Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0080289	12/28/2023
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) (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 a (PT) score of less than 100% was received. Findings include: 1. Record review on 12/28/2023 of the CASPER 0096D, 'CLIA Application and Survey Summary' report revealed the laboratory received a score of 80% for the regulated analytes Red Blood Count (RBC) and Hemoglobin (HGB) for 2022 Event 1 . 2. Record review on 12/28/2023 of the laboratory's 2022 API PT Hematology/Coagulation Event 1 records revealed: a. The laboratory received a score of 80% for the regulated analyte RBC and an 80% for the regulated analyte HGB. b. The PT Performance Evaluation report was signed as reviewed by the laboratory director (LD) on 5/12/22. c. "100% - No ,corrective action needed," was written on the form and signed by testing personnel #1. 3. The laboratory did not investigate or document corrective action for the above 80% scores. 4. Staff interview with clinical operations manager #1 and #2 on 12/28/2023 at 11:00 AM confirmed the above findings. 5. Staff interview with the LD on 12/28/2023 at 11:30 AM confirmed the above findings. The LD stated, "We need to pay more attention to detail." 6. The laboratory performs 11,247 tests annually in the specialty of Hematology.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 include the reference ranges for complete blood count (CBC) in the procedure manual in the specialty of Hematology. Findings include: 1. Record review on 12/28/2023 of the 'Pediatric Associates of Brockton Emerald User Guide and Policy and Procedure for Obtaining Hemoglobin and CBC' compared to the CMS form 116 test list and a final patient test report, revealed, the procedure did not contain the reference ranges for the Complete Blood Count (CBC) test containing Hemoglobin, Hematocrit, Red Blood Count, White Blood Count, Mean Corpuscular Volume, Mean Corpuscular Hemoglobin, Mean Corpuscular Hemoglobin Concentration, Red Cell Distribution Width, Mean Platelet Volume, Platelet Count, and Automated White Blood Cell differential. 2. Staff interview with clinical operations manager #1 and #2 on 12/28 /2023 at 11:30 AM confirmed the above findings. 3. Staff interview with the LD on 12 /28/2023 at 11:30 AM confirmed the above findings. The LD stated, "We will add the reference ranges to the procedure." 4. The laboratory performs 11,247 Hematology tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to label reagents with the appropriate expiration dates in the specialty of Hematology. Findings include: 1. Surveyor observation on 12/28/2023 at 11:15 AM

	of the laboratory refrigerator, revealed the following Hematology controls open and in use without a new expiration date after opening: a. Cell Dyn 18 Plus Control level N, lot number N3317 b. Cell Dyn 18 Plus Control level L, lot number L3317 c. Cell Dyn 18 Plus Control level H, lot number H3317 2. Record review on 12/28/2023 of the Cell Dyn 18 Plus Control package insert revealed, "8 consecutive day open tube stability." 3. Staff interview on 12/28/2023 at 11:30 AM with the laboratory director and Clinical Operations Manager #1 and #2, confirmed the Cell Dyn controls listed above were open and in use and did not have an new expiration date after opening indicated. 4. The laboratory performs 11,247 Hematology tests annually.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on personnel competency record review and staff interview, the Technical Consultant (TC) failed to evaluate the performance of testing personnel (TP) responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: 1. Record review on 12/28/2023 of the laboratory's CMS209 signed by the laboratory director (LD) on 12/28/2023 revealed 7 new TP. 2. Record review on 12/28/2023 of the laboratory's CASPER 0096D, 'CLIA Application and Survey Summary' report revealed the laboratory received a score of 80% for the regulated analytes Red Blood Count (RBC), HGB, Hematocrit (HCT), and Platelet (PLT) for 2023 Event 2. 3. Record review on 12/28/2023 of the laboratory's 2023 American Proficiency Institute (API) Hematology/Coagulation 2nd Event records revealed: a. The laboratory received a score of 80% for the regulated analytes RBC, HGB, HCT and PLT. The incorrect results were reported for sample HEM-09. b. TP2 signed the attestation sheet as having performed testing of the above analytes on PT specimen HEM-09. c. "Re-ran Hem-09, results WNL" was written on the 'PT Checklist Office' document. d. "Re-ran Hem-09. All values within normal limits." was written on the API PT Hematology /Coagulation 2nd Event Performance Evaluation form. e. The API PT Hematology /Coagulation 2nd Event Performance Evaluation form was signed as reviewed by the laboratory director (LD). f. The laboratory did not document retraining or corrective action for new TP2's incorrect result. 4. Record review on 12/28/2023 of the laboratory's 'Pediatric Associates Inc. of Brockton Lab Yearly Checklist' for new TP2 revealed: a. New TP2 was hired on 8/1/2022. b. The 'Test Unknown Specimen' section was left blank for Complete Blood Count and Hemoglobin (HGB) c. The checklist was signed by TP1 who is not the TC. d. The checklist did not contain documentation of retraining or corrective action taken for new TP2 concerning the incorrect PT results for API PT 2023 Event 2 Hematology/Coagulation specimen HEM-09. e. "Observed daily by charge nurse in Brockton. No concerns observed" was written at the bottom of the second page. 5. Staff interview with clinical operations manager #1 and #2 on 12/28/2023 at 11:00 AM confirmed, new TP2 received an unacceptable score for HEM-09 and was evaluated as competent with no corrective action or documented retraining. 6. Staff interview with the LD on 12/28/2023 at 11: 30 AM confirmed the above findings. The LD stated, "We need to pay more attention to detail." 7. The laboratory performs 11,247 tests annually in the specialty of Hematology.