# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 26D0438768	**(X3) Date Survey Completed** 09/06/2022
Name of Provider or Supplier Carestl Health	**Street Address, City, State** 5471 Dr Martin Luther Dr, Saint Louis, MO	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was completed on September 6, 2022. It was determined that Immediate Jeopardy (IJ) existed for the following condition level deficiencies: 42 C.F. R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1447 Condition: Technical Supervisor
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2021/2022 and interview with the technical supervisor (TS), the laboratory failed to provide attestation documentation for 2 of 5 PT testing events in 2022. Findings: 1. Review of PT records for 2022 showed for PT testing event GH2-A and GB, the laboratory could not provide attestation records for testing personnel and the laboratory director to show routine integration of samples into the patient workload. 2. Interview with the TS on August 30, 2022 at 11:30 AM confirmed the laboratory could not provide 2 PT testing events attestation records.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's "Quality Assessment Program" procedure, competency/performance evaluations, quality control (QC) data, and interview with the technical supervisor (TS), the laboratory failed to follow the "Quality Assessment Program" procedure. Findings: 1. Review of "Quality Assessment Program" procedure stated "The ability of each individual to accurately perform each step of testing (i.e., their competency) must be evaluated annually" and "QC must be acceptable before testing and/or reporting of results is permitted. Any results obtained when the QC is unacceptable or not performed are invalid and must be repeated. There are no exceptions." 2. Review of personnel records showed no evaluation for competency/performance for testing personnel (TP) #1, TP #2, and TP #3 performing patient testing during 2021 and to date August 30, 2022 (Refer to D6128). 3. Review of Abbott Alinity chemistry analyzer QC results from May 1, 2022 to date August 30, 2022 showed the laboratory failed to follow established criteria for acceptability of control materials providing quantitative results for 83 of 83 testing days (Refer to D5469). 4. Review of Excyte M automated ESR analyzer quality control logs from January 5, 2022 to date August 30, 2022 showed no QC was performed on February 23, 2022, March 23, 2022, or April 25, 2022 (Refer to D5447). 5. Interview with the TS on August 30, 2022 at 12:15 PM confirmed the laboratory failed to follow the "Quality Assessment Program" procedure.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of Abbott Alinity chemistry analyzer and quality control (QC), Vital Diagnostics Excyte M analyzer and QC, Sysmex XN550 analyzer, review of manufacturer's instructions, freezer temperature logs, room temperature logs and humidity logs, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to provide a procedure for the Abbott Alinity chemistry analyzer (Refer to D5401); failed to provide a procedure for acceptability of QC results and reference intervals (normal values) (Refer to D5403); failed to follow manufacturer's instructions for reagent storage (Refer to D5411); failed to follow manufacturer's instructions for monitoring and documenting temperature and humidity (Refer to D5413); failed to verify performance specifications prior to reporting patient test results (Refer to 5421); failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for Alk phos, ALT, AST, DLDL, HDL, chloride, potassium, sodium, thyroid-stimulating hormone (TSH), and syphilis (Refer to D5439); failed to include two control materials each day of patient testing for ESR (Refer to D5447); and the laboratory failed to follow established criteria for acceptability of control materials providing quantitative results (Refer to D5469).

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 review of laboratory procedures and interview with the technical supervisor (TS), the laboratory failed to ensure a chemistry procedure is available. Findings: 1. Review of procedures showed no procedure for the Abbott Alinity chemistry analyzer. 2. Interview with the TS on August 30, 2022 at 12:15 PM confirmed the laboratory failed to ensure a procedure for the Abbott Alinity chemistry analyzer is available.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedures and interview with the technical supervisor (TS), the laboratory failed to provide a procedure for acceptability of quality control (QC) results and reference intervals (normal values) for tests performed on the Abbott Alinity chemistry analyzer, the Vital Diagnostics Excyte M analyzer, and the Sysmex XN550 hematology analyzer. Findings: 1. Review of the laboratory procedures showed no procedure for acceptability of QC results and no procedure for laboratory reference intervals (normal values) for tests performed on the Abbott Alinity chemistry analyzer, the Vital Diagnostics Excyte M analyzer, and the Sysmex XN550 hematology analyzer. 2. Interview with the TS on August 30, 2022 at 11:00 AM confirmed the laboratory failed to provide a procedure for acceptability of QC results and reference intervals (normal values) for tests performed on the Abbott Alinity chemistry analyzer, the Vital Diagnostics Excyte M analyzer, and the Sysmex XN550 hematology analyzer.

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 review of the Bio-Rad Liquichek Diabetes Control package insert, Bio-Rad Liquichek Immunoassay Plus Control package insert, Bio-Rad Liquichek Immunology Control package insert, observation of the laboratory, and interview with the technical supervisor (TS), the laboratory failed to follow manufacturer's instructions for reagent storage. Findings: 1. Review of the Bio-Rad Liquichek Diabetes Control package insert states, "Storage and stability: This product will be stable until the expiration date when stored unopened at -20C to -50C." 2. Review of the Bio-Rad Liquichek Immunoassay Plus Control package insert states, "Storage and stability: This product will be stable until the expiration date when stored unopened at -20C to -70C." 3. Review of the Bio-Rad Liquichek Immunology Control package insert states, "Storage and stability: This product will be stable until the expiration date when stored unopened at -20C to -70C." 4. Observation of the laboratory showed no freezer capable of maintaining a temperature of -20 Celsius. 5. Interview with the TS on August 30, 2022 at 11:00 AM, confirmed the laboratory failed to follow manufacturer's instructions for reagent storage.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the Abbott Alinity operations manual, review of the Excyte M operator's manual, lack of temperature and humidity logs, and interview with the technical supervisor (TS), the laboratory failed to follow manufacturer's instructions for monitoring and documenting temperature and humidity. Findings: 1. Review of the Abbott Alinity operations manual states, "Temperature during operation 15 C to 30 C (59 F to 86 F)" and "Relative humidity from 20% through 85%". 2. Review of the Excyte M operator's manual states, "Operating conditions: 15 C to 32 C room temperature Humidity: 10% - 98%". 3. Lack of temperature logs confirmed no documentation of temperature and humidity in 2021, and to date August 30, 2022 in the Abbott Alinity room or the Excyte M room. 4. Interview with the TS on August 30, 2022 at 11:00 AM confirmed the laboratory failed to follow manufacturer's instructions for monitoring and documenting temperature and humidity.
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 review of the performance verification procedures for the Abbott Alinity chemistry analyzer, patient results, and interview with the technical supervisor (TS), the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Abbott Alinity chemistry analyzer showed the laboratory failed to verify accuracy, precision, reportable range, and that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: albumin, alkaline phosphatase (Alk Phos), amylase, alanine transaminase (ALT), aspartate aminotransferase (AST), direct bilirubin, total bilirubin, calcium, cholesterol, carbon dioxide (CO_2), creatinine, direct low-density lipoprotein (DLDL), glucose, high-density lipoprotein (HDL), chloride, potassium, sodium, lactate dehydrogenase (LD), phosphorus, total protein, triglycerides, blood urea nitrogen (BUN), hemoglobin A1C, thyroid-stimulating hormone (TSH), and syphilis prior to the beginning of patient testing in March 2022. 2. Review of patient results from May 2022 to date August 30, 2022 showed 42,931 patient results were reported. 3. Interview with the TS on August 30, 2022 at 11:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
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 review of 2022 calibration records for the Abbott Alinity chemistry analyzer and interview with the technical supervisor (TS), the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of the Abbott Alinity chemistry analyzer calibration records for 2022 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: alkaline phosphatase (Alk phos), alanine transaminase (ALT), aspartate aminotransferase (AST), direct low-density lipoprotein (DLDL), high-density lipoprotein (HDL), chloride, potassium, sodium, thyroid-stimulating hormone (TSH), and syphilis. 2. Interview with the TS on August 30, 2022 at 11:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for Alk phos, ALT, AST, DLDL, HDL, chloride, potassium, sodium, thyroid-stimulating hormone (TSH), and syphilis.
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 review of the Excyte M automated erythrocyte sedimentation rate (ESR) analyzer quality control (QC) logs from January 5, 2022 to date August 30, 2022, patient results, and interview with the technical supervisor (TS), the laboratory failed to include two control materials of different concentrations for ESR for 3 of 118 patient testing days. Findings: 1. Review of Excyte M automated ESR analyzer quality control logs from January 5, 2022 to date August 30, 2022 showed no QC was performed on February 23, 2022, March 23, 2022, or April 25, 2022. 2. Review of patient results showed four patient test results were verified when ESR QC was not performed. 3. Interview with the TS on August 30, 2022 at 11:00 AM confirmed the laboratory failed to include two control materials each day of patient testing for ESR.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the

laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on interview with the technical supervisor (TS), review of Bio-Rad Liquid Assayed Multiqual Control package insert, Bio-Rad Lyphochek Immunoassay Plus Control, Abbott Alinity chemistry analyzer, Orchard LIS system, Abbott Alinity chemistry analyzer quality control (QC) results for 5 of 25 analytes from May 1, 2022 to date August 30, 2022, and patient results, the laboratory failed to follow established criteria for acceptability of control materials providing quantitative results for 83 of 83 testing days. Findings: 1. Interview with the TS stated three levels of chemistry controls are performed on the Abbott Alinity each day of patient testing and each level must be within acceptable limits before patient testing is performed. The TS stated they used assayed controls, followed package insert ranges and accepted QC in the LIS system. Review of Abbott Alinity chemistry analyzer internal QC ranges, Orchard LIS system QC ranges, and Bio-Rad controls showed the ranges in the LIS system where QC is accepted does not match QC ranges in the Abbott Alinity chemistry analyzer or the the package insert for Bio-Rad controls. 2. Review of Bio-Rad Liquid Assayed Multiqual Control level 1 lot # 45911 package insert in use showed: Alkaline Phosphatase acceptable QC range as 25.9-41.7 ALT/SGPT acceptable QC range as 18.0-26.0 Direct Bilirubin acceptable QC range as 0.209-0.424 Total Bilirubin acceptable QC range as 0.419-0.723 3. Review of Bio-Rad Assayed Multiqual Control Level 2 lot # 45912 package insert in use showed: Alkaline Phosphatase acceptable QC range as 132-175 ALT/SGPT acceptable QC range as 83.5-100 Direct Bilirubin acceptable QC range as 1.41-1.79 Total Bilirubin acceptable QC range as 2.53-3.47 4. Review of Bio-Rad Liquid Assayed Multiqual Control Level 3 Lot # 45913 package insert in use showed: Alkaline Phosphatase acceptable QC range as 268-348 ALT/SGPT acceptable QC range as 182-211 Direct Bilirubin acceptable QC range as 2.43-2.97 Total Bilirubin acceptable QC range as 6.54-8.58 5. Review of Bio-Rad Lyphochek Immunoassay Plus Control package insert in use showed: thyroid stimulating hormone (TSH) Lot # 40411 Level 1 acceptable QC range 0.301-0.433 TSH Lot # 40412 Level 2 acceptable QC range 3.78-4.93 TSH Lot # 40413 Level 3 acceptable QC range 23.9-31.4 6. Review of Abbott Alinity analyzer showed: Alkaline Phosphatase Level 1 acceptable QC range as 19.00000-28.00000 Alkaline Phosphatase Level 2 acceptable QC range as 119.00000-182.00000 Alkaline Phosphatase Level 3 acceptable QC range as 251.00000-308-00000 ALT/SGPT Level 1 acceptable QC range as 19.00000-28.00000 ALT/SGPT Level 2 acceptable QC range as 72.00000-109.00000 ALT/SGPT Level 3 acceptable QC range as 153.00000-174.00000 Direct Bilirubin Level 1 acceptable QC range as 0.20000-0.30000 Direct Bilirubin Level 2 acceptable QC range as 1.20000-1.70000 Direct Bilirubin Level 3 acceptable QC range as 2.40000-2.90000 Total Bilirubin Level 1 acceptable QC range as 0.40000-0.60000 Total Bilirubin Level 2 acceptable QC range as 2.40000-3.50000 Total Bilirubin Level 3 acceptable QC range as 6.40000-7.50000 7. Review of the Orchard LIS showed: Alkaline Phosphatase Level 1 acceptable QC range as 22.20-33.80 Alkaline Phosphatase Level 2 acceptable QC range as 119.00-161.00 Alkaline Phosphatase Level 3 acceptable QC range as 250.00-330.00 ALT/SGPT Level 1 acceptable QC range as 19.0-27.0 ALT/SGPT Level 2 acceptable QC range as 69.60-90.40 ALT/SGPT Level 3 acceptable QC range as 151.00-189.00 Direct Bilirubin Level 1 acceptable QC range as 0.16-0.36 Direct Bilirubin Level 2 acceptable QC range as 1.20-1.60 Direct Bilirubin Level 3

	acceptable QC range as 2.42-2.98 Total Bilirubin Level 1 acceptable QC range as 0.37-0.77 Total Bilirubin Level 2 acceptable QC range as 2.12-3.08 Total Bilirubin Level 3 acceptable QC range as 6.20-8.20 thyroid stimulating hormone (TSH) Level 1 acceptable QC range 0.30-0.43 TSH Level 2 acceptable QC range 3.58-4.73 TSH Level 3 acceptable QC range 23.90-31.40 8. Review of Abbott Alinity analyzer QC showed the following unacceptable results: Alkaline Phosphatase QC unacceptable results for: Level 1 QC in 2022: 5/26, 7/18, 7/20, 8/11, 8/12, 8/15 and 8/29 Level 2 QC in 2022: 5/17, 5/26, 7/18, 7/19, 7/20, 8/2, 8/11, 8/12, 8/15, 8/29. Level 3 QC in 2022: 5/26,7/22, 8/11, 8/12 and 8/15 ALT/SGPT QC unacceptable results for: Level 1 QC in 2022: 5/16 Level 2 QC in 2022: 5/2 to 5/27 for 19 days 6/1 to 8/29 for 49 days Level 3 QC in 2022: not in acceptable limits from 5/2 to 8/29 for 71 days Direct Bilirubin QC unacceptable results for: Level 1 QC in 2022: 5/26, 7/6, 7/7, 7/8, 7/15. 7 /18, 7/19, 7/20, 7/21, 7/22, 7/25, 7/26, 8/1, 8/2, 8/11, 8/15 and 8/17 Level 2 QC in 2022: not in acceptable limits from 5/2 to 5/12 and 5/17 to 8/18 for 63 days Level 3 QC in 2022: 5/26 Total Bilirubin QC unacceptable results for: Level 1 QC in 2022: 5 /26 Level 2 QC in 2022: 5/13, 5/16, 5/17, 5/18, 6/3, 7/7, 7/8, 7/11, 7/12, 7/13, 7/14, 7 /15, 7/18, 7/25, 7/26, 7/28, 7/29, 8/2, 8/3, 8/4, 8/11, 8/12, 8/26 and 8/29 Level 3 QC in 2022: 5/19, 7/18 to 8/4 for 15 days total TSH QC unacceptable results for: Level 2 QC in 2022: 5/20 8. Review of patient results showed the laboratory reported 2,162 alakaline phosphatase, 2,162 ALT/SGOT, 3 direct bilirubin's, 2,161 total bilirubin's and 894 TSH patient test results while QC was not acceptable from May 1, 2022 to date August 30, 2022. 9. Interview with the TS on August 30, 2022 at 12:00 PM confirmed the laboratory failed to follow established criteria for acceptability of control materials providing quantitative results.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient test report and interview with the technical supervisor (TS), the laboratory failed to include the name and address of the laboratory location where the testing was performed on the patient test report. Findings: 1. Review of the patient test report showed no name and address of the laboratory location where the test was performed. 2. Interview with the TS on August 30, 2022 at 11:00 AM confirmed the laboratory failed to include the name and address of the laboratory location where the testing was performed on the patient test report.
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 review of Abbott Alinity chemistry analyzer quality control (QC), Vital Diagnostics Excyte M analyzer QC, and personnel records in 2020/2021/2022 and interviews, the technical supervisor (TS) failed to fulfill the TS responsibilities. The TS failed to provide technical and scientific oversight of the laboratory (Refer to D6112); the TS failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained (Refer to D6117); the TS failed to evaluate and document competency/performance for three of three testing personnel (TP) at least annually during 2021, and to date August 30, 2022 (Refer to D6128).
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on review of chemistry and hematology quality control (QC), annual competencies, performance specifications, and interview with the technical supervisor (TS), the TS failed to provide technical and scientific oversight of the laboratory. Findings: 1. Review of chemistry and hematology QC showed the TS failed to ensure the laboratory's established parameters for acceptable levels of analytic performance were maintained throughout the entire testing process (refer to D5447 and D5469). 2. Review of competencies showed the TS failed to document annual competency for 3 of 3 testing personnel in 2021. 3. Review of performance specifications for the Abbott Affinity chemistry analyzer showed the TS failed to verify performance specifications prior to reporting patient test results. 4. Interview with the TS on August 30, 2022 at 11:00 AM confirmed the TS failed to provide technical and scientific oversight of the laboratory.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of chemistry and hematology quality control (QC) and interview with the technical supervisor (TS), the TS failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained. Findings: 1. Review of Abbott Alinity chemistry analyzer QC results from May 1, 2022 to date August 30, 2022 showed the TS failed to follow established criteria for acceptability

	of control materials providing quantitative results for 83 of 83 testing days (Refer to D5469). 2. Review of Excyte M automated ESR analyzer quality control logs from January 5, 2022 to date August 30, 2022 showed no QC was performed on February 23, 2022, March 23, 2022, or April 25, 2022. 3. Interview with the TS on August 30, 2022 at 12:15 PM confirmed the TS failed to establish a quality control program appropriate for the testing performed and establish the parameters for acceptable levels of analytic performance and ensure that these levels are maintained.
D6128	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 annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor (TS), the technical supervisor (TS) failed to evaluate and document competency /performance for three of three testing personnel (TP) at least annually during 2021, and to date August 30, 2022. Findings: 1. Review of personnel records showed the TS did not evaluate competency/performance for TP #1, TP #2, and TP #3 performing patient testing during 2021 and to date August 30, 2022. 2. Interview with the TS on August 30, 2022 at 11:00 AM, confirmed competency/performance evaluations were not conducted at least annually in 2021 and to date August 30, 2022.