# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0470083	**(X3) Date Survey Completed** 03/03/2023
Name of Provider or Supplier Weatherford Regional Hospital	**Street Address, City, State** 3701 E Main, Weatherford, OK	
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	The recertification survey was performed on 02/28/23 through 03/03/2023. The laboratory was found out of compliance with the following CLIA Conditions: 493.1409; D6033: Technical Consultant 493.1447; D6108: Technical Supervisor The findings were reviewed with the chief executive officer, laboratory director, and laboratory manager during an exit conference performed at the conclusion of the survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for one of three Immunohematology Proficiency testing events reviewed in 2022. Findings include: (1) On 02/28/2023, a review of Immunohematology Proficiency testing records for three events (First 2022, Second 2022, and Third 2022) identified the following failure with no evidence that corrective action had been documented as performed: (a) Third 2022 Event - The laboratory attained a score of 80% for D (Rho) Type. (2) The records were reviewed with the laboratory director and laboratory manage. Both stated on 03/01/2023 at 11:15 am, corrective action had not been taken and documented for the failure.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance

	(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the laboratory failed to evaluate the accuracy of testing when a proficiency result had not been graded by the proficiency program for three of three Microbiology events and one of three Hematology events reviewed in 2022. Findings include: (1) On 02/28/2023, a review of 2022 proficiency testing records identified the following for three of three Microbiology events and one of three Hematology events: (a) First 2022 Microbiology Event (i) Urine Culture MIC/Zone Diameter Value - sample UR-01; 10 of 10 antibiotics (Ampicillin, Ciprofloxacin, Daptomycin, Levofloxacin, Linezolid, Nitrofurantoin, Penicillin, Rifampin, Tetracycline, and Vancomycin) had not been graded by the proficiency testing program. The results stated "See data summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their results; (b) Second 2022 Microbiology Event (i) Urine Culture MIC/Zone Diameter Value - sample UR-06; 11 of 11 antibiotics (Ceftaroline, Ciprofloxacin, Daptomycin, Gentaminic, Levofloxacin, Linezolid, Oxacillin, Rifampin, Tetracycline, Trimethoprim/Sulfamethoxazole, and Vancomycin) had not been graded by the proficiency testing program. The results stated "See data summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their results; (c) Third 2022 Microbiology Event (i) Urine Culture MIC/Zone Diameter Value - sample UR-11; 22 of 22 antibiotics (Amikacin, Amoxicillin, Ampicillin, Ampicillin /Sulbactam, Aztreonam, Cefazolin, Cefepine, Cefotaxime, Ceftazidime, Ceftriaxone, Cefuroxime, Ciprofloxacin, Ertapenem, Gentamicin, Imipenem, Levofloxacin, Nitrofurantoin, Piperacillin, Tazobactam, Tetracycline, Ticarcillin/Clavulanate, Tobramycin, and Trimethoprim/Sulfamethoxazole) had not been graded by the proficiency testing program. The results stated "See data summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their results; (d) Third 2022 Hematology Event - Blood Cell Identification - sample BCI-14; one of five results had not been graded by the proficiency testing program. The result stated "See data summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (2) The records were reviewed with the laboratory director and laboratory manager. Both stated on 03/01/2023 at 10:50 am, the laboratory had not evaluated the results that were not graded by the proficiency testing program.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, observation, and interview with the laboratory manager, the laboratory failed to follow their written procedure for

	coagulation lot change studies for two of two reagent lot numbers. Findings include: (1) On 02/28/2023 at 11:18 am, the laboratory manager stated the laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing on adult and pediatric patients using the ACL Elite analyzer; (2) On 03/02/2023 at 09:00 am, the laboratory manager stated the following: (a) PT Reagent - HemosIL Recombiplastin 2G lot #N0623655 was put into use on 03/01/2023; (b) PTT Reagent - HemosIL APTT-SP, lot #N0723974 was put into use on 01/10/2023. (3) A review of the procedure titled, "ACL Coagulation PT, PTT, DDimer Lot Change and Calibration" identified the following: (a) The section titled, "Protime and PTT Lot Change" stated: "Run 20 platelet poor Normal patients for adult and child ranges, to establish Normal Patient Range (see the instructions for normal PT study in Performance Verification Manual). The GEOMETRICAL MEAN, of the PT seconds, established from the normal patient study must go into the PT reagent's Material Definition screen. Normal patient study and geometrical mean needs to be established for both adults and children"; (b) The section titled, "Normal Patient Study Questionnaire" stated: "The following may cause elevated values and should not be included in the Normal patient Study. Each patient will be asked if they have any of the following before the study:" (i) "Pathological conditions such as Diabetes, Cancer, Heart Disease, RF, or Lupus" (ii) "Currently taking oral contraceptives or estrogen hormones" (iii) "Recently taken Blood Thinner (warfarin, Coumadin, or high dose of aspirin" (4) With the assistance of the laboratory manager on 03/02/2023 at 10:00 am, observation of the normal patient means that had been programmed into the analyzer to calculate the INR values for adult and pediatric patients identified the following: (a) The normal patient geometric mean for adults was 11.10 (b) The normal patient geometric mean for pediatrics was 11.10 (5) A review of the implementation records for the new reagent lot numbers identified the written procedure had not been followed: (a) PT Adult Study (i) For the normal patient geometric mean, although 20 donors had been tested, a questionnaire had not been completed for each donor and there was no documentation of the health status and medication history of the donors; (ii) The geometric mean that had been calculated by the laboratory was 12.32 which did not match the value that had been programmed into the analyzer (11.10). (b) PT Pediatric Study (i) For the normal patient geometric mean, although 17 donors had been tested, a questionnaire had not been completed for each donor and there was no documentation of the health status and medication history of the donors; (ii) The geometric mean that had been calculated by the laboratory was 11.56 which did not match the value that had been programmed into the analyzer (11.10). (c) PTT Adult Study (i) For the normal patient range, although 20 donors had been tested, a questionnaire had not been completed for each donor and there was no documentation of the health status and medication history of the donors. (d) PTT Pediatric Study (i) For the normal patient geometric mean, although 17 donors had been tested, a questionnaire had not been completed for each donor and there was no documentation of the health status and medication history of the donors. (6) The records were reviewed with the laboratory manager who stated on 03/03/2023 at 11:23 am, the laboratory had not followed their procedure for the coagulation lot change studies.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 a review of records and interview with the laboratory manager, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test system; and failed to demonstrate the performance specifications for one of one replacement iSTAT handheld analyzer. Findings include: REPORTABLE RANGE (1) On 02/28/2023 at 10:45 am, the laboratory manager stated the laboratory began performing D-dimer testing using the Biosite Triage Meter Pro on 11/13/2021; (2) On 03/01/2023 a review of the performance specification records identified the laboratory had demonstrated a reportable range of 184-3250 ng/ml; (3) Interview with the laboratory manager on 03/01/2023 at 04:35 pm confirmed the laboratory was using the manufacturer's reportable range of 100-5000 ng/ml instead of the reportable range that had been demonstrated by the laboratory. REPLACEMENT ISTAT ANALYZER (1) On 03/02/2023 at 02:25 pm, the laboratory manager stated the laboratory obtained a replacement iSTAT 1 handheld analyzer, serial number 407500 to replace serial number 400195 approximately 01/14/2022 to perform the following testing: (a) Blood Gas (pH, pCO_2, pO_2) testing using the G3+ cartridge; (b) Troponin I testing using the cTnI cartridge as a backup to the Beckman Coulter Access 2 analyzer; (c) BUN, Creatinine, Glucose, Chloride, Potassium, Sodium, and CO_2 testing using the Chem 8+ cartridge as a backup to the Beckman Coulter DXC AU 700 analyzer. (2) Interview with the laboratory manager on 03/02/2023 at 02:30 pm confirmed the laboratory did not demonstrate the performance specifications (accuracy, precision, reportable range) for the replacement analyzer prior to putting into use for patient testing.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for two of four analyzers. Findings include: BECKMAN COULTER ACCESS 2 (1) On 02/28/2023 at 10:56 am, the laboratory manager stated Vitamin B12 testing was performed on Mondays, Wednesdays, and Fridays using the Beckman Coulter Access 2 analyzer; (2) On 03/03/2023 a review of the "Access 2 Instructions for Use" manual under Section 6 "Maintenance" stated, "If you use the Access 2 system to process the Vitamin B12 assay, you should also run the Special Clean routine at the end of every day or whenever the instrument will not process samples for 8 hours or more"; (3) A review of patient and maintenance logs for testing performed from 01/02/2023 through 01/30/2023 identified the special clean routine had not been documented as performed for 15 of 15 days of patient Vitamin B12 testing reviewed. The days of patient testing when the special clean had not been documented as performed were 01/02,04,06,09,10,11,13,16,18,20,23,25,26,27,30 /2023; (4) The records were reviewed with the laboratory manager who stated on 03

	/03/2023 at 01:07 pm, the special clean routine had not been performed after Vitamin B12 testing was performed. ACL ELITE (1) On 02/28/2023 at 11:18 am, the laboratory manager stated the laboratory performed PT/INR (Prothrombin Time /International Normalized Ratio), PTT (Partial Thromboplastin Time) and D-dimer testing using the ACL Elite analyzer; (2) On 03/03/2023 a review of the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log for the analyzer required the following monthly maintenance: (a) Clean Air Filter (3) A review of maintenance records from January 2022 through January 2023 identified no documentation to prove the monthly maintenance had been performed; (4) The findings were reviewed with the laboratory manager who stated on 03/03 /2023 at 02:06 pm, the monthly maintenance had not been documentated as performed.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform calibration verification procedures at least once every six months for three of five test systems reviewed from January 2022 through the current date. Findings include: (1) On 02/28/2023 at 09:53 am, the laboratory manager stated the laboratory performed the following: (a) Troponin I testing using the cTnI cartridge and the iSTAT 1 analyzer as a backup to the Beckman Coulter Access 2 analyzer; (b) BUN, Creatinine, CO2, Glucose, Ionized Calcium, Chloride, Potassium, and Sodium testing using the Chem 8+ cartridge and the iSTAT 1 analyzer as a backup to the Beckman Coulter DXC AU 700 analyzer; (c) Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), Total Bilirubin, Direct Bilirubin, BUN (Blood, Urea, Nitrogen), Calcium, Chloride, Cholesterol, CO2, CK (Creatine Kinase), Creatinine, Glucose, HDL (High Density Lipoprotein), Lactic Acid, Lipase, Magnesium, Phosphorus, Potassium, Total Protein, Sodium, Triglyceride, and Uric Acid testing using the Beckman Coulter DXC AU 700 analyzer. (2) On 03/02/2023 a review of records for the test systems from January

	2022 through the current date identified calibration verification had not been performed as follows: (a) Troponin I - Not performed between 01/14/2022 and 12/09/2022 (b) Chem 8+ - Not performed between 01/19/2022 and 11/25/2022 (c) Testing on the Beckman Coulter DXC AU 700 analyzer - Not performed after July 2022. (3) The records were reviewed with the laboratory manager who stated on 03/02/2023 at 01:50 pm, calibration verification had not been performed every six months as stated above.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of written policies and interview with the laboratory manager and director of nursing, the laboratory failed to ensure that written policies provided safety for individuals being transfused for one of three patients reviewed. Findings include: (1) On 02/28/2023 at 11:20 am, the laboratory manager stated the laboratory stored units of PRBC's (packed red blood cells) in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 03/01/2023 a review of the hospital policy titled, "Blood Product Checkout and General Guidelines for Administration" stated "Vital signs to be monitored and recorded every 15 minutes x two, then every 30 minutes until the transfusion is complete"; (3) A review of records for three patients receiving transfusions in July 2022, August 2022, and November 2022 identified no evidence the policy had been followed for one of three patients for two of two units transfused as follows: (a) Patient transfused on 08/03/2022 (i) Unit #W091022276008 - Although the first 15 minute vitals had been documented, there was no documentation of vitals between 04:36 pm and 07:14 pm (ii) Unit #W091022276378 - Although the first 15 minute vitals had been documented, there was no documentation of vitals between 08:05 pm and 09:00 pm; and between 09:00 pm and 11:52 pm. (4) The records were reviewed with the laboratory manager and director of nursing. Both stated on 03/01/2023 at 04:40 pm, the above vitals had not been taken and documented as required by policy.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Troponin I testing performed using two test methods during the review period of January 2022 through the current date. Findings include: (1) On 02/28/2023 at 10:56 am, the laboratory manager stated the laboratory performed Troponin I testing using the Beckman Coulter Access 2 analyzer as the primary method and the iSTAT 1 analyzer and the cTnI cartridge as the backup method; (2) On 03/02/2023 a review of records from January 2022 through the current date identified no records to prove the relationship between the different test methods had been evaluated since 03/17/2022; (3) The records were reviewed with the laboratory manager who stated on 03/02/2023 at 01:30 pm, the relationship between the above test methods had not been evaluated since 03/17/2022.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of two patient reports and interview with the laboratory manager, the laboratory failed to make appropriate reference ranges available for two of two PTT (Partial Thromboplastin Time) reagent lot number changes. Findings include: (1) On 02/28/2023 at 10:05 am, the laboratory manager stated the ACL Elite analyzer was used to perform PTT testing; (2) On 03/02/2023 at 03:15 pm, interview with the laboratory manager and a review of implementation records identified the following: (a) PTT SynthaSIL Reagent lot #N1209119 was put into use on 06/25/2021 and the normal reference interval had been verified as 24.7-36.5; (b) PTT SynthaSIL Reagent lot #N0723974 was put into use on 01/10/2023 and the normal reference interval had been verified as 26.77-36.74. (3) A review of two patient PTT reports identified the following: (a) Testing performed on 08/16/2022 showed the normal PTT range on the report was 21.6-35.0; (b) Testing performed on 01/23/2023 showed the normal PTT range on the report was 21.6-35.0. (4) The reports and implementation records were reviewed with the laboratory manager who stated on 03/02/2023 at 04:10 pm, the laboratory had not updated the normal reference ranges into the laboratory's computer information system for both lot changes as shown above.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to provide technical supervision in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual

	who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for four of four testing persons. Refer to D6053.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant met the qualifications to sign Hematology and Microbiology attestation statements for two of eight proficiency testing events. Findings include: (1) On 02/28/2022 a review of Hematology and Microbiology proficiency testing records for 2021 and 2022 identified the attestation statements for the third 2022 Hematology and third 2022 Microbiology events had been signed by an individual who did not meet the regulatory requirements of a technical consultant; (2) The records were reviewed with the laboratory director and laboratory manager. Both stated on 03/01/2023 at 09:10 am, the attestation statements

	had not been signed by an individual meeting the regulatory qualifications of a technical consultant for Hematology and Microbiology.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for four of four testing persons. Findings include: (1) On 02/28/2023 a review of personnel records for four persons hired to perform moderate complexity testing after the previous recertification survey identified the following for four of four persons: (a) Testing Person #1/Laboratory Manager - The initial training was complete on 04/22/2022. There was no evidence a competency evaluation had been performed to date; (b) Testing Person #2 - The initial training was complete on 06/24 /2022. There was no evidence a competency evaluation had been performed to date; (c) Testing Person #6 - The initial training was complete on 05/28/2022. There was no evidence a competency evaluation had been performed to date; (d) Testing Person #11 - The initial training was complete on 05/21/2022. There was no evidence a competency evaluation had been performed to date. (2) The records were reviewed with the laboratory director and laboratory manager. Both stated on 03/01/2023 at 11: 30 am, semiannual competency evaluations had not been performed as stated above.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the technical supervisor failed to provide technical supervision in accordance with 493.1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the educational qualifications. Refer to D6111; (2) The technical supervisor failed to ensure competency evaluations for high complexity testing had been performed semiannually during the first year of testing for four of four testing persons. Refer to D6127.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties

and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are

	equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the qualifications to sign Immunohematology attestation statements for one of four proficiency testing events. Findings include: (1) On 02/28/2022 a review of Immunohematology proficiency testing records for 2021 and 2022 identified the attestation statement for the third 2022 event had been signed by an individual who did not meet the regulatory requirements of a technical supervisor; (2) The records were reviewed with the laboratory director and laboratory manager. Both stated on 03/01/2023 at 09:10 am, the attestation statement had not been signed by an individual meeting the regulatory qualifications of a technical supervisor for Immunohematology.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and laboratory manager, the technical supervisor failed to ensure competency evaluations for high complexity testing had been performed semiannually during the first year of testing for four of four testing persons. Findings include: (1) On 02/28/2023 a review of personnel records for four persons hired to perform high complexity testing after the previous recertification survey identified the following for four of four persons: (a) Testing Person #1/Laboratory Manager - The initial training was complete on 04/22/2022. There was no evidence a competency evaluation had been performed to date; (b) Testing Person #2 - The initial training was complete on 06/24/2022. There was no evidence a competency evaluation had been performed to date; (c) Testing Person #6 - The initial training was complete on 05/28/2022. There was no evidence a competency evaluation had been performed to date; (d) Testing Person #11 - The initial training was complete on 05/21/2022. There was no evidence a competency

	evaluation had been performed to date. (2) The records were reviewed with the laboratory director and laboratory manager. Both stated on 03/01/2023 at 11:30 am, semiannual competency evaluations had not been performed as stated above.