

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0723277	(X3) Date Survey Completed 06/25/2024
Name of Provider or Supplier Nicklaus Children's Pediatric Specialists, Llc	Street Address, City, State 208 N University Dr, Pembroke Pines, 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 June 25, 2024. Nicklaus Children's Pediatric Specialists, LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to assess the appropriate corrective action for unsatisfactory proficiency testing (PT) of white blood cell (WBC) for hematology specialty in one out of six events reviewed. Findings included: 1-Review of American Proficiency Institute (API) Event Documented Performance Review and Corrective Action form did not identify the failure for the white blood cell differential (WBC DIFF) parameter with a 73 % for the API 2024 1st Event Hematology/Coagulation. 2-Review of the Medonic M-Series printouts for the Granulocyte (%) analyte did not match the results on the API response forms on four samples (HSY-01, HSY-02, HSY-04, HSY-05). 3- On June 25th, 2024, at 10:30am conducted an interview with TP2, who admitted to filling in the wrong results for the Granulocyte (%) analyte.</p>