Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0080475	(X3) Date Survey Completed 12/28/2023
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	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 12/18/2023 of the CASPER 0096D, 'CLIA Application and Survey Summary' report revealed the laboratory received a score of 80% for the regulated analyte platelets for 2022 Event 2. 2. Record review on 12/18 /2023 of the laboratory's 2022 API PT Hematology/Coagulation Event 2 records revealed: a. The laboratory received a score of 80% for the regulated analyte platelets. b. The PT Performance Evaluation report was signed as reviewed by the laboratory director (LD) on 9/15/22. c. "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% score. 4. Staff interview with clinical operations manager #1 and #2 on 12/18/2023 at 11:45 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 8,858 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 12/18/2023 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 12/18/2023 at 11:45 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 8,858 Hematology tests annually.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with the technical consultant (TC), the TC 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. Findings include: 1. Record review on 12/18/2023 of the laboratory's 2023 American Proficiency Institute PT attestation sheets revealed 1 of 13 moderate complexity TP

	did not have their competency assessed through testing previously analyzed specimens, internal blind samples or external PT samples in the specialty of Hematology. 2. Record review on 12/18/2023 of the 2023 competency assessment records for TP#2 revealed: a. Hemoglobin, Test Unknown Specimen was checked off as completed. b. CBC, Test Unknown Specimen was checked off as completed. c. "Currently works per diem as she is in nursing school ft so has not done proficiencys will work on it in future as will be coming in ft," was written at the end of the form. d. The competency records were signed by Clinical Operations Manager #1 (COM1). 3. Staff interview on 12/18/2023 at 11:45 AM with COM1 confirmed TP#2 did not perform PT or test a previously analyzed or blind sample in 2023 in the specialty of Hematology. COM1 stated, "TP#2 is only here per diem." 4. Staff interview on 12/28 /2023 at 11:30 AM with the TC confirmed TP#2 did not perform PT or test a previously analyzed or blind sample in 2023 in the specialty of Hematology. The TC also confirmed the above indicated competency sheets were signed as completed for testing PT, previously analyzed or blind samples. The TC stated, "We will get this organized and done." 5. The laboratory performs 8,858 tests annually in the specialty of Hematology.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on personnel competency record review and interview with the technical Consultant (TC) and Clinical Operations Manager #1 and #2 (COM1 and COM2) the Technical Consultant (TC) failed to evaluate and document the performance of testing personnel (TP) responsible for moderate complexity testing at least annually, after the first year the individual tested patient specimens. Findings include: 1. Record review on 12/18/2023 of the laboratory's CMS form 209 revealed TP3 is listed as a current TP. 2. Record review on 12/18/2023 of the laboratory's competency records revealed that annual competency evaluations were not performed and documented in 2022 and 2023 for TP3. 3. Staff interview with COM1 and COM2 on 12/18/2023 at 11:45 AM confirmed the above findings. 4. Staff interview with TP3 on 12/18/2023 at 11:45 AM confirmed the above findings. TP3 also stated, "I perform testing very infrequently." 5. Staff interview with the LD on 12/28/2023 at 11:30 AM confirmed the above findings. The LD stated, "We need to make sure competency is performed on all TP." 6. The laboratory performs 8,858 tests annually in the specialty of Hematology.