

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D0515113	(X3) Date Survey Completed 05/07/2025
Name of Provider or Supplier Pediatric Center, Pllc, The	Street Address, City, State 4745 Arapahoe Ave, Boulder, CO	
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	Based on an on-site recertification survey conducted on May 7, 2025, deficiencies were cited for The Pediatric Center, PLLC laboratory in Boulder, Colorado.
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, proficiency testing (PT) records, and an interview with the laboratory director (LD), the laboratory failed to document the evaluation and verification of all unsatisfactory scores and the corrective actions taken for all unsatisfactory scores for PT events from 2022 through 2024. Findings include: 1. A review of the laboratory's policies and procedures manual for PT revealed the laboratory must "[r]edo the test that failed ... Investigate the root cause of the failure with all steps documented." And: "[u]ndertake and document appropriate training to correct problems associated with the failure." 2. A review of the laboratory's PT records revealed the laboratory received scores of less than 100% for the following PT events: 2022 MC3-A, 2022 MC3-C, 2022 D1-A, 2023 MC3-C, 2024 D1-B, 2024 MC3-B, and failed to document any investigation, or corrective action documentation for those unsatisfactory scores as required by their PT policy. 3. An interview with the LD on May 7, 2025 at approximately 12:15 PM, confirmed the laboratory received scores of less than 100% for the following PT events: 2022 MC3-A, 2022 MC3-C, 2022 D1-A, 2023 MC3-C, 2024 D1-B, 2024 MC3-B, and failed to document any investigation, or corrective action documentation for those unsatisfactory scores as required by their PT policy.</p>