Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0971726	08/06/2025
Name of Provider or Supplier	**Street Address, City, State**	
Santa Barbara Pulmonary Associate	2403 Castillo St, Ste 206, Santa Barbara, 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
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 surveyor's observation during the laboratory tour, review of the laboratory's policy and procedure, and interviews with office manager (OM) and laboratory director (LD), the laboratory failed to establish safety procedures to ensure protection from physical, chemical, and biochemical materials. The findings include: 1. Based on the surveyor's review of policies and procedures on the day of the survey, August 6, 2025, at approximately 1:00 p.m. the laboratory failed to provide a written policy and procedure for laboratory safety. 2. Based on the surveyor's observations during the laboratory tour where processing and testing of samples took place, it was found that the laboratory lacked eye washing in the testing area. 3. The OM and LD affirmed by interviews August 6, 2025, at approximately 1:15 p.m. that the laboratory lacked safety procedures and eyewash in the sample processing and testing area. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 08/6/2025, the laboratory processed and reported annually approximately 3,000 patients' test samples.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's quality assessment (QA) policies and procedures, personnel competency documentation, five (5) randomly selected patient records, and an interview with the office manager (OM) as specified in the personnel requirements in subpart M, the laboratory failed to perform competency assessments for all testing personnel (TP) for the years 2023, 2024 and 2025. The findings include: 1. Based on the surveyor's review of documentation, the laboratory lacked competency documentation for testing personnel for the years 2023, 2024, and 2025. 2. None of the three (3) testing personnel listed in the CMS-209 form had complete records of competency assessment for the years 2023, 2024, and 2025 in Routine Chemistry including Respiratory Blood Gases, and Hematology testing performed in the laboratory. 3. The OM affirmed by interview on the day of the survey August 6, 2025, at approximately 12:00 p.m., of this deficient practice: all competency assessments performed for testing personnel for 2023, 2024, and 2025 were not performed. 4. According to the laboratory's annual testing declaration form submitted at the time of the survey, the laboratory reported and performed approximately 3,000 Chemistry, and Hematology specialties during the time competency assessments for all TP were not performed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on the lack of laboratory written policies and procedures for the GEM 500 and interviews with the laboratory's office manager, the laboratory failed to have available and follow by all testing personnel written procedure for blood gasses and electrolytes tests performed in the laboratory. The findings included: 1. The laboratory uses on the daily basis the instrument GEM 500 for testing blood gases and electrolytes. 2. On the day of the survey on August 6, 2025, at approximately 12:15 p.m. the laboratory failed to provide written policies and procedures for the instrument GEM 500 to test patients' samples for blood gases and electrolytes performed daily in the laboratory. 3. The OM confirmed on 8/6/2025 at approximately 12:30 p.m. that the laboratory did not have written policies and procedures available for the blood gases and electrolytes test performed in the laboratory in the GEM 500 instrument. 4. Based on the laboratory's annual testing volume declaration signed by the laboratory director on 8/6/2025, the laboratory processes and reports 1,500 Routine Chemistry, including blood gases, samples annually for which the laboratory did not have a written procedure approved by the laboratory director, available, and followed by all testing personnel.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) (a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of policies and procedures, five (5) randomly selected patient records, and interviews with the laboratory's office managers (OMs); the laboratory failed to establish and follow a laboratory director's approved policy and procedure for corrective action. Findings include: 1. Based on the surveyor's review of policies and procedures; no corrective action documentation for the years 2023, 2024, and 2025 were found at the time of inspection. 2. The OM confirmed by interview on August 6, 2025, at approximately 1:15 p.m. that the laboratory did not have a written policy and procedure for corrective action documentation as mentioned in statement #1. 3. Based on the testing declaration submitted at the time of the survey, the laboratory performed and reported 3,000 tests annually during the time that no corrective action was documented; thus, the quality and accuracy of patient records cannot be assured.
D5813	TEST REPORT CFR(s): 493.1291(g) (g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on the lack of a policy and a list of critical values for Hematology and Routine Chemistry tests performed in the laboratory, review five (5) randomly selected patient sampling test results, and interview with the office manager (OM) and laboratory director (LD); the laboratory failed to have and follow a policy for reporting of critical values. The findings included: 1. The laboratory's lacked a policy and procedure manual, did not have a critical results notification policy, neither was a list of established critical values for all tests performed in the laboratory. 2. For one (1) out of five (5) patients' results reviewed there were no documentation notes on how critical values were handled and reported by the testing personnel. 3. The OM affirmed on August 6, 2025, at approximately 1:45 p.m. that the laboratory did not have a written policy and procedure on critical values documentation for reporting.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the lack of the laboratory personnel competency evaluations for the years 2023, 2024, and 2025 and interviews with the office manager, the laboratory director is herein cited for failure to ensure that policies and procedures were established and followed to monitor individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their

	competency to process specimens and perform test procedures promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D5209
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on the surveyor's direct observation and interview with the office manager; it was determined that the laboratory director failed to ensure that a signed and dated approved written test procedure for the GEM 500 instrument used in the laboratory is always available to all personnel responsible for any aspect of the testing process. See D5401.