Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0942887	04/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pulmonary Disease Specialists Pa	1121 N Central Ave Ste B, Kissimmee, FL	

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
D0000	A recertification survey was conducted on April 11, 2022. Pulmonary Disease Specialists PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review, and interview, the laboratory failed to enroll in Proficiency Testing (PT) with an approved Proficiency Testing program for the Blood Gases analyte Glucose in 2020 (1st, 2nd 3rd events), 2021 (1st, 2nd 3rd events), and 2022 (1st event). This is a repeat deficiency from the survey on 06/09/2020. Findings: Review of the College of American Pathologists (CAP) PT records showed there was not any proficiency testing performed on the analyte glucose in 2020 to 2022. During an interview on 04/11/2022 at 9:38 AM, Testing Personnel A stated they were not enrolled in proficiency testing for glucose.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (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 record review, and interview, the laboratory failed to perform calibration /linearity on the Nova Stat Profile Prime blood gases instrument at least once every 6 months from 04/11/2020 to 04/11/2022. Findings: Review of the laboratory's quality control records showed there was not any documentation of the calibration/linearity being performed. Review of the package insert for the Nova Linearity Levels 1 - 4 listed the intended use as "Use for in vitro diagnostic use to verify calibration, analytic linearity, estimate test imprecision, and detect systematic analytical deviations that may arise from calibrator cartridges or analytical instrument variations for pH (potential of Hydrogen), PCO2 (Partial Pressure of Carbon Dioxide), PO2 (Partial Pressure of Oxygen), Na (Sodium), K (Potassium), Cl (Chloride) , iCa (Ionized Calcium), iMg (Ionized Magnesium), Glu (Glucose), and Lac (Lactate)." The package insert also noted to "use as frequently as required by local regulatory and hospital requirements. On 04/11/2022 at 11:55 AM, Testing Personnel A stated they did not perform linearity.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to list the normal values of the laboratory tests for two (#1, #2) of three (#1, #2, #3) patients' laboratory test reports. Findings: Review of the patients' laboratory pulmonary function laboratory report, instrument printout, and the pulmonary function testing (PFT) test results showed the normal values were not listed on the reports given to two of three patients, (#1 and #2) On 04/11/2022 at 12:30, the Office Manager stated they gave the patients who requested their laboratory results, copies of the pulmonary function laboratory report, instrument printout and the PFT results. On 04/11/2022 at 9:38 AM, Testing

	Personnel A stated normal values were on the bottom of the instrument print out and were not on the copies given to two (#1, #2) of the patient's reports examined.