Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461786	08/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Imperial Health Laboratory	501 Dr Michael Debakey Drive, Lake Charles, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	A Validation survey was conducted at Imperial Health Laboratory - CLIA ID # 19D0461786 on August 27, 2025 through August 28, 2025. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard level deficiencies were cited.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory's policy, quality control (QC) and patient records as well as interview with personnel, the laboratory failed to follow

their quality control (QC) policy for two (2) of two (2) Ortho Vitros 7600 chemistry analyzers for quality control (QC) records reviewed from June 2, 2025 through June 6, 2025. Findings: 1. Observation by surveyors during the laboratory tour on August 27, 2025 at 9:50 am revealed the laboratory utilizes the following two (2) Ortho Vitros 7600 analyzers for chemistry testing: a) Ortho Vitros 7600 (Serial Number 76001507) b) Ortho Vitros 7600 (Serial Number 76001506) 2. Review of the laboratory's policy for "Quality Control Program" under "Corrective Action" revealed "For any quality control failures, corrective action should be implemented and documented. Examples of corrective actions are listed below: ***FIRST****IS THIS A NEW LOT OF REAGENT AND ARE WE ESTABLISHING A MEAN??? 1. Check expiration of QC material & reagent (open date expiration may be different) 2. Remix and repeat QC (make sure QC material has reached room temperature) 3. If volume of QC or reagent is low or you suspect the material may have been compromised, open new QC/reagent." 3. Review of quality control (QC) records from June 2, 2025 through June 6, 2025 revealed the QC documented did not follow the established laboratory policy for two (2) of two (2) Ortho Vitros 7600 chemistry analyzers: a) Ortho Vitros 7600 (Serial Number 76001507) * June 2, 2025: Thyroid Stimulating Hormone (TSH) - recorded as increased BR (BioRad QC) ok Follicle Stimulating Hormone (FSH) - recorded as decreased BR (BioRad QC) ok * June 4, 2025: Phosphorus (PO4) - recorded as decreased BR (BioRad QC) ok * June 6, 2025: Aspartate Aminotransferase (AST) - recorded as increased BR (BioRad QC) ok Phosphorus (PO4) - recorded as decreased BR (BioRad QC) ok b) Ortho Vitros 7600 (Serial Number 76001506) * June 2, 2025: Iron (FE) - recorded as decreased BR (BioRad QC) ok Free Thyroxine (FT4) - increased BR (BioRad QC) ok Parathyroid Hormone (iPTH) - decreased BR (BioRad QC) ok * June 3, 2025: High Density Lipoprotein (dHDL) - decreased BR (BioRad QC) ok Phosphorus (PO4) - decreased BR (BioRad QC) ok Parathyroid Hormone (iPTH) - decreased BR (BioRad QC) ok Vitamin B12 (B12) - decreased BR (BioRad QC) ok * June 4, 2025: Phosphorus (PO4) - decreased BR (BioRad QC) ok Iron (Fe) - decreased BR (BioRad QC) ok Free Thyroxine (FT4) - increased BR (BioRad QC) ok Parathyroid Hormone (iPTH) - decreased BR (BioRad QC) ok * June 5, 2025: Parathyroid Hormone (iPTH) - decreased BR (BioRad QC) ok Phosphorus (PO4) - decreased BR (BioRad QC) ok * June 6, 2025: Phosphorus (PO4) - decreased BR (BioRad QC) ok Parathyroid Hormone (iPTH) - decreased BR (BioRad QC) ok 4. In interview on August 28, 2025 at 11:38 am, Testing Personnel 3 stated that quality control (QC) is performed on BioRad controls. If the first run is out +/- 2SD, then personnel will look at the manufacturer ranges and accept the run if within the manufacturer ranges for some of the analytes tested. The personnel does not rerun the QC if the original run is within the manufacturer's ranges. 5. Review of patient records from June 2, 2025 through June 6, 2025 revealed the following patients were resulted with no repeat of QC per laboratory policy on two (2) of two (2) Ortho Vitros 7600 chemistry analyzers: a) Ortho Vitros 7600 (Serial Number 76001507) * June 2, 2025: Thyroid Stimulating Hormone (TSH) 1) Patient 280696 2) Patient 281401 3) Patient 289368 4) Patient 5005895 5) Patient 5020032 6) Patient 5025475 7) Patient 5026125 8) Patient 5028360 9) Patient 5029618 10) Patient 5034245 11) Patient 5045451 12) Patient 5045920 13) Patient 5047273 14) Patient 5048058 15) Patient 5048417 16) Patient 5049478 17) Patient 5054005 18) Patient 5054505 19) Patient 5056309 20) Patient 5065278 21) Patient 5068108 22) Patient 5070470 23) Patient 5074954 24) Patient 5102545 25) Patient 5111999 26) Patient 5122318 27) Patient 5127179 28) Patient 5130803 29) Patient 5161921 30) Patient 5169889 31) Patient 5173589 32) Patient 5178783 33) Patient 11845-1 34) Patient 25215-1 35) Patient 33409-1 36) Patient 37435-1 37) Patient 56695-1 38) Patient 57370-1 39) Patient 62381 -1 40) Patient 702811-1 41) Patient 72195-1 42) Patient 74759-1 43) Patient 77179-1 44) Patient

796220-1 45) Patient 82109-1 46) Patient 827058-1 47) Patient 832392-2 48) Patient 844578-2 49) Patient 90602-1 50) Patient 9239-1 51) Patient 9469-1 Follicle Stimulating Hormone (FSH) 1) Patient 289368 2) Patient 5065278 3) Patient 5102545 4) Patient 5122084 * June 4, 2025: Phosphorus (PO4) 1) Patient 5171138 * June 6, 2025: Phosphorus (PO4) 1) Patient 5141192 Aspartate Aminotransferase (AST) 1) Patient 116483-3 2) Patient 116483-4 3) Patient 14465-1 4) Patient 16549-1 5) Patient 19213-1 6) Patient 19902-1 7) Patient 271286 8) Patient 274958 9) Patient 27592-1 10) Patient 276741 11) Patient 290051 12) Patient 29113-2 13) Patient 32929-1 14) Patient 44532-1 15) Patient 5011399 16) Patient 5012588 17) Patient 5014322 18) Patient 5018805 19) Patient 5020847 20) Patient 5036449 21) Patient 5045617 22) Patient 5045849 23) Patient 5046979 24) Patient 5048126 25) Patient 5049697 26) Patient 5059423 27) Patient 5063709 28) Patient 5069839 29) Patient 5074757 30) Patient 5084532 31) Patient 5094598 32) Patient 5095089 33) Patient 5107384 34) Patient 5117829 35) Patient 5128033 36) Patient 5128423 37) Patient 5157712 38) Patient 5162982 39) Patient 5171119 40) Patient 5177405 41) Patient 5179689 42) Patient 5179872 43) Patient 5181065 44) Patient 542466-1 45) Patient 55088-1 46) Patient 61100-2 47) Patient 665231-1 48) Patient 67879-1 49) Patient 735604-1 50) Patient 763322-1 51) Patient 7644-1 52) Patient 78638-1 53) Patient 821836-1 54) Patient 82421-1 55) Patient 827684-1 56) Patient 832849-1 57) Patient 833688-1 58) Patient 836583-2 59) Patient 837081-1 60) Patient 851931-1 61) Patient 857961-2 62) Patient 86944-1 63) Patient 88235-1 64) Patient 902219-1 65) Patient 903831-2 66) Patient 95018-1 67) Patient 989868-1 68) Patient 990674-3 b) Ortho Vitros 7600 (Serial Number 76001506) * June 2, 2025: Parathyroid Hormone (iPTH): 1) Patient 265629 2) Patient 281026 3) Patient 5131748 4) Patient 843660-1 Iron (Fe): 1) Patient 18982-1 2) Patient 25215-1 3) Patient 284035 4) Patient 5034245 5) Patient 5161782 6) Patient 81440-1 7) Patient 840149-1 8) Patient 845406-1 Free Thyroxine (FT4): 1) Patient 276288 2) Patient 16523-1 3) Patient 278432 4) Patient 5124516 5) Patient 5152120 6) Patient 5180678 7) Patient 55367-1 8) Patient 821903-1 9) Patient 92248-1 10) Patient 11845-1 11) Patient 14348-1 12) Patient 14454-1 13) Patient 25215-1 14) Patient 261180 15) Patient 279962 16) Patient 280696 17) Patient 289368 18) Patient 5005895 19) Patient 5010764 20) Patient 5025475 21) Patient 5026125 22) Patient 5029618 23) Patient 5036450 24) Patient 5036787 25) Patient 5045451 26) Patient 5045920 27) Patient 5047273 28) Patient 5048058 29) Patient 5048945 30) Patient 5049478 31) Patient 5050250 32) Patient 5065278 33) Patient 5068108 34) Patient 5074954 35) Patient 5080028 36) Patient 50980-1 37) Patient 5102545 38) Patient 5105706 39) Patient 5111999 40) Patient 5122318 41) Patient 5123143 42) Patient 5127179 43) Patient 5132298 44) Patient 5161921 45) Patient 5167336 46) Patient 5168897 47) Patient 5169889 48) Patient 5181124 49) Patient 56695-1 50) Patient 60995-1 51) Patient 62381-1 52) Patient 72195-1 53) Patient 74759-1 54) Patient 827840-1 55) Patient 832392-2 56) Patient 844578-2 57) Patient 87242-1 58) Patient 9239-1 59) Patient 9469-1 60) Patient 960679-1 * June 3, 2025 Parathyroid Hormone (iPTH): 1) Patient 285013 2) Patient 287512 3) Patient 436496-1 4) Patient 5017552 5) Patient 5137303 6) Patient 62297-1 7) Patient 857151-2 8) Patient 908076-1 Vitamin B12 (B12): 1) Patient 22031-81 2) Patient 820402-1 High Density Lipoprotein (dHDL): 1) Patient 12421-1 2) Patient 14454-1 3) Patient 1588-1 4) Patient 22031-81 5) Patient 27542-2 6) Patient 285013 7) Patient 286149 8) Patient 296300 9) Patient 4379-1 10) Patient 49792-1 11) Patient 5005533 12) Patient 5027487 13) Patient 5046063 14) Patient 5058599 15) Patient 50749-1 16) Patient 5075898 17) Patient 5112991 18) Patient 5160750 19) Patient 5175979 20) Patient 60006-12 21) Patient 64940-1 22) Patient 66629-1 23) Patient 74987-1 24) Patient 77430-1 25) Patient 82780-1 26) Patient 83547-1 27) Patient 84164-2 28) Patient 847726-1 29) Patient 853956-1 30) Patient 858798-1 31) Patient 8743-1 32) Patient 92944-1 33) Patient 95685-1 34) Patient 960277-1 35) Patient 991804-1 Phosphorus

	(PO4): 1) Patient 5017552 2) Patient 62297-1 * June 4, 2025 Parathyroid Hormone (iPTH): 1) Patient 44708-1 2) Patient 5171138 3) Patient 710113-1 Phosphorus (PO4): 1) Patient 44708-1 2) Patient 48256-1 Iron (Fe): 1) Patient 17017-1 2) Patient 28352-2 3) Patient 5107049 4) Patient 5158818 5) Patient 563803-1 6) Patient 57800-1 7) Patient 67658-1 8) Patient 790206-2 Free Thyroxine (FT4): 1) Patient 5056476 2) Patient 5098110 3) Patient 5164908 4) Patient 831593-1 5) Patient 25335-2 6) Patient 281249 7) Patient 284683 8) Patient 286832 9) Patient 29112-1 10) Patient 295819 11) Patient 38635-1 12) Patient 5006095 13) Patient 5009185 14) Patient 5012625 15) Patient 5033227 16) Patient 5035564 17) Patient 5045148 18) Patient 5048532 19) Patient 5048569 20) Patient 5072440 21) Patient 5073503 22) Patient 5091562 23) Patient 5108666 24) Patient 5125246 25) Patient 5169497 26) Patient 5180824 27) Patient 535540-2 28) Patient 537594-2 29) Patient 55152-1 30) Patient 57800-1 31) Patient 62750-1 32) Patient 67863-1 33) Patient 719846-1 34) Patient 722413-2 35) Patient 72971-2 36) Patient 79577-1 37) Patient 847801-2 38) Patient 849835-1 39) Patient 858460-1 40) Patient 88371-1 41) Patient 901420-1 42) Patient 91028-1 43) Patient 961674-2 44) Patient 980294-2 45) Patient 982365-1 46) Patient 982804-1 47) Patient 984008-2 * June 5, 2025 Parathyroid Hormone (iPTH): 1) Patient 14773-2 2) Patient 272367 3) Patient 5010020 4) Patient 5037235 5) Patient 5152310 6) Patient 821227-2 Phosphorus (PO4): 1) Patient 272367 2) Patient 5152310 * June 6, 2025 Parathyroid Hormone (iPTH): 1) Patient 37854-1 2) Patient 43681-1 3) Patient 5141192 4) Patient 665231-1 5) Patient 92944-1 Phosphorus (PO4): 1) Patient 37854-1 2) Patient 43681-1 6. In interview on August 28, 2025 at 11:38 am, the Technical Consultant confirmed the laboratory did not follow the quality control (QC) policy for the identified analytes tested.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on observation by surveyors, review of the manufacturers' instructions and the laboratory's temperature records, as well as interview with personnel, the laboratory failed to monitor the room temperature for the phlebotomy room where specimen collection supplies were stored. Findings: 1. Observation by surveyor during the laboratory tour on August 27, 2025 at 09:44 a.m. revealed the laboratory stored the following specimen collection supplies in the phlebotomy room: a) BD Vacutainer EDTA collection tubes b) BD Vacutainer Sodium Heparin collection tubes c) BD Vacutainer Serum Collection tubes 2. Review of the BD vacutainer collection tubes package inserts revealed the manufacturer's storage requirements as 4 - 25 degrees celsius. 3. Review of the laboratory's temperature logs from January 2025 through June 2025 revealed the laboratory did not have documentation of room temperature monitoring in the phlebotomy room. 3. In interview on August 27, 2025 at 03:43 p.m., the Technical Consultant confirmed the laboratory did not monitor the room temperature in the phlebotomy room. II. Based on review of laboratory policy and

	temperature records as well as interview with personnel, the laboratory failed to monitor weekend and after hours temperature and humidity levels from January 2025 through June 2025. Findings: 1. Review of the laboratory policy for maintenance and equipment revealed "Temperature/humidity dependent instruments, test kits, room temperature/humidity and temperature dependent equipment used for reagent and specimen storage, including incubators that have specified temperature and humidity controlled environments are checked for acceptable ranges each day of testing. Charts are posted near each controlled area and temperature/humidity (if applicable) is documented each day of testing. If temperatures/humidity or other storage conditions are outside acceptable range, corrective action is documented on the log". 2. Review of the laboratory's temperature logs from January 2025 through June 2025 revealed the laboratory did not document temperature and/or humidity levels during weekend and after hours for the following: a) Frigidare refrigerator located in Microbiology room - SN 2818 b) Fisherbrand Traceable Thermo-Hygro temperature monitor located on wall in Microbiology room - SN 180001000 c) Traceable Thermometer located in Hematology section refrigerator - SN 180023488 d) Summit Freezer located in specimen processing area - SN 200310214 e) Black and Decker Refrigerator - SN 180012697 f) Haier Refrigerator - SN 18588 g) EverReady Thermometer Incubator located in Microbiology room - SN 1-030-1 h) Small Supply Room Room Temperature and Humidity - SN 221367205 i) Fisherbrand Isotemp refrigerator (Ref D) - SN 210840641 j) Laboratory Supply Room Room Temperature/Humidity - SN 180000871 k) K2 Scientific Freezer Thermometer - SN 180023483 l) Northland Freezer Thermometer (B) - SN 43257 m) Frigidare Refrigerator Thermometer (C) - SN 2916 n) Frigidare Refrigerator Thermometer (A) - SN 2915 3. In interview with personnel on August 27, 2025 at 09:44 am, the Technical Consultant stated the thermometers have minimum and maximum readings but the laboratory does not document those levels. 4. In further interview on August 27, 2025 at 09:44 am, the Technical Consultant confirmed the laboratory does not monitor the temperatures and humidity levels during weekend and after hours time frames.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory policy and performance specification studies and interview with personnel, the laboratory failed to verify complete performance specification studies to include reference range studies and a LIS verification for two (2) of two (2) Ortho Vitros 7600 chemistry analyzers. Findings: 1. Observation by surveyors during the laboratory tour on August 27, 2025 at 9:50 am revealed the laboratory utilizes the following two (2) Ortho Vitros 7600 analyzers for chemistry testing: a) Ortho Vitros 7600 (Serial Number 76001507) b) Ortho Vitros 7600 (Serial Number 76001506) 2. Review of laboratory policy manuals revealed the laboratory did not have a policy for performance specification and verification studies. 3. Review of the laboratory's two (2) Ortho Vitros 7600 chemistry

	analyzers validation records revealed the laboratory did not include the following: a) Reference Range studies and the supporting documentation b) Evaluation of the validation studies c) LIS verification documentation 4. In interview on August 27, 2025 at 1:00 pm, the Technical Consultant confirmed the laboratory did not have a policy for performance specification and verification as well as reference range studies and LIS verification for both chemistry analyzers.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with laboratory personnel, the laboratory failed to establish complete function check protocols for timers, thermometers, and hygrometers in use for laboratory testing. Findings: 1. Observation by surveyors during the laboratory tour on August 28, 2025 at 09:46 am revealed the laboratory utilizes the following laboratory equipment: a) Frigidare refrigerator thermometer located in Microbiology room - SN 2818; Due 04 /2023 b) Fisherbrand Traceable Thermo-Hygro temperature monitor located on wall in Microbiology room - SN 180001000; Due 12/28/19 c) Traceable Thermometer located in Hematology section refrigerator - SN 180023488; Due 01/10/2020 d) Summit Freezer Traceable thermometer located in specimen processing area - SN 200310214; Due 05/21/22 e) Black and Decker Refrigerator thermometer - SN 180012697; Due 01/08/2020 f) Haier Refrigerator thermometer - SN 18588; Due 03 /19/21 g) Small Supply Room Room Temperature and Humidity thermometer - SN 221367205; Due 03/22/24 h) Fisherbrand Isotemp refrigerator (Ref D) thermometer - SN 210840641; Due 10/03/23 i) Laboratory Supply Room Room Temperature /Humidity Traceable thermometer - SN 180000871; Due 12/28/19 j) K2 Scientific Freezer Thermometer - SN 180023483; Due 08/2023 k) Northland Freezer Thermometer (B) - SN 43257; Due 01/2020 l) Frigidare Refrigerator Thermometer (C) - SN 2916; Due 03/2023 m) Frigidare Refrigerator Thermometer (A) - SN 2915; Due 09/2023 n) FisherScientific Traceable Timer - SN 130654035; Due 10/30/15 2. Review of the laboratory's policy manual revealed the laboratory does not have a policy to define function checks for timers, thermometers, and hygrometers. 3. In interview with personnel on August 28, 2025 at 10:28 am, the Technical Consultant confirmed the laboratory did not define function checks for the identified equipment.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified

	by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of manufacturer's package insert, laboratory's test menu and Quality Control (QC) records, and interview with personnel, the laboratory failed to establish their own means and ranges for Quality Control (QC) material utlized for erythrocyte sedimentation rate (ESR) testing. Findings: 1. Observation by surveyors during the laboratory tour on August 27, 2025 at 9:50 am revealed the laboratory performed ESR testing utlizing ELITechGroup Accu-Sed Plus QC on the Excyte 20 Automated ESR analyzer. 2. Review of the "Accu-Sed Plus" package insert revealed "Each laboratory establish its own intralaboratory mean and standard deviation for each lot of ESR Control according to its own established procedures". 3. Review of the laboratory's QC records revealed the laboratory did not have docementation of establishing their own QC means and ranges for Accu-Sed Plus Normal Lot 246010 and Abnormal Lot 247110. 4. Interview with testing personnel in Hematology on August 27, 2025 at 1:30pm confirmed the laboratory uses the manufacturer range for quality control acceptability. 5. Review of the laboratory's test menu revealed the laboratory performs 1,524 ESR tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on review of laboratory's policy and verification records as well as interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy and records and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to monitor the room temperature for the phlebotomy room where specimen collection supplies were stored. Refer to D5413 I. 2. The laboratory failed to monitor weekend and after hours temperature and humidity levels from January 2025 through June 2025. Refer to D5413 II.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure the quality control (QC) program was maintained to assure the quality of laboratory testing results. Refer to D5469.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory records and policy, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Refer to D5435.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on review of laboratory's policy, records and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory records, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to monitor the room temperature for the phlebotomy room where specimen collection supplies were stored. Refer to D5413 I. 2. The laboratory failed to monitor weekend and after hours temperature and humidity levels from January 2025 through June 2025. Refer to D5413 II. 3. The laboratory failed to establish complete function check protocols for timers, thermometers, and hygrometers in use for laboratory testing. Refer to D5435.

D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's performance verification studies, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of laboratory records and policy as well as interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5469.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, personnel records and interview with personnel, the Laboratory Director failed to delegate responsibilities to three (3) of three (3) General Supervisors. Findings: 1. Review of laboratory policy and personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks of General Supervisor to the applicable staff. 2. Review of laboratory competency assessments revealed General Supervisors participated in direct observation and competency assessment for Testing Personnel. 3. In interview on August 28, 2025 at 9:00 am, the Technical Supervisor confirmed the laboratory did not delegate the tasks of General Supervisor to the applicable staff.