Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0080289	01/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Inc Of Brockton	291 East Center St, West Bridgewater, 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	HEMATOLOGY CFR(s): 493.851(e) (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. 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 93% for the regulated analyte Cell ID for 2024 Event 2 and 3 . b. The laboratory received a score of 93% for the regulated analyte WBC Differential and a score of 80% for Hemoglobin for 2025 event 1. c. The laboratory received a score of 80% for the regulated analyte WBC Differential for 2025 Event 2. d. The laboratory received a score of 87% for the regulated analyte WBC Differential for 2025 Event 2. 2. Record review on 1/20/2026 of the laboratory's 2024 and 2025 API PT Hematology /Coagulation records revealed: a. The laboratory received a score of 93% for the regulated analyte Cell ID for 2024 Event 2 and 3 . b. The laboratory received a score of 93% for the regulated analyte WBC Differential and a score of 80% for Hemoglobin for 2025 event 1. c. The laboratory received a score of 80% for the regulated analyte WBC Differential for 2025 Event 2. d. The laboratory received a score of 87% for the regulated analyte WBC Differential for 2025 Event 2. e. The PT

	Performance Evaluation reports were signed as reviewed by the laboratory director (LD). f. The 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 (COM1) on 1/20/2026 at 11:00 AM confirmed the above findings. COM1 stated, "I thought we only had to investigate if we got less than 80%." 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 11,295 tests annually in the specialty of Hematology.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to have a procedure to monitor quality control (QC) material for shifts and trends in the specialty of Hematology. Findings include: 1. Record review on 1/20/2026 of the laboratory's 2025 American Proficiency Institute (API) proficiency testing (PT) scores revealed, the laboratory received a score of 20% for the regulated analyte Red Blood Cell. 2. Record review on 1/20/2026 of the laboratory's 'PT Investigation Checklist' for the above 20% score revealed, the laboratory documented that no shifts or trends were identified in QC results during the timeframe in which the 20% PT score was received. 3. Record review on 1/20/2026 of the Levy-Jennings (LJ) chart for timeframe when the failing PT score was received, revealed: a. The QC was shifting high. b. The LJ chart was signed as reviewed. 4. Record review on 1/20/2026 of the laboratory's QC procedure revealed, the procedure did not contain instructions for monitoring LJ charts for shifts and trends. 5. Staff interview with Clinical Operations manager #1 on 1/20/2026 at 2:00 PM confirmed the above findings. 6. Staff interview with the laboratory Director on 1/20/2026 at 3:00 PM confirmed the above findings. 7. The laboratory performs 11,295 tests annually in the specialty of Hematology.