Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0474836	**(X3) Date Survey Completed** 02/28/2019
Name of Provider or Supplier Saint Francis Hospital Vinita	**Street Address, City, State** 735 North Foreman, Vinita, 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 02/25/19 through 02/28/19. The findings were reviewed with the technical consultant and general supervisor at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1210; D5016: Routine Chemistry 493.1403; D6000: Laboratory Director, Moderate Complexity
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and general supervisor, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records. The following was identified for 1 of 22 testing events: (a) Second 2017 Chemistry Miscellaneous Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the technical consultant and general supervisor who stated the attestation had not been signed as indicated above.

D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant and general supervisor, the laboratory failed to ensure the requirements were met for the subspecialty of Routine Chemistry for Troponin I and ABG (G3+ cartridge: pH, pCO2, pO2) testing. Findings include: (1) The laboratory failed to perform two levels of quality control materials each day of patient Troponin I and ABG (Arterial Blood Gas G3+ cartridge: pH, pCO2, pO2) testing. Refer to D5447; (2) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy and interview with the general supervisor, the laboratory failed to follow their written technical consultant and general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018 and 2019. There was no evidence competencies had been performed for the technical consultant and general supervisor, based on their job responsibilities; (2) The surveyor asked the technical consultant and general supervisor if a written policy to evaluate the technical consultant and general supervisor based on job responsibilities was available. The general supervisor provided the policy for the surveyors review; (3) The surveyor reviewed the policy which required annual competencies be performed for the technical consultant and general supervisor based on job responsibilities. (4) The surveyor asked the technical consultant and general supervisor if annual competencies based on job responsibilities had been performed during the review period. The technical consultant and general supervisor stated annual competencies had not been performed.
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 general supervisor, the laboratory

	failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records. The following failures were identified, in which corrective action documentation could not be located: (a) Third 2018 Event (i) Mononucleosis (IM-13) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (2) The surveyor asked the general supervisor if corrective action had been taken for the failure. After reviewing the records, the general supervisor stated corrective action had not been taken for the failure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and general supervisor, the laboratory failed to follow the manufacturer's instructions. Findings include: (1) On the fourth day of the survey, the technical consultant and general supervisor stated to the surveyor the Stago Compact Max analyzer was put into use to perform PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplastin Time), and D-Dimer testing on 06/26 /18; (2) The surveyor reviewed the manufacturer's instructions for establishing a normal reference interval (the manufacturer required the establishment of a reference interval with a new analyzer). The manufacturer referred the reader to CLSI C28-A2 for information about establishing a reference interval. In addition, the manufacturer required the following for establishing a normal reference interval: (a) "6.1.1.For routine tests (PT, APTT, Fibrinogen, D-Dimer) the number of reference samples as suggested by CLSI is 120 donors for no-parametric analysis. 50% of the routine reference samples should be processed and assayed 'fresh'. Any deviation from this minimum 120 samples requirement will be noted on the final signoff sheet." (3) The surveyor reviewed the implementation records for the analyzer. The following was identified for PT, PTT and D-Dimer: (a) The normal reference intervals had been established for PT, PTT and D-Dimer as follows: (i) 98 donors had been utilized for PT, PTT and D-Dimer (instead of the 120 donors as required for establishment studies for a new analyzer); (4) The surveyor reviewed the records with the technical consultant and general supervisor who stated the laboratory did not perform the 120 sample study;
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor and testing person #2, the laboratory failed to ensure reagents had not exceeded their expiration

	date. Findings include: (1) On the first day of the survey, the general supervisor stated to the surveyor Crossmatch testing was performed in the laboratory which included: (a) ABO Typing and Antibody Screen using the Ortho ID-MTS gel system (2) On the second day of the survey, the surveyor reviewed the package inserts for the following reagents: (a) Ortho Confidence System - used for QC testing to confirm the reactivity of anti-A, anti-B, anti-A,B anti-D and the anti-IgG component of anti-human globulin, as well as reverse grouping cells and reagent red blood cells used for antibody detection; (b) Ortho Selectogen - used for Antibody Screen testing; (c) Ortho Affirmagen - used for ABO serum grouping. (3) The surveyor reviewed quality control (QC) and patient testing records for 19 months (June 2017 through December 2018). It was identified that expired Confidence, Selectogen, and Affirmagen had been used during 1 of 19 months reviewed: (a) Confidence lot #CNF1111, expiration date of 06/05/18, Selectogen lot #VS114, expiration date of 06/05/18, and Affirmagen lot# A104, expiration date of 06/05/18 had been used to perform QC and patient testing on the following day: (i) Patient #1 - 06/11/17 (3) The surveyor reviewed the records with the general supervisor and testing person #2 who both stated expired reagents had been used as indicated above.
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 general supervisor, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) On the first day of the survey, the general supervisor stated the following to the surveyor: (a) The laboratory performed Acetaminophen, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, Amphetamine, AST (Aspartate Aminotransferase), Barbiturates, Benzodiazepine, Chloride, Cocaine, CK (Creatine Kinase), Ethanol, Lipase, Lithium, Potassium, Salicylate, Sodium and TSH (Thyroid Stimulating Hormone) testing using the Abbott Architect Plus ci4100 analyzer; (b) The analyzer was installed on 05/22/18 and available for patient testing on 05/29/18. (2) On the third day of the survey, the surveyor reviewed 2018

	calibration records and identified that calibration procedures for the above analytes had been performed with one or two levels of calibrators. Since the calibration procedures included only one or two levels, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) The surveyor could not locate records to verify calibration verification procedures had been performed for the above analytes since the analyzer was installed on 05/22/18 (due 11/2018); (4) The surveyor asked the general supervisor if calibration verification procedures had been performed since 05 /22/18. The general supervisor stated calibration verification procedures had not been performed since the analyzer was installed on 05/22/18;
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process. Findings include: (1) On the third day of the survey, the general supervisor stated the following to the surveyor: (a) BNP (Brain Natriuretic Peptide), AST (Aspartate Amino Transferase) and cholesterol testing were performed using the Abbott Architect ci400 analyzer; (b) Three levels (Level 1, Level 2, and Level 3) of Bio Rad control materials were performed each day of patient testing. (2) The surveyor reviewed quality control records for testing performed between 10/01/18 through 01/03/19. Biases were identified as follows: (a) BNP (level 3 lot#23693) - 169 out of 278 control results were consistently below the established mean Level 3 (lot#23693); (b) AST (level 2 lot#31862) - 134 out of 182 control results were consistently below the established mean; (c) Cholesterol (level 1 Lot# 31861) - 203 out of 246 control results were consistently below the established mean; (d) Cholesterol (level 2 Lot#31862) - 211 out of 246 control results were consistently below the established mean. (3) There was no evidence in the records the control biases had been identified and addressed; (4) The surveyor reviewed the records with the general supervisor and asked if there was documentation to prove the biases had been identified and addressed. The general supervisor stated the biases had not been addressed; (5) Since the above biases had not been identified and addressed, the surveyor determined the laboratory failed to have control procedures that monitored the accuracy of testing for the above analytes.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations

	Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to perform two levels of control materials each day of patient Troponin I and ABG (Arterial Blood Gas G3+ cartridge: pH, pCO2, pO2) testing. Findings include: (1) On the first day of the survey, the general supervisor stated to the surveyor the laboratory performed Troponin I and ABG (G3+ cartridge: pH, pCO2, pO2) testing using the Abbott iSTAT analyzer; (2) On the third day of the survey, the surveyor asked the technical consultant if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The general supervisor stated an IQCP had been written but not approved by the laboratory director. Therefore, the surveyor determined two levels of QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records from January 2018 through December 2018. The review indicated negative and positive QC materials had not been performed 41 of 41 days of patient testing reviewed; (4) The surveyor reviewed the records with the general supervisor who stated two levels of QC materials had not been performed each day of patient testing; (5) The following patient Troponin I and ABG testing had been performed when two levels of QC materials had not been tested: (a) Troponin I (i) Patient #2 - testing performed on 01 /06/18 (ii) Patient #3 - testing performed on 01/04/18 (iii) Patient #4 - testing performed on 01/23/18 (iv) Patient #5 - testing performed on 02/17/18 (v) Patient #6 - testing performed on 02/26/18 (vi) Patient #7 - testing performed on 03/08/18 (vii) Patient #8 - testing performed on 03/26/18 (viii) Patient #9 - testing performed on 04 /16/18 (ix) Patient #10 - testing performed on 04/30/18 (xi) Patient #11 - testing performed on 05/05/18 (xii) Patient #12 - testing performed on 05/27/18 (xiii) Patient #13 - testing performed on 06/14/18 (xiv) Patient #14 - testing performed on 07/06/18 (xv) Patient #15 - testing performed on 07/11/18 (xvi) Patient #16 - testing performed on 07/30/18 (xvii) Patient #17 - testing performed on 08/02/18 (xviii) Patient #18 - testing performed on 08/13/18 (xix) Patient #19 - testing performed on 08/30/18 (xx) Patient #20 - testing performed on 09/07/18 (xxi) Patient #21 - testing performed on 09 /13/18 (xxii) Patient #22 - testing performed on 10/03/18 (xxiii) Patient #23 - testing performed on 10/19/18 (xxiv) Patient #24 - testing performed on 10/29/18 (xxv) Patient #25 - testing performed on 11/06/18 (xxvi) Patient #26 - testing performed on 11/17/18 (xxvii) Patient #27 - testing performed on 11/30/18 (xxviii) Patient #28 - testing performed on 12/02/18 (xxiv) Patient #29 - testing performed on 12/11/18 (xxx) Patient #30 - testing performed on 12/31/18 (b) ABG (i) Patient #31 - testing performed on 01/23/18 (ii) Patient #32 - testing performed on 05/29/18 (iii) Patient #33 - testing performed on 06/15/18 (iv) Patient #34 - testing performed on 06/20/18 (v) Patient #35 - testing performed on 07/23/18 (vi) Patient #36 - testing performed on 08/04/18 (vii) Patient #37 - testing performed on 09/25/18 (viii) Patient #38 - testing performed on 10/01/18 (ix) Patient #39 - testing performed on 10/26/18 (x) Patient #40 - testing performed on 11/08/18 (xi) Patient #41 - testing performed on 12/13/18
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--

	At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the general supervisor, the laboratory failed to perform a negative and positive control material each day of patient serum pregnancy testing. Findings include: (1) On the first day of the survey, the general supervisor stated to the surveyor the laboratory performed serum pregnancy testing using the Beckman Coulter ICON 25 test kit; (2) The surveyor asked the general supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The general supervisor stated an IQCP had not been developed. Therefore, the surveyor determined negative and positive QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records for December 2017. The review indicated negative and positive QC materials had not been performed 1 of 8 days of patient testing reviewed (12/02/17); (4) The surveyor reviewed the records with the general supervisor who stated negative and positive QC materials had not been performed each day of patient testing.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions and interview with the technical consultant and general supervisor, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow the manufacturer's instructions for a new coagulation analyzer Refer to D5411; (b) The laboratory failed to ensure reagents had not exceeded their expiration date. Refer to D5417; (c) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (d) The laboratory failed to have control procedures that monitored the accuracy and precision of the analytic process. Refer to D5441; (e) The laboratory failed to perform two levels of control materials each day of patient Troponin I and ABG (G3+ cartridge: pH, pCO2, pO2) testing. Refer to D5447; (f) The laboratory failed to perform a negative and positive control material each day of patient serum pregnancy testing. Refer to D5449.
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 records and interview with the technical consultant and general supervisor, the laboratory failed to make appropriate reference ranges available. Findings include: (1) On the fourth day of the survey, the general supervisor stated to the surveyor, the Stago Compact Max analyzer was put into use on 06/26/18; (2) The surveyor reviewed the implementation records for the current lot numbers of reagents. The following was identified: (a) PTT Reagent (i) Stago STA-Automate, lot #253141 put into use on 06/26/18; (ii) The normal reference range that had been established was 26.2 - 35.8 seconds. (3) The surveyor then reviewed a patient PT report: (a) Patient testing performed on 05/17/18 with the following reference range: (i) PT reference range of 22.2 - 36.1 seconds. (4) The surveyor reviewed the findings with the technical consultant and general supervisor who stated the established normal reference ranges for PT were not included on the patient report.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant and general supervisor, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Refer D6016; (2) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (3) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and general supervisor, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018 and 2019 proficiency testing records. It was identified for 8 of 15 events, the attestation statements had been signed approximately 3-6 months after the samples had been tested (not within a timeframe for the director to

	attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2018 Chemistry Core Event - The samples had been tested on 01/29/18 and the attestation statement had not been signed by the laboratory director until 04/19/18; (b) Third 2018 Chemistry Core Event - The samples had been tested on 09/04/18 and the attestation statement had not been signed by the laboratory director until 02/19/19; (c) First 2018 Chemistry Miscellaneous Event - The samples had been tested on 04/28/18 and the attestation statement had not been signed by the laboratory director until 07/27/18; (d) Second 2018 Chemistry Core Event - The samples had been tested on 10/27/18 and the attestation statement had not been signed by the laboratory director until 01/14/19; (e) First 2018 Hematology/Coagulation Event - The samples had been tested on 03/23/18 and the attestation statement had not been signed by the laboratory director until 07/27/18; (f) Second 2018 Hematology/Coagulation Event - The samples had been tested on 07/23/18 and the attestation statement had not been signed by the laboratory director until 11/01/18; (g) Third 2018 Hematology/Coagulation Event - The samples had been tested on 11/27/18 and the attestation statement had not been signed by the laboratory director until 01/14/19; (h) First 2018 Microbiology Event - The samples had been tested on 02/26/18 and the attestation statement had not been signed by the laboratory director until 07/27/18. (2) The surveyor reviewed the findings with the technical consultant and general supervisor and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and general supervisor, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services for Troponin I and ABG (G3+ cartridge: pH, pCO2, pO2) testing. Findings include: (1) The laboratory director failed to ensure two levels of quality control materials were performed each day of patient testing. Refer to D5447.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant and general supervisor, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 technical consultant and general supervisor, the technical consultant failed to provide technical oversight 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.
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 technical consultant and general supervisor, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) On the first day of the survey, the surveyor reviewed records for 8 persons performing moderate complexity testing in 2018 and 2019. The records indicated the evaluations for 8 of 8 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 (i) The 02/08/18 and 01/02/19 evaluations had been performed by the general supervisor (this person had earned an associate degree in applied science). (b) Testing Person #3 (i) The 02/08/18 and 01/08/19 evaluations had been performed by the general supervisor (c) Testing Person #4 (i) The 02/05/18 and 01/05/19 evaluations had been performed by the general supervisor (d) Testing Person #5 (i) The 09/01/18 evaluation had been performed by the general supervisor (e) Testing Person #6 (i) The 02/05/18 and 01/01/19 evaluations had been performed by the general supervisor (f) Testing Person #9 (i) The 02/08/18 and 09/20/18 evaluations had been performed by the general supervisor (g) Testing Person #11 (i) The 02/18 and 10/21/18 evaluations had been performed by the general supervisor (h) Testing Person #12 (i) The 02/08/18, 10/30/18 and 01/08/19 evaluations had been performed by the general supervisor (2) The surveyor explained to the technical consultant and general supervisor that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).
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 technical consultant and general supervisor, 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.
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 technical consultant and general supervisor, the technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor, met the qualifications. Findings include: (1) On the first day of the survey, the surveyor reviewed records for 5 testing persons who had been hired to perform high complexity testing (ABO/Rh, Antibody Screen and Compatibility testing and Cerebrospinal fluid count) since the previous recertification survey performed 06/26/17 through 06/29/17. The records indicated the semi-annual evaluations for the testing persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical supervisor: (a) Testing Person #2 - The 02/18/18 semi-annual evaluation had been performed by the general supervisor (this person had earned an associate degree in applied science); (b) Testing Person #4 - The 02/05/18 semi-annual evaluation had been performed by the general supervisor; (c) Testing Person #9 - The 02/08/18 semi-annual evaluation had been performed by the general supervisor; (d) Testing Person #11 - The 02/07/18 semi-annual evaluation had been performed by the general supervisor; (e) Testing Person #12 - The 02/08/18 semi-annual evaluation had been performed by the general supervisor. (2) The surveyor explained to the technical consultant and general supervisor that all components of the semi-annual competency evaluations must be performed by a person who qualifies as a technical supervisor (493.1449 (q) an individual with an MD or DO with a current medical license in state of laboratory's location and certified in anatomic pathology by ABP or AOBP or equivalent qualifications or resident in a program leading to ABP or AOBP certification in anatomic and clinical pathology who performs duties delegated by the technical supervisor for histopathology). NOTE: The regulations only allow for an individual qualifying as a general supervisor to perform initial training and annual competency evaluations as stated at 493.1463 "Standard; General supervisor responsibilities: (b)(3) Providing orientation to all testing personnel; and (b)(4) Annually evaluating and documenting the performance of all testing personnel"