Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2293206	03/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Alpha Medical Laboratory, Llc	1563 Rosewood Unit C, Nixa, 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
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 procedures and interview with laboratory director (LD), the laboratory failed to provide written procedures for performing chemistry quality control (QC). Findings: 1. Review of procedures showed no procedure for performing QC on Piccolo Xpress chemistry analyzer 2. Review of procedures showed no procedure for performing QC on the Triage chemistry analyzer. 3. Interview with LD on March 7, 2024 at 10:30 AM confirmed the laboratory failed to provide written procedures for performing chemistry QC.

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 Sysmex XN550 hematology analyzer and the Piccolo Xpress analyzer, Triage analyzer, patient results, and interview with the laboratory director (LD), the laboratory failed the laboratory failed to verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Sysmex XN550 hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing. 2. Review of performance specifications for the Piccolo Xpress analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: magnesium, phosphorus, lactic acid, sodium, potassium, chloride, carbon dioxide, albumin, total protein, alkaline phosphatase, aspartate aminotransferase, glucose, calcium, total bilirubin, blood urea nitrogen and creatinine prior to the beginning of patient testing. 3. Review of performance specifications for the Triage analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: Ddimer, CKMB and troponin prior to the beginning of patient testing. 4. Interview with the LD on March 7, 2024 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of procedures and interview with the laboratory director (LD), the technical consultant (TC) failed to ensure a procedure for evaluating competency was available. Findings: 1. Review of procedures showed no procedure for evaluating competency. 2. Interview with the LD on March 7, 2024 at 10:30 AM confirmed the LD failed to ensure a procedure for evaluating competency was available.
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417

	The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of clinical consultant credentials, and interview with the laboratory director (LD), the laboratory failed to ensure the clinical consultant was qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. Findings: 1. Review of the clinical consultant's credentials revealed no documentation to show clinical consultant is qualified. 2. Interview with the LD on March 7, 2024 at 10:30 AM confirmed the laboratory failed to ensure the clinical consultant was qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care.