation validation report. for these nine sand the 493.1451(b)(8)(iv RESPONSIBILITY). The procedures for the staff must indirect observation maintenance and This STANDARD Based on review assessment form supervisor failed to performance of infunction checks in Findings include:  a. Competency FRM-0316-F59, so documentation of maintenance and b. Testing person supervisor stated 1:30 pm that instruction check do part of annual correspondence.	ged from 21-39%. The for both the Predicate method at the same for samples (5, 8, 25, 36, 54, 74, e reviewed from the study (Table 20) from the The allowable bias calculation apples ranged from 22-146%. In the same for	D612	All testing personnel currently performing tests have completed competency testing with direct observation of, among other things, maintenance and function checks for the tests they are performing.  The lab has completed an assessment to identify any patients affected or having the potential to be affected by this issue.  The laboratory management, including the new lab director and newly appointed quality director, will ensure that technical supervisors follow required procedures, including personnel procedures. The lab will further assure the adequacy and competency of staff during monthly QA meetings. In addition, the lab will	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIP A. BUILDING	LE CONSTRUCTION		E SURVEY MPLETED
		05D2025714	B. WING		11/	20/2015
NAME OF	PROVIDER OR SUPPLIER	3	43	STREET ADDRESS, CITY, STATE, ZIP COE 7333 GATEWAY BLVD NEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENT	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORR (EACH CORRECTIVE ACTION SI CROSS-REFERENCED TO THE AP DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE
D6168	The laboratory ha individuals who m requirements of §493.1489 of this specified in §493. volume and composition of the composit	s a sufficient number of eet the qualification  subpart to perform the functions 1495 of this subpart for the elexity of testing performed.  is not met as evidenced by: subpart and severity of the herein, the Condition: forming high complexity testing; was not met. The laboratory lified testing personnel complexity testing. Refer to 1.  TING PERSONNEL.  Serforming high complexity ess a current license issued by the laboratory is located, if required.  is not met as evidenced by: frequired interviews and record review on November 17, dual performing high complexity esting failed to possess a sued by the State of California.  In pillary specimens, it was the perform and report patient in the performing high complexity esting failed to possess a sued by the State of California.	D6170	monitor the implementation procedures through audits procedures.  This improved oversight withat technical supervisors in and monitor the lab's enhant training and competency procedures require, a other things, direct observationstrument maintenance and checks in competency assess. The lab has conducted train	erformed adit  all ensure inplement aced ocedures, mong ition of a function is sments, ing on that	

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NAME OF I	PROVIDER OR SUPPLIER			STREET ADDRESS, CITY, STATE, ZIP CODE	11/20/2010
THERAN	IOS INC			7333 GATEWAY BLVD NEWARK, CA 94560	
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPF DEFICIENCY)	BE COMPLETION
D6170	individuals who me requirements of §493.1489 of this specified in §493.1 volume and complete This CONDITION Based on the number deficiencies cited I Laboratories perfortesting personnel of failed to have qual performing high condition of the state of the Individual personnel of the In	s a sufficient number of set the qualification subpart to perform the functions 1495 of this subpart for the exity of testing performed.  Is not met as evidenced by: The nerein, the Condition: Trming high complexity testing; Twas not met. The laboratory ified testing personnel omplexity testing. Refer to TING PERSONNEL  To proming high complexity the laboratory is located, if the laboratory is located by: The laboratory is located by: The laboratory is located by: The laboratory is located, if the laboratory is located, if the laboratory is located, if the laboratory is located by: The laboratory is located by: The laboratory is located, if the laboratory is	D6168	ensuring that all of its testing personnel who perform high complexity testing are qualified, strict adherence to the regulatory requirements (see D6170, D617).  The lab has completed an assess to identify any patients affected having the potential to be affected this issue (see D6170, D6171).  The new lab director has approve enhanced policies and procedure	with (1). ment or ed by ed es n and e ly. on ts (see

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STATEMENT OF DEFICIENCIES (2) AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 05D2025714	(X2) MULTIF A. BUILDING B. WING	7. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2. 2.	DATE SURVEY COMPLETED
NAME OF I	PROVIDER OR SUPPLIES		100000000000000000000000000000000000000	STREET ADDRESS, CITY, STATE, ZIP CODE	11/20/2015
THERAN					
(X4) ID PREFIX TAG	(EACH DEFICIENT	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL 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
D6168	individuals who m requirements of §493.1489 of this specified in §493. volume and composition. This CONDITION Based on the nur deficiencies cited Laboratories perfetesting personnel failed to have quaperforming high condition of the second performing must possible state in which such licensing is not second performing the second performing high condition of the second performance of the laboratory of the laborato	s a sufficient number of eet the qualification  subpart to perform the functions 1495 of this subpart for the elexity of testing performed.  is not met as evidenced by: subpart and severity of the herein, the Condition: forming high complexity testing; was not met. The laboratory lified testing personnel complexity testing. Refer to 1.  FING PERSONNEL.  Substitute of the laboratory is located, if required is not met as evidenced by: for ory personnel interviews and record review on November 17, and performing high complexity testing failed to possess a sued by the State of California.  Supplication of the substitute of the performing high complexity testing failed to possess a sued by the State of California.  Supplication of the substitute of the performing high complexity testing failed to possess a sued by the State of California.  Supplication of the substitute of the substitut	D6168		nt y

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:		The second second	X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING	11/2	11/20/2015		
THERAN	PROVIDER OR SUPPLIE	R	7	STREET ADDRESS, CITY, STATE, ZIP COD 333 GATEWAY BLVD NEWARK, CA 94560	E		
(X4) ID PREFIX TAG	(EACH DEFICIEN	TATEMENT OF DEFICIENCIES CY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRE (EACH CORRECTIVE ACTION SH CROSS-REFERENCED TO THE APP DEFICIENCY)	OULD BE	(X5) COMPLETION DATE	
D6170	WBC differential were released by personnel without California license	scatter plots. The scatter plots California unlicensed testing t any further review by a d testing person.  e 1, 2015 and September 21, bry reported patient WBC	D6170	D6170 (continued) These procedures also define other things, the responsibilitiensed and unlicensed personsectively. The responsibilitation approved activities of unlice personnel are limited, with a sadherence to regulatory requand may only be performed	ities of sonnel, ilities and ensed strict nirements, under the		
D6171	(b) Meet one of the (b)(1) Be a doctor osteopathy, or do licensed to practic podiatry in the Stallocated or have elbachelor's degree biological or clinic medical technological or clinic medical technology from a laboratory science technology from a (b)(2)(ii) Have edreto that specified in section that include (b)(2)(ii)(A) At lease equivalent, from a minimum, include (b)(2) medical laboratory (b)(2) science courses to thours of chemistry of the course of the c	ne following requirements: r of medicine, doctor of ctor of podiatric medicine ce medicine, osteopathy, or ate in which the laboratory is arned a doctoral, master's or e in a chemical, physical, cal laboratory science, or gy from an accredited institution; ned an associate degree in a e, or medical laboratory an accredited institution or ucation and training equivalent in paragraph (b)(2)(i) of this des st 60 semester hours, or an accredited institution that, at a e either (ii)(A)(1) 24 semester hours of that include (b)(2)(ii)(A)(2)(i) Six semester (c)(ii)(A)(2)(ii) Six semester (d)(ii)(A)(2)(ii) Six semester (d)(ii)(A)(2)(ii) Six semester	D6171	direct supervision of license personnel. The lab has conditraining on these procedures that its practice is consistent them.  The laboratory management the new lab director and new appointed quality director, is responsible for ensuring that is consistent with these proceduring the lab will further assure the adequacy and competency of during monthly QA meeting addition, the lab will monitor implementation of these protections and the lab's new audit procedure.	ducted to ensure with , including vly s t practice edures. he f staff ss. In or the cedures ursuant to		

	TATEMENT OF DEFICIENCIES (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  05D2025714		(X2) MULTIPL A. BUILDING B. WING		(X3) DATE SURVEY COMPLETED	
NAME OF I	PROVIDER OR SUPPLIE		S   7   N	11/20/2015		
(X4) ID PREFIX TAG	(EACH DEFICIEN	STATEMENT OF DEFICIENCIES ICY MUST BE PRECEDED BY FULL R LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATI DEFICIENCY)	(X5) COMPLETION DATE	
D6170	WBC differential were released by personnel withou California license	scatter plots. The scatter plots California unlicensed testing t any further review by a d testing person.  e 1, 2015 and September 21, ory reported patient WBC	D6170			
D6171	(b) Meet one of the (b)(1) Be a doctorosteopathy, or dolicensed to practipodiatry in the Stalocated or have estable bachelor's degree biological or clinic medical technological or clinic medical technology from a (b)(2)(ii) Have early laboratory science technology from a (b)(2)(iii) Have ed to that specified is section that include (b)(2)(iii)(A) At least equivalent, from a minimum, include (b)(2) medical laboratorom (b)(2) science courses (hours of chemistics)	ne following requirements: r of medicine, doctor of actor of podiatric medicine ce medicine, osteopathy, or ate in which the laboratory is arned a doctoral, master's or a in a chemical, physical, cal laboratory science, or gy from an accredited institution; rned an associate degree in a e, or medical laboratory an accredited institution or ucation and training equivalent in paragraph (b)(2)(i) of this des ast 60 semester hours, or an accredited institution that, at a e either (ii)(A)(1) 24 semester hours of (ii)(A)(2) 24 semester hours of that include b)(2)(ii)(A)(2)(i) Six semester (y; b)(2)(ii)(A)(2)(ii) Six semester	D6171	D6171: TP14 has been retrained to ensure for TP14 only performs activities within the scope of TP14's job description a clinical laboratory associate, under the supervision of testing personnel Because TP14 is not testing personnel the high complexity personnel educational requirements do not appear to identify any patients affected or having the potential to be affected by this issue.  The new lab director has approved enhanced procedures to ensure that testing personnel meet the requisite educational qualifications. These procedures also define, among other things, the responsibilities of licensiand unlicensed personnel, respectively. The responsibilities as approved activities of unlicensed	n as r	

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	OF DEFICIENCIES OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:			E CONSTRUCTION	(X3) DATE COMF	SURVEY
		05D2025714	B. WING			11/2	0/2015
NAME OF	PROVIDER OR SUPPLIER			S	TREET ADDRESS, CITY, STATE, ZIP CODE		
THERAN	OS INC			i	333 GATEWAY BLVD IEWARK, CA 94560		
(X4) ID PREFIX TAG	(EACH DEFICIENC)	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREF TAG		PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD CROSS-REFERENCED TO THE APPROPE DEFICIENCY)	BE	(X5) COMPLETION DATE
D6171	semester hours of laboratory technolo (b)(2)(ii)(B) includes either of the (b)(2)(ii)(B)(1) Compared training program at ABHES, the CAHE approved by HHS. In the 60 semester (2)(ii)(A) of this section (b)(2)(ii)(B)(2) At lest laboratory training individual performs (b)(3) Have previous qualified as a technological aboratory training individual performs (b)(4) On or before school graduate or (b)(4)(i) Graduated clinical laboratory tracedited by ABHI organization approvious (b)(4)(ii) Successfur military medical laboratory traced the military endical Laboratory Technician); (b)(5)(i) Until Septe (b)(5)(i)(A) Have diploma or equivaled (b)(5)(i)(B) Have diappropriate for the analyzing patient spensure that the individio)(5)(i)(B)(1) The sensure that the individion of th	(2)(ii)(A)(2)(iii) Twelve chemistry, biology, or medical gy in any combination; and Have laboratory training that he following: pletion of a clinical laboratory oproved or accredited by the A, or other organization (This training may be included hours listed in paragraph (b) tion.) ast 3 months documented in each specialty in which the high complexity testing. Itsly qualified or could have hologist under §493.1491 on or 1, 1992; April 24, 1995 be a high equivalent and have either-from a medical laboratory or raining program approved or ES, CAHEA, or other wed by HHS; or lly completed an official U.S. Horatory procedures training 0 weeks duration and have listed occupational specialty of specialist (Laboratory mber 1, 1997e earned a high school ent; and occumentation of training testing performed before pecimens. Such training must	D6	171	D6171 (continued) personnel are limited, with strict adherence to regulatory requirent and may only be performed under direct supervision of licensed personnel. The lab has conducted training on these procedures to ethat its practice is consistent with them.  The laboratory management, incompany the new lab director and newly appointed quality director, is responsible for ensuring that practice is consistent with these procedures. The lab will further assure the adequacy and competency of standuring monthly QA meetings. In addition, the lab will monitor the implementation of these proceduthrough audits performed pursuathe lab's new audit procedures.	nents, er the d ensure h luding ctice res.	

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		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING			(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/	20/2015	
NAME OF PROVIDER OR SUPPLIER  THERANOS INC			STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560				
(X4) ID PREFIX TAG	(EACH DEFICIENCY	TEMENT OF DEFICIENCIES MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTI (EACH CORRECTIVE ACTION SHOU CROSS-REFERENCED TO THE APPRO DEFICIENCY)	LD BE	(X5) COMPLETION DATE	
D6171	if applicable, labelin fixation, processing and storage of spect (b)(5)(i)(B)(2) The stall standard laborate (b)(5)(i)(B)(3) The stall standard laborate (b)(5)(i)(B)(4) The stall standard laborate (b)(5)(i)(B)(4) The stall standard laboraters (b)(5)(i)(B)(5) A worstability and storage (b)(5)(i)(B)(6) The stall standard performed; (b)(5)(i)(B)(6) The stall standard performed; (b)(5)(i)(B)(6) The stall standard performed; (b)(5)(i)(B)(7) An avail standard performed (b)(5)(i)(B)(8) The standard performing patient test (b)(5)(i)(B)(8)(ii) Astall standard paragraph (b)(5)(i) performing high contains (b)(6)(ii) Be quall (b)(2), (b)(3), (b)(4) (b)(6)(iii) Have earnorespiratory therapy from an accredited (b)(6)(iii) Have earnorelated to pulmonarin stitution; or	ig, handling, preservation or or preparation, transportation cimens; skills required for implementing ory procedures; skills required for performing and for proper instrument use; skills required for performing ance, troubleshooting, and res related to each test reside and procedures of the vareness of the factors that is; and skills required to assess and patient test results through sality control values before at results; and of September 1, 1997, be 3.1489(b)(1), (b)(2), or (b)(4), dividuals qualified under of this section who were implexity testing on or before analysis—lified under §493.1489(b)(1), or (b)(5); ed a bachelor's degree in or cardiovascular technology	D617				

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING		(X3) DATE SURVEY COMPLETED	
		05D2025714	B. WING		11/2	20/2015
NAME OF PROVIDER OR SUPPLIER  THERANOS INC				STREET ADDRESS, CITY, STATE, ZIP CODE 7333 GATEWAY BLVD NEWARK, CA 94560	•	
(X4) ID PREFIX TAG	(EACH DEFICIENC)	SUMMARY STATEMENT OF DEFICIENCIES  CH DEFICIENCY MUST BE PRECEDED BY FULL  ULATORY OR LSC IDENTIFYING INFORMATION)  SUMMARY STATEMENT OF DEFICIENCIES  PROVIDER'S PLAN OF CORRECTION  (EACH CORRECTIVE ACTION SHOULD BE  CROSS-REFERENCED TO THE APPROPRIATE  DEFICIENCY)			) BE	(X5) COMPLETION DATE
D6171	of §493.1449 (b) or examinations.  This STANDARD is Based on review of and interview, one of (TP14) failed to meet personnel education include:  a. Review of TP14 a bachelors degree be. The general suconsultant stated the were kept in the pect. No further recesshowed a bachelor physical, biological, medical technology 493.1495(b)(4) TES RESPONSIBILITIE  Each individual pertesting must follow policies and procedure not within the la acceptable levels of This STANDARD is Based on laborato complete blood coucorrective action received action received action received action received to the stablished policies CBC test systems in the stablished policies can be stablished pol	s not met as evidenced by: If personnel documentation of thirty five testing personnel et the high complexity nal qualifications. Findings  A's personnel records revealed in Liberal Studies.  pervisor and technical nat all personnel documents resonnel records.  Ords were identified which as degree in a chemical, clinical laboratory science or complexity the laboratory's established fures whenever test systems aboratory's establish	D61		or ed by /ed e that results /e been	2/12/16

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION  A. BUILDING		(X3) DATE SURVEY COMPLETED		
05D2025714			B. WING_			20/2015	
NAME OF PROVIDER OR SUPPLIER  THERANOS INC				STREET ADDRESS, CITY, STATE, ZIP CO 7333 GATEWAY BLVD NEWARK, CA 94560			
(X4) ID PREFIX TAG	(EACH DEFICIENC	ATEMENT OF DEFICIENCIES BY MUST BE PRECEDED BY FULL LSC IDENTIFYING INFORMATION)	PREFIX TAG	PROVIDER'S PLAN OF CORF (EACH CORRECTIVE ACTION S CROSS-REFERENCED TO THE AI DEFICIENCY)	HOULD BE	(X5) COMPLETION DATE	
D6178	Continued From page 120 Findings included:  a. It was the practice of the laboratory to use the stated values of commercially assayed quality control materials to monitor patient CBC testing using the instrument. In the event any CBC quality control material test results did not fall within the stated assay values, laboratory personnel were to follow the procedure detailed in the protocol titled "Quality Control (document number CL QOP-00013, revision F)."  b. Laboratory records for the instrument the laboratory designated as indicated that on July 11, 12, 14, and 16, 2015 CBC quality control material test results failed to meet stated assay values. The laboratory's documentation of these quality control failures indicated that the laboratory's "Quality Control" protocol was not followed.  c. Laboratory records indicated that the instrument the laboratory designated as was used to test and report patient CBC specimens on July 11, 2015, patient CBC specimens on July 12, 2015, patient CBC specimens on July 14, 2015, and patient CBC specimens on July 16, 2015.		TAG CROSS-REFERENCED TO THE APPROPRIATE		of practice cedures. In or the ocedures ursuant to		