Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0688433	03/14/2025
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the procedure, review of calibration records, and interview with the testing person (TP), the laboratory failed to define the acceptable limits for calibration verification and record corrective actions when the level 5 calibrator for partial pressure of oxygen (pO2) was outside the manufacturer's acceptable ranges in two of three calibration verifications reviewed. Findings: 1. The laboratory used an Abbott i-STAT for blood gas analysis. 2. The "Analyzer Standardization and Calibration" section of the laboratory's "Procedure Manual for the i-STAT 1 System" stated that "Standardization and Calibration is performed twice a year," "5 levels of Calibration Verification materials (from Abbott) are tested and documented on the i-

	STAT QC Log," "If controls are WNL [within normal limits], the analyzer may be used for patient testing," and "If the controls fail, the analyzer is taken out of service immediately." 3. The procedure did not specify if all five levels of calibration verification materials were required to be WNL for patient testing to continue. 4. The laboratory performed calibration verifications on 11/27/2024, 05/01/2024, and 11/02/2023. 5. The laboratory's result for pO2 level 5 (lot 23307 CLEW A49) on 11/27/2024 was 310 mmHg with a manufacturer's acceptable range of 315-435 mmHg. 6. The laboratory's result for pO2 level 5 (lot 23102 CLEW A48) on 05/01/2024 was 302 mmHg with a manufacturer's acceptable range of 303-423 mmHg. 7. There was no documentation of corrective actions taken for the pO2 level 5 values that were outside the manufacturer's acceptable ranges. 8. During the exit interview on 03/14/2025 at 2:00 PM, the TP confirmed that the level 5 calibration verification controls were outside the manufacturer's acceptable ranges and no corrective actions were documented.