Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2115237	04/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Florida Pediatric Group Pa	2105 Palm Bay Rd Unit #1, Palm Bay, 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 survey was conducted at Florida Pediatric Group PA on April 30, 2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the manufacturer's temperature requirements, quality control records, and interview, the laboratory failed to record the humidity of the laboratory from 12/19/2024 to 04/30/2025. Findings: Review of the Cell-Dyn Emerald Operator's Manual noted the "Relative Humidity - 80% maximum at 80 degrees Fahrenheit (31 degrees Celsius)." Review of the Daily Temperature Chart showed there were no humidity readings recorded on the chart. During an interview on 04/30 /2025 at 1:38 PM, Testing Personnel A stated they did not record the humidity of the Laboratory
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)

	(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide the documentation of training for one of one Testing Personnel's training on the Cell-Dyn Emerald hematology analyzer demonstrating they could perform all testing operations reliably to provide and report accurate results for the hematology testing from 12/19 /24 to 04/30/2024. Findings: The Laboratory Personnel Report signed by the Laboratory Director 04/24/2025 listed one Testing Personnel. Review of the personnel record failed to include documentation of training on the Cell-Dyn Emerald Hematology analyzer testing performed. Review of the section titled Laboratorian Training and Safety in the Quality Assurance procedure manual noted, "You must ensure the proper training is provided to people performing the laboratory tests." During an interview on 04/30/2025 at 2:20 PM, the Testing Personnel stated her training documentation was at their other laboratory and she would have to get it.