Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0942887	06/09/2020
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 June 9, 2020. 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 with an approved proficiency testing (PT) program for Blood Gases in 2019. Findings: Review of the College of American Pathologists (CAP) proficiency testing records showed there was not any proficiency testing performed in 2019. The laboratory performed testing on the following analytes in 2019: pH (hydrogen ion concentration), CO2 (carbon dioxide), PO2 (partial pressure of oxygen), hematocrit, sodium, potassium, chloride, and glucose. During an interview on 6/9/20 at 9:40 AM, Testing Personnel A stated they were not enrolled in proficiency testing for 2019 and reinstated their enrollment for 2020.
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 record review and interview, the laboratory failed to retain quality control (QC) records for the Nova Biomedical Stat Profile Prime blood gas analyzer instrument. The laboratory performs blood gas analysis on approximately 200 patients per year. Findings: 1. Review of the laboratory's QC records showed that the blood gas analyzer instrument failed to retain the control records from 2/13/19 to 5/6/19. No printouts of the daily controls were available for review. During an interview on 6/9 /20 at 11:44 AM, Testing Personnel A stated she was unable to retrieve the control records and did not know how long the instrument kept the records. 2. Review of the laboratory's QC records showed the laboratory failed to maintain the package insert for controls and calibration reagents from 2/13/19 to 6/9/20. During an interview on 6 /9/20 at 12:30 PM, Testing Personnel A stated she was not aware they needed to keep the package inserts. 3. Review of the laboratory's QC records showed the blood gas analyzer instrument failed to retain the calibration records from 2/13/19 to 12/31/19. There were no printouts of the calibrations available for review. Review of the Stat Profile Prime Instructions for User Manual showed that automatic calibrations are preformed "30 minutes after being powered on." During an interview on 6/9/20 at 12: 45 PM, Testing Personnel A stated she was unable to retrieve the calibration records and did not know how long the instrument kept the records.
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 record review and interview, the laboratory failed to document competency assessments for 2 of 2 testing personnel, (A, B) from June 9, 2018 to June 9, 2020. Findings: Review of the Laboratory Personnel Report (CMS 209) signed and dated by the Laboratory Director on 6/9/2020, showed that there were two testing personnel. Review of personnel records showed there were no competency evaluations performed in 2018, 2019, and 2020. During an interview on 6/9/2020 at 10:28 AM, Testing Personnel A stated that competency assessments were not performed from 2018 to 2020.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of ionized calcium and lactate at least twice annually in 2019. Findings: Review of the

	College of American Pathologists (CAP) proficiency testing records showed that there was not any proficiency testing performed in 2019. The laboratory is using CAP proficiency testing in 2020 to verify ionized calcium and lactate. During an interview on 6/9/20 at 9:40 AM, Testing Personnel A stated they were not enrolled in proficiency testing in 2019 and had reinstated their enrollment for 2020.