Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D2273426	**(X3) Date Survey Completed** 09/05/2024
Name of Provider or Supplier Alpha Medical Laboratory, Llc	**Street Address, City, State** 1404 S Fretz, Ste 100, Edmond, 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 initial survey was performed on 09/05/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the owner, laboratory director, and testing person #1 at the conclusion of the survey.
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 a review of records, observation, and interview with the laboratory director, the laboratory failed to ensure two of two boxes of Triage total 5 quality control materials were stored as required by the manufacturer. Findings include: (1) On 09/05/2024 at 11:00 am observation of the contents of the laboratory freezer identified the following materials: (a) One box of Triage Total 5 quality control materials, level one, lot# C3977AN; (b) One box of Triage Total 5 quality control materials, level two, lot# C4020AN. (2) The storage requirement, as stated on the box for the materials was -20 degrees C (Celsius) or colder; (3) Observation of the freezer temperature logs from May 2024 to June 2024 identified the following: (a) The temperatures were warmer than -20 degrees C for 14 of 61 days reviewed. (4) The findings were reviewed with the laboratory director who stated on 09/05/2024 at 11:00 am, the freezer temperatures were not within the manufacturer's storage requirements.
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, observation, and interview with the laboratory director, the laboratory failed to ensure Triage cartridges had not exceeded their room temperature expiration date for one of one cartridge types observed and failed to ensure expired supplies were not available for use. Findings include: CARDIAC MARKERS (1) On 09/05/2024 at 11:30 am, the laboratory director stated Cardiac Marker (CKMB, and Troponin I) testing was performed using the cardiac marker cartridge and the Triage meter pro analyzer; (2) Observation of the laboratory on 09/05 /2024 at 11:30 am identified one cardiac marker cartridge stored at room temperature (Lot #T14679R), without documentation of when it was removed from refrigeration; (3) Review of the manufacturer's storage requirements showed the following: (a) The cartridges were stable at 2-8 degrees C (Centigrade) until the expiration date listed on the box; (b) The cartridges were stable at room temperature (18-30 degrees C) for 14 days. (4) Interview with the laboratory director on 09/05/2024 at 11:00 am confirmed the cardiac marker cartridge had not been dated appropriately. AFFIRM VPIII TRANSPORT SYSTEM (1) Observation of the supply room on 09/05/2024 at 11:00 am, identified the following expired supplies were available for use: (a) Eight BD Affirm VPIII Ambient temperature transport systems, lot #B01E264M, expired 10/30 /2023. (2) Interview with the laboratory director on 09/05/2024 at 11:00 am confirmed the transport systems were available for use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to utilize the demonstrated reportable range for five of five analytes reviewed for the Piccolo test system and two of two analytes reviewed for the Triage Meter Pro. Findings include: (1) On 09/05/2024 at 1:30 pm, the laboratory director stated the laboratory began using the Piccolo analyzer to perform routine chemistry testing which included the analytes ALT (Alanine Aminotransferase), Albumin, Glucose, Sodium, and BUN (Urea) on plasma samples on 12/30/2022; (2) A review of the performance specifications records identified the laboratory had demonstrated the following reportable ranges for five of five analytes reviewed: (a) ALT - 27-1401 (b) Albumin - 1.5-5.5 (c) BUN - 2 - 80 (d) Sodium - 116-167 (e) Glucose - 37-658 (3) Interview with the laboratory director on 09/05/2024 at 1:30 pm confirmed the laboratory was using the following manufacturer's reportable ranges instead of the

	reportable ranges that had been demonstrated by the laboratory: (a) ALT - 5-2000 (b) Albumin - 1-6.5 (c) BUN - 7-175 (d) Sodium - 110-170 (e) Glucose - 10-700
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 laboratory director, the laboratory failed to ensure data supported the QC (Quality Control) frequency as defined in the IQCP (Individualized Quality Control Plan) for one of one test system. Findings include: (1) On 09/05/2024 at 1:30 pm, the laboratory director stated the following: (a) Troponin I and CKMB testing were performed using the Quidel Triage Meter Pro analyzer and the Triage Cardiac Marker cartridge beginning 12/20/2022; (b) An IQCP had been developed for the test system. (2) A review of the IQCP identified the QCP (Quality Control Plan) required two levels of external QC materials be performed each month; (3) A review of supporting documentation for the QCP identified the following: (a) Cardiac Markers (i) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (ii) Two levels of QC had been tested for 20 days (not at least 30-31 days). (4) The records were reviewed with the laboratory director who stated on 09/05/2024 at 01:30 pm, the QC had not been tested to support the QC frequency.