

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2053151	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Florida Pediatric Group	Street Address, City, State 25 E Silver Palm Ave, 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	An announced CLIA recertification survey was conducted at Florida Pediatric Group on September 2, 2026. The laboratory was surveyed under 42 CFR, Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to follow manufacturer's instruction to not use expired equipment for Lead testing from 6/29/26 to 9/02/26 and test cassettes for Mononucleosis from 1/31/26 to 9/02/26. Findings: A 1. Observations made during a tour of the laboratory on 9/02/26 at 9:30 AM, revealed the Heparinized Capillary Tubes/Plungers lot #1803 used for Lead testing expired on 6/29/25. A 2. Review of the package insert titled Lead Care II Blood Lead Test Kit revealed, the materials provided in the kit included Heparinized Capillary Tubes /Plungers. The package insert noted, "Do Not use the test kit past the expiration date," and "The earliest expiring component is used to set the test kits expiration date." A 3. Review of the Competency Assessment Checklist revealed, Testing Personnel D's initial competency was completed and signed by the Laboratory Director on 2/24/26. A 4. During an interview on 9/02/26 at 10:36 AM, Testing Personnel D confirmed she had performed Lead testing using the expired tubes, and she was not aware of a record of the patients tested. A 5. On 9/02/26 at 1:25 PM, Testing Personnel D re-confirmed she had performed Lead testing, and that she started in January 2026. B 1. Observations made during a tour of the laboratory on 9/02/26 at 9:30 AM, revealed an opened box of Mononucleosis Test Cassette lot #224A11 was on the counter in the laboratory and expired on 1/31/26. No other boxes of the Mononucleosis Test

	Cassette were opened. B 2. Review of the package insert titled Mononucleosis Test Cassette noted, "Do not use after expiration date." B 3. Review of the patient logs titled, In House Labs and Results, revealed there was one patient tested on 5/18/26. Patient logs were not available for review before 2/18/26. B 4. On 9/02/26 at 10:36 AM, Testing Personnel D acknowledged the test kits were expired and she did not know where the previous logs were located.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on interview, and record review, the laboratory failed to have all testing personnel rotate performing proficiency testing (PT) for the specialties of Hematology for five of five (2025 1st, 2nd, 3rd, and 2026 1st, 2nd) events. Findings: 1. Review of the Laboratory Personnel Report, signed and dated by the Laboratory Director on 6/09/26, listed four testing personnel. 2. Review of the procedure titled, Proficiency Testing noted, "It is run by the same lab technician who usually performs the test." 3. Review of the American Proficiency Institute PT Attestation Statement, showed all the PT attestations for 2025 1st, 2nd, and 3rd; and 2026 1st and 2nd events were signed by Testing Personnel A as the person performing the test. 4. On 9/02/26 at 1:19 PM, Testing Personnel A acknowledged she ran all the PT samples.