

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2297281	(X3) Date Survey Completed 12/05/2025
Name of Provider or Supplier Pediatric Associates Inc	Street Address, City, State 901 South Miami Avenue, Miami, 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 PEDIATRIC ASSOCIATES INC from 11/24/2025 to 12/05/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to keep records of the testing of Proficiency Testing (PT) in the Specialty of Hematology for one out of five events reviewed. Findings included: 1-Review of American Proficiency Institute (API) PT records for Hematology (1st, 2nd and 3rd third event of 2024 and 1st and 2nd event of 2025), revealed that the laboratory did not maintain Medonic M analyzer printed results for the second event of 2024. 2-During an interview on 11/24/2025 at 12:30 PM, the Lead Technician confirmed that the laboratory failed to have the instrument print out for 2nd event of PT in 2024.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program</p>

within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on record review of American Proficiency Institute (API) Hematology Proficiency Testing (PT) results and staff interview, the laboratory failed to submit PT results in the specified timeframe for second event of 2025 for the specialty of Hematology, resulting in a score of 0% for all analytes. Findings included: 1-Review of second event API Hematology PT records for 2025 revealed that the laboratory had obtained a score of 0% "Failure to Participate" for the following analytes: Cell Identification or White Blood Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cells and Platelets. 2-Review of instruments prints out revealed that the samples were tested on 07/30/2025, the test list include: Cell Identification or White Blood Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cells and Platelets. 3-Review of API "PREVIEW RESULT FORM", printed by the laboratory revealed a message in red "THESE RESULTS HAVE NOT BEEN SUBMITTED." During an interview on 11/24/2025 at 12:00 PM, the Lead Technician confirmed that the laboratory failed to submit on time the results for the second event of 2025.