Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1032296	08/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Florida Pediatric Group Pa	250 S Wickham Rd, West Melbourne, 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 August 10, 2019. Florida Pediatric Group PA was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to receive a passing proficiency test (PT) score for the second testing event of 2018 for the specialty of Hematology. Findings: Review of the PT Performance Summary from American Proficiency Institute (API) for the second event of 2018 showed unsatisfactory scores for the CMS (Center for Medicare & Medicaid Services) reportable analytes of Erythrocyte Count (20%), Hematocrit (60%), and Hemoglobin (80%). The overall score for the specialty of hematology was 76% (Erythrocyte count 20% + Hematocrit 60% + Hemoglobin 80% + Leukocyte Count 100% + Platelet Count 100% + White Blood Cell Differential 100% = 460% divided by 6 analytes = 77%). During an interview on 8/06/19 at 1:30 PM, Testing Personnel A confirmed the laboratory had failed proficiency testing.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control

	materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (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 perform quality control lot to lot comparisons from 8/06/17 to 8/06/19 for hematology. Findings: Review of the quality control logs showed that there were no lot to lot comparisons of the hematology controls from 8/06/17 to 8/06/19 for the Horiba ABX Micros 60 and the Cell Dyn Emerald hematology analyzers. During an interview on 8/06/19 at 2:32 PM, Testing Personnel A acknowledged that the laboratory did not perform quality control lot to lot comparisons.