Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0279963	10/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pulmonary & Critical Care Physician Of	351 Nw 42nd Ave Suite 101, Miami, 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 October 25, 2019. Pulmonary and Critical Care Physician of South Florida Inc., clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in proficiency testing (PT) that resulted in a score of zero percent (0%) for the first event in 2018 in the specialty of Routine Chemistry. Findings: Review of the College of American Pathologist (CAP) records for 1st event of 2018 showed the laboratory had an email stating the proficiency testing kit had been sent to an old address. The laboratory performs Routine Chemistry testing for the analytes of pH (potential of hydrogen), pCO2 (partial pressure of carbon dioxide) and pO2 (partial pressure of oxygen). During an interview on 10/25/19 at 10:35 AM, the Testing Personnel Administrator acknowledged that the proficiency testing kit was sent to the wrong address and that the proficiency testing was not performed for the 1st event in 2018.
D5481	CONTROL PROCEDURES

	CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide all the quality control (QC) documentation on the Irma TruPoint Blood Analysis System. Findings: Review of the laboratory's records revealed that the quality control records on the cartridges used for Blood Gas analyzer were missing from 10/25/17 to 10/24/18 and instrument temperature reading were missing form 10/25/17 to 9/30/18 During an interview on 10/25/19 at 10:20 AM, the Testing Personnel stated the printer on the instrument was not working and that the instrument saves only one year's worth of records.