

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0080475	(X3) Date Survey Completed 01/20/2026
Name of Provider or Supplier Pediatric Associates Inc Of Brockton	Street Address, City, State 370 Oak Street, Brockton, MA	
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
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(e)(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 of the laboratory's American Proficiency Institute (API) proficiency testing (PT) scores and staff interview, the laboratory failed to investigate and perform corrective action when an unacceptable PT score was received. This is a repeat deficiency cited during the last CLIA inspection performed on 12/28/2023. Findings include: 1. Record review on 1/20/2026 of the CASPER 0096D, 'CLIA Application and Survey Summary' report revealed: a. The laboratory received a score of 80% for the regulated analyte Red Blood Cell (RBC) for 2024 Event 1. b. The laboratory received a score of 80% for the regulated analyte White Blood Cell Differential Mids for 2024 Event 3. c. The laboratory received a score of 80% for the regulated analyte Platelet for 2025 Event 1. d. The laboratory received a score of 80% for the regulated analytes RBC, Hemoglobin, and Hematocrit for 2025 Event 3. 2. Record review on 1/20/2026 of the laboratory's 2024 and 2025 API PT Hematology /Coagulation records revealed: a. "No corrective action needed." was written on the 2024 event 1 PT Evaluation Report and signed by Testing Personnel (TP) #5. b. "No corrective action needed." was written on the 2024 Event 3 PT Evaluation Report and signed by TP1. c. "No CA needed." was written on the 2025 Event 3 PT Evaluation Report and signed by TP1. d. The PT Performance Evaluation reports for the PT events noted above were signed as reviewed by the laboratory director (LD). e. The</p>

laboratory did not investigate or document corrective action for the above PT scores of less than 100%. 3. Staff interview with Clinical Operations Manager #1 on 1/20/2026 at 3:00 PM confirmed the above findings. 4. Staff interview with the LD on 1/20/2026 at 3:00 PM confirmed the above findings. The LD stated, "We need to pay more attention to detail." 5. The laboratory performs 8,725 tests annually in the specialty of Hematology.

D6051

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

(b)(8)(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

This STANDARD is not met as evidenced by:
Based on record review and confirmed through an interview with the Laboratory Director (LD), the Technical Consultant failed to assess the competency of all testing personnel (TP) through testing previously analyzed specimens, internal blind testing samples or external proficiency testing (PT) samples in the specialty of Hematology. This is a repeat deficiency cited during the last CLIA inspection performed on 12/28/2023. Findings include: 1. Record review on 1/20/2026 of the laboratory's 2024 American Proficiency Institute PT attestation sheets revealed 1 of 7 moderate complexity TP (TP#8) did not run external PT samples in the specialty of Hematology. 2. Record review on 1/20/2026 of the 2024 competency assessment records for TP#8 revealed: a. CBC, Test Unknown Specimen was checked off as completed. b. The competency records were signed by Clinical Operations Manager #2 (COM2). 3. Staff interview on 1/20/2026 at 3:00 PM with COM1 and the LD confirmed, a. CBC, Test Unknown Specimen was checked off as completed, but TP#8 did not perform PT or test a previously analyzed or blind sample in 2024. b. The form indicated in #2 above was signed as reviewed by COM2. 4. The laboratory performs 8,725 tests annually in the specialty of Hematology.