Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0688433	07/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pulmonologists Pc	10605 Concord Street #500, Kensington, MD	

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 observation in the laboratory testing area and interview with the testing person (TP), the laboratory failed to provide an eyewash station within the work area. Findings: 1. Occupational Safety and Health Act (OSHA) regulation 29 CFR 1910.151 (c) requires that "where the eyes or body of any person may be exposed to injurious corrosive materials, suitable facilities for quick drenching or flushing of the eyes and body shall be provided within the work area for immediate emergency use." 2. The area where the TP was performing blood gas analysis was toured during the survey. There was no eyewash attached to the sink or the wall next to the sink. 3. During the survey on 07/06/2023 at 3:00 PM, the TP confirmed that there was no eyewash station within the laboratory where testing is performed.
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 the laboratory's procedure manual and interview with the testing person (TP), the laboratory failed to have written policies and procedures for all required activities performed by the TP. Findings: During the survey on 07/06/2023 at 3:00 PM, the TP confirmed that the laboratory's procedure manual did not have written instructions for attaching the original patient test printouts to the appropriate date in the monthly/daily annual planner used for storing patient and electronic simulator results and how to document the results into the computer system.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patients final reports and interview with the testing person (TP), the laboratory failed to ensure that the final test report included the units of measurement for the interpretation of the patient results. Findings: 1. A final patient report was selected for review in the computer. The final report that was reviewed listed the results of the tests performed but failed to include the normal reference range for interpretation of normal vs. abnormal values. 2. During the survey on 07/06 /2023 at 3:00 PM, the TP confirmed that the final reports did not include the normal reference ranges for interpretation of the final results.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the laboratory director failed to ensure that there was an approved quality assessment (QA) program to assure the quality of the laboratory services. Findings: During the survey on 07/06/23 at 3:00 PM, the TP confirmed that the procedure manual did not include a written QA program designed to monitor the activities of the laboratory. Please note: The QA program must include, but is not limited to the following: patient test management, testing methods, quality control, proficiency testing, comparison of test results, relationship of patient information to patient test results, personnel assessment, communication, complaint investigation and quality assessment reviews.