

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1032296	(X3) Date Survey Completed 12/12/2023
Name of Provider or Supplier Florida Pediatric Group Pa	Street Address, City, State 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 from December 8, 2023 to December 12, 2023. Florida Pediatric Group PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on review of the maintenance logs, and interview, the laboratory failed to document the semi annual maintenance on the Cell-DYN Emerald hematology analyzer from 09/01/2023 to 12/08/2023. Findings: Review of the Cell-DYN Emerald maintenance logs noted to lubricate the pistons semi-annually. Review of the Cell-DYN Emerald maintenance logs showed the lubrication of the pistons was not documented. On 12/08/2023 at 12:47 PM, Testing Personnel A stated she did lubricate the pistons, but failed to document it on the maintenance logs.</p>
D6045	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of personnel records, and interview, the laboratory failed to document the initial training of four (D, E, F, G) of seven testing personnel (A to G) hired in 2023. Findings: Review of personnel documents showed there were no records of the training for Testing Personnel D, E, F, or G. On 12/08/2023 at 1:35 PM, Testing Personnel A stated she did not think the Laboratory Director had any documentation of training for the employees hired in 2023. On 12/12/23 in an email correspondence, Testing Personnel A reported Testing Personnel D was hired on 03/31/2023, Testing Personnel E was hired on 10/16/2023, Testing Personnel F was hired on 04/25/2023, and Testing Personnel G was hired on 10/02/2023

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of competency evaluations, and interview, the Technical Consultant (Laboratory Director) failed to evaluate competency of testing personnel listed on the Laboratory's Personnel Report for seven of seven testing personnel (A, B, C, D, E, F, G) for 2022 and 2023. Findings: Review of the Laboratory Personnel Report signed by the Laboratory Director on 12/06/2023 showed there were eight employees listed on the form, that included the Laboratory Director and seven Testing Personnel. The Laboratory Director was also listed as the Clinical Consultant and Technical Consultant. Review of the Annual Evaluation of Testing Personnel Competency for Testing Personnel A to G, dated 11/09/2023 showed they were signed by Testing Personnel A. Review of the Annual Evaluation of Testing Personnel Competency for Testing Personnel A, B, and C, dated 04/11/2022 showed they were signed by Testing Personnel A. On 12/08/2022 at 12:53 PM, Testing Personnel A stated it was her signature on the competency evaluations for 2022 and 2023.