

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D1032296	<b>(X3) Date Survey Completed</b>  03/31/2026
<b>Name of Provider or Supplier</b>  Florida Pediatric Group Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Florida Pediatric Group PA on March 31, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 493.1421 - Condition: Laboratory Testing Personnel
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API), Proficiency Testing (PT) records and interview, the Laboratory Director failed to sign the attestation for two (2025 2nd , 3rd) of six (2024 1st, 2nd, 3rd and 2025 1st, 2nd, 3rd) events and the Testing Personnel failed to sign the attestation for one (2025 3rd ) of six (2024 1st, 2nd, 3rd and 2025 1st, 2nd, 3rd) events in the specialty of hematology. Findings: 1. Review of the API Attestation Statement noted, "Signatures Required - For all PT results, an attestation statement must be signed by Testing Personnel and Laboratory Director and retained for a minimum of 2 years." 2. Review of the API PT records revealed, the attestations for 2025 2nd event and 2025 3rd event were not signed by the Laboratory Director. 3. Review of the API PT records revealed, the attestations for 2025 3rd event was not signed by the Testing Personnel. 4. During an interview on 03 /31/2026 at 3:06 AM, Testing Personnel A acknowledged the attestations were not signed by the Laboratory Director and Testing Personnel.</p>
<b>D5413</b>	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 observation, review of the instrument manual, and interview, the laboratory failed to monitor and document temperatures and humidity of the laboratory from 12 /13/2023 to 03/31/2026. Findings: 1. During a tour of the laboratory on 03/31/2026 at 1:30 PM, the Cell-Dyn Emerald hematology analyzer was seen in the laboratory. 2. Review of the Cell-Dyn Emerald Operations Manual noted the environmental requirements as "Temperature Range: 64 degrees - 90 degrees Fahrenheit (F) (18 degrees - 32 degrees Celsius (C))" and "Maximum relative humidity 80% for temperatures up to 90 degrees F (32 degrees C)." 3. During an interview on 03/31 /2026 at 3:05 PM, Testing Personnel A stated they were not taking the temperatures or humidity of the laboratory where the hematology analyzer was located.

**D6063**

**LABORATORY TESTING PERSONNEL**  
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:  
Based on review of the Laboratory Personnel Report, personnel records, and interview, the laboratory failed to verify educational qualifications (degree) for one (B) out of four Testing Personnel (A - D). (See D6065)

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report, personnel records, and interview, the laboratory failed to verify educational qualifications (degree) for one (B) out of four Testing Personnel (A - D). Findings: 1. Review of the Laboratory's Personnel Report, signed by the Laboratory Director on 03/30/2024, showed there were four Testing Personnel employees listed as moderate complexity Testing Personnel. 2. Review of the laboratory's personnel records revealed there was no documentation of the educational degree (high school) for Testing Personnel B available for review. 3. During an interview on 03/31/2026 at 3:06 PM, Testing Personnel A revealed they did not have a copy of Testing Personnel B's high school diploma.