

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2045867	(X3) Date Survey Completed 01/16/2025
Name of Provider or Supplier Pediatric Associates	Street Address, City, State 748 Harrison Ave, Panama City, 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 01/16/2025 at Pediatric Associates, a clinical laboratory in Panama City, FL. The laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to rotate American Proficiency Institute (API) proficiency events for one (2024) of two years reviewed (2023 and 2024). The findings include: 1) A record review of the CMS 209 (signed by the Laboratory Director on 01/16/2025) shows four testing personnel (TP) (#A, #B, #C, #D). 2) A review of the API attestation from the 1st Event 2024 was performed by TP #A, a review of API attestation from the 2nd Event 2024 was performed by TP #A, and a review of API attestation from the 3rd Event 2024 was performed by TP #A. 3) The lab policy and procedures, effective 05/05/2024, indicates, "Proficiency test samples must be tested with the laboratory's patient workload by personnel who routinely perform testing. All laboratory testing personnel will rotate testing events equally, using the API test schedule table." 4) A review of the Quality Assurance Checklists dated and signed by lab director 6/28/2024 and 12/27/2024 revealed that the laboratory director reviewed the staff rotating proficiency testing responsibilities. 5) During an interview on 01/16/2025 at 11:16 am, the Lead Laboratory Technician confirmed that the QA Checklist includes, "rotate lab staff for PT responsibilities" and that the Testing Personnel did not rotate proficiency testing in 2024.</p>