Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2293206	01/20/2026
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (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 2024/2025 and interview with the laboratory director (LD), the laboratory failed to provide attestation documentation for four of twelve PT testing events in 2024. Findings: 1. Review of PT records for 2024 showed the laboratory could not provide attestation records for testing personnel and the laboratory director to show routine integration of samples into the patient workload for the following proficiency testing events: 2024 Chemistry-first event 2024 Hematology/Coagulation-first event 2024 Chemistry-second event 2024 Hematology-third event 2. Interview with the LD on January 20, 2026 at 11:30 AM confirmed the laboratory could not provide PT testing events attestation records for four PT testing events in 2024.
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) 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.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2024/2025 and interview with the laboratory director (LD), the laboratory failed to maintain copies of all PT records including raw data of PT test results for three of twelve PT testing events in 2024 and 2025. Findings: 1. Review of PT records for 2024 showed the laboratory could not provide raw data of PT test results for the following proficiency testing events: 2024 Hematology/Coagulation-first event 2024 Chemistry-second event 2. Review of PT records for 2025 showed the laboratory could not provide raw data of PT test results for the following proficiency testing event: 2025 Chemistry-third event 3. Interview with the LD on January 20, 2026 at 11:30 AM confirmed the laboratory could not provide raw data of PT test results for three PT testing events in 2024 and 2025.
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 Sysmex XN550 calibrations, review of the Sysmex XN550 quality control (QC), review of Triage chemistry QC, and interviews, the laboratory failed to meet the condition of analytic systems. The laboratory failed to perform calibration verification on the Sysmex XN550 hematology analyzer in 2024 to date January 21, 2026 (Refer to D5437); and the laboratory failed to provide documentation of two control materials of different concentrations each day of patient testing for complete blood count (CBC), differential and creatine kinase-myocardial band (CK/MB) and troponin (Refer to D5447).
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of Sysmex XN550 hematology analyzer's calibration records and interview with the laboratory director, the laboratory failed to perform calibration

	verification on the Sysmex XN550 hematology analyzer in 2024 to date January 21, 2026. Findings: 1. Review of 2024, 2025, and to date January 20, 2026 calibration records for the Sysmex XN550 hematology analyzer showed the laboratory failed to perform a calibration verification every six months in 2024, 2025 and to date January 20, 2026 for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelet. 2. The laboratory was performs 1422 complete blood counts annually. 3. Interview with the laboratory director on January 20, 2026 at 10:00 AM confirmed the laboratory failed to perform calibration verification every six months for calibration of the Sysmex XN550 hematology analyzer.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of Sysmex XN550 quality control (QC), triage QC and interview with the lab director, the laboratory failed to provide documentation of two control materials of different concentrations each day of patient testing for complete blood count (CBC), differential and creatine kinase-myocardial band (CK/MB) and troponin. Findings: 1. Review of Sysmex XN550 hematology QC showed the laboratory could not provide QC each day of patient testing for white blood cell, red blood cell, hemoglobin, hematocrit, platelet count and differentials from January 2024 to date January 20, 2026. 2. The laboratory performs 1422 CBC's annually. 3. Review of Triage chemistry QC showed the laboratory could not provide QC each day of patient testing for CK/MB and troponin from January 2024 to date January 20, 2026. 4. The laboratory performs 196 CK/MB and troponin's annually. 5. Interview with the laboratory director on January 20, 2026 at 11:30 AM, confirmed the laboratory failed to provide documentation of two control materials of different concentrations each day of patient testing for CBC's, differential, CK/MB and troponin.
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 review of proficiency testing (PT), review of quality assessment program, review of testing personnel (TP) training, the laboratory failed to meet the condition of laboratory director (LD). The LD failed to ensure three of twelve PT testing events were reviewed by appropriate staff to evaluate, identify problems requiring corrective action and to evaluate ungraded results (Refer to D6018); the LD failed to ensure a quality assessment program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (Refer to D6020); and the LD failed to ensure one TP received the appropriate training prior to performing patient testing in 2025 (Refer to D6029).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2024 and 2025 and interview with the laboratory director, the laboratory director failed to ensure three of twelve PT testing events were reviewed by appropriate staff to evaluate, identify problems requiring corrective action and to evaluate ungraded results. Findings: 1. Review of the chemistry 1st event PT testing event of 2024 the laboratory did not have documentation to show the testing reports received were reviewed and ungraded results were evaluated by appropriate staff for: total bilirubin CH-02, CH-03, CH-05 potassium CH-05 sodium CH-04 pilot BNP PCS-01, PCS-02 pilot BNP CK-MB PCS-01, PCS-02 pilot D-dimer PSC-01, PSC-02 pilot troponin PSC-01, PSC-02 2. Review of the chemistry 2nd event PT testing event of 2024 the laboratory did not have documentation to show the testing reports received were reviewed and ungraded results were evaluated by appropriate staff for: ALT/SGPT CH-08 3. Interview with the laboratory director on January 20, 2026 at 11:00 AM confirmed the laboratory director failed to ensure appropriate staff review, evaluate and identify problems requiring corrective action for all PT results received.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on lack of quality assessment program and interview with the laboratory director, the laboratory director failed to ensure a quality assessment program was established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. Review of quality assessment program revealed no quality assessment program available to established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 2. Interview with the laboratory director on January 20, 2026 at 11:30 AM confirmed no quality assessment program was available for review.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by:

	Based on review of testing personnel (TP) training documents and interview with the laboratory director, the laboratory director (LD) failed to ensure one of three TP received the appropriate training prior to performing patient testing in 2025. Findings: 1. Review of training documents showed TP #4 had no documented training prior to performing patient testing in 2025. 2. Interview with the laboratory director on January 20, 2026 at 11:30 AM confirmed the LD failed to ensure TP received the appropriate training prior to performing patient testing.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the laboratory director, the technical consultant (TC) whom is also the laboratory director failed to evaluate and document the performance of one of three TP at least semiannually during the first year the individual tests patient specimens in 2025. Findings: 1. Review of performance evaluations showed the TC failed to perform the semiannual competency evaluation for TP #3. 2. Interview with the laboratory director on January 20, 2026 at 11:30 AM, confirmed the TC failed to evaluate and document the performance of TP #3 semiannually during the first year the individual tests patient specimens.