Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1006209	02/12/2025
Name of Provider or Supplier	**Street Address, City, State**	
Antelope Valley Lung & Sleep Institute, Inc	525 Commerce Avenue Suite A, Palmdale, 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) 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 review of the American Proficiency Institute (API) proficiency testing (PT) records, six (6) randomly selected patient test records, and interviews with the office manager (OM) and testing personnel (TP); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for potential of Hydrogen (pH) analyte in Blood Gas analysis in 2022. The findings include: 1. Based on review of PT records for the second event of 2022 (Q2-2022), API reported an unsatisfactory score report as follows: pH PT Q2-2022 Overall score: 60% Specimen Reported Expected BG-06 7.52 7.44 - 7.53 BG-07 *7.62 7.52 - 7.61 BG-08 *7.68 7.59 - 7.67 BG-09 7.14 7.09 - 7.18 BG-10 7.23 7.18 - 7.27 * Unacceptable result 2. The OM and TP affirmed by interview on February 12, 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 2,300 Routine Chemistry tests, including the pH analyte in Blood Gas analysis, during the time the laboratory received unsatisfactory proficiency testing results.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's protocol for the retention and storage requirements, six (6) patient test records, lack of documentation of quality control (QC) and preventive maintenance (PM) records, and interviews with the office manager (OM) and testing personnel (TP) on February 12, 2025; it was determined that the laboratory failed to retain QC and PM records for 2022. The findings include: 1. Based on the CFR 493.1105(a)(3), the laboratory is required to retain quality control and patient test records documenting all analytic activities for at least 2 years. 2. Based on the review of 6 patient test records covering April 8, 2022 to December 5, 2024, one (1) out of 6 records was unable to be retrieved by the laboratory for QC and PM. 3. In an interview on February 12, 2025 at approximately 11:50 a.m., the OM and TP stated that the 2022 records were possibly included in the discard pile and were only discovered to be missing on the day of the survey. Thus, no records were available for review. 4. According to the testing declaration form submitted at the time of survey, the laboratory performed and reported 2,300 Blood Gas test results.