Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2172992	08/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pulmonary Disease Specialists Pa	110 Park Place Blvd, Davenport, 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	An announced CLIA initial certification survey was conducted at Pulmonary Disease Specialists PA on 08/25/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency attestation sheets and interview with the Respiratory Therapist, the Laboratory Director failed to sign the attestation sheets for two out of two events reviewed (CAP Blood Gas Panel 2020 1st and 2nd Event). Findings Included: Review of the CAP Blood Gas Panel proficiency records revealed the Testing Personnel #B had signed as the Laboratory Director designee on the CAP 1st and 2nd events attestation sheet, affirming that proficiency samples were treated in the same manner as patient specimens. Testing Personnel #B did not qualify to be designated as the Laboratory Director designee. Testing Personnel #B had been delegated to perform the initial review of proficiency testing. Interview on 08/25/20 at 11:00 a.m. with the Respiratory Therapist (Testing Personal #B) revealed that she thought she could be the Laboratory Director's designee.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with the Respiratory Therapist, the laboratory failed to document room temperature and humidity in the laboratory from October 2019 to date of survey August 25, 2020. Findings Included: Review of temperature logs revealed no room temperature and humidity logs from October 2019 to August 25, 2020. Review of manufacturers instruction revealed that the the Nova Prime blood gas instrument should be maintained at 15 - 32 degrees Celsius and humidity 20 - 85%. Interview on 08/25/20 at 12:00 PM with the Respiratory Therapist revealed she did not know that room temperature and humidity were to be monitored and documented.