Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0556637	05/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Altitude Pulmonary And	435 Arden Ave Ste 310, Glendale, CA	

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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) (a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, College of American Pathologists (CAP) proficiency testing (PT) records, and an interview with the medical assistant (MA), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Partial pressure of Oxygen (pO2) analyte in the second event of 2024 (Q2-2024). The findings include: 1. The surveyor reviewed the PT records for Q2-2024, where CAP reported an unsatisfactory score. The results were as follows: a. pO2 PT Q2-2024 Overall score: 20% Specimen Reported Expected AQ-06 *158 65 - 87 AQ-07 *113 82 - 109 AQ-08 87 78 - 99 AQ-09 *100 104 - 128 AQ-10 *75 136 - 169 Legend: * = unsatisfactory score reported 2. The MA affirmed by interview on May 1, 2025, at approximately 11:50 a.m. that the laboratory obtained the PT scores mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 1,500 pO2 patient test samples during the time the laboratory received an unsatisfactory proficiency testing score. Thus, the accuracy and reliability of patient test reported cannot be determined.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

	This STANDARD is not met as evidenced by: Based on the lack of a laboratory safety procedure, surveyor's observations during the tour, and an interview with medical assistant (MA); it was determined that the laboratory failed to establish safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: 1. The laboratory lacked an established and approved safety policy and procedure to provide protection from physical, chemical, biochemical, and biohazardous materials as needed based on the laboratory's risk assessment. 2. The laboratory had an eye wash station, as observed and noted by the surveyor during the facility tour on May 1, 2025 at approximately 12:40 p.m. However, no documentation was available to review that it was checked. 3. The MA affirmed by interview on May 1, 2025, at approximately 12:40 p.m., that the laboratory lacked a safety policy and procedure and failed to check the eye wash station in the laboratory area. The MA also added that until the day of the survey, she was uncertain that the eye wash station was working. 4. The safety of laboratory personnel could not be assured. 5. The annual testing declaration form (Lab-144) signed by the director on April 24, 2025, stated that the laboratory processed and reported approximately 5,700 patient tests for Routine Chemistry and Hematology during the time when neither a safety protocol nor an eye wash station documentation log was in place.
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. This STANDARD is not met as evidenced by: Based on the surveyor's review of an incomplete quality assessment policy and procedure, proficiency testing records, five randomly chosen patient results and an interview with the medical assistant (MA) on May 1, 2025, it was determined that the laboratory failed to have a complete policy and procedure for an ongoing mechanism to monitor and assess, and when indicated, correct problems identified in the all phases of the testing system. The findings include: 1. The laboratory's current protocol was limited to competency assessment, quality control logs, and maintenance and function check log. 2. The incomplete quality assessment policy and procedure found lacked a risk assessment, safety protocol, criteria for rejection of samples, any documentation tracking to show comparison of test results. 3. The MA affirmed by interview on May 1, 2025, at approximately 11:40 a.m., that the laboratory had an incomplete system to monitor, assess, or correct problems, when identified in any phase of their processes. 4. The laboratory's testing declaration form submitted at the day of the survey stated approximately 5,700 patient test samples were processed and reported for Blood Gas Analysis, including the Hematocrit tests annually during the time the laboratory had an incomplete quality assessment protocol in place.
D6011	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2) (e)(2) provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

	This STANDARD is not met as evidenced by: Based on the surveyor's direct observations during the tour of the laboratory and an interview with the medical assistant; it was determined that the laboratory director failed to provide a safety protocol to ensure a safe environment in which employees and patients are protected from physical, chemical, and biological hazards. See D3011.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the surveyor's review of proficiency testing (PT) event scores on May 1, 2025, at approximately 11:50 a.m., and an interview with the medical assitant, the laboratory director is herein cited for failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. The findings include: 1. The laboratory received an unsatisfactory PT score of 20 percent in Blood Gas analysis. See. D2087.
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 the surveyor's review of the laboratory's incomplete quality assessment policy and procedure, proficiency testing records (PT) from the College of American Pathologists (CAP) for the second and third event of 2022 and an interview with the medical assistant on May 1, 2025 at approximately 11:50 a. m., the laboratory director is herein cited for failing to ensure that all proficiency testing reports received are reviewed to evaluate the laboratory 's performance and to identify any problems that require corrective action. The findings include: 1. The laboratory had a protocol for corrective action report (CAR) but was not followed, resulting to failure in addressing the less than 100% score for CAP PT for the second event (Q2) and third event (Q3) of 2022. 2. The laboratory obtained PT scores of 80% for: a. Hematocrit and Ionized Calcium for Q2-2022. b. Potassium for Q3-2022. 3. The MA affirmed by interview on May 1, 2025 at approximately 11:50 a.m., that the laboratory received the scores for all analytes mentioned in statement #2 and failed to have a CAR as mentioned in statement #1. Thus, the accuracy and reliability of patient test results reported cannot be assured. 4. Based on the laboratory's testing declaration submitted at the time on survey, 5,700 patient test samples were processed and reported annually during the time the laboratory obtained the less than 100% PT scores wherein a CAR was failed to be performed.
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 the surveyor's findings on May 1, 2025, the laboratory director is herein cited for the deficient practice of failure to ensure quality assessment programs were completely established and followed to assure and monitor the quality of laboratory services provided, and to identify issues as it occured. See D5791.