

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0099462	<b>(X3) Date Survey Completed</b>  07/23/2025
<b>Name of Provider or Supplier</b>  Pediatric Healthcare Associates	<b>Street Address, City, State</b>  99 Hawley Ln, Stratford, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to obtain a proficiency testing (PT) score of at least 80 percent for White Blood Cell (WBC) differential testing for Event 2 of 2025 in the specialty of Hematology. Findings include: 1. Record review on 7/23/2025 of the Center of Medicare and Medicaid Services (CMS), generated "Casper Report 0155D" revealed the laboratory obtained an unsatisfactory PT score of 40% for WBC Differential analyte, Event 2, 2025. 2. Record review on 7/23/2025 of the College of American Pathologist (CAP), "Original Evaluation" report for "FH16-B 2025 Hematology Auto Differentials, FH-16" revealed following unacceptable results for the WBC Differentials: a."Test: Neut /Gran % : Specimens FH16-06, FH16-07, FH16-09, and FH16-10." b. "Test: Neut /Gran Absolute: Specimens FH16-06, FH16-07, FH16-08, FH16-09, and FH16-10." c. "Test: Lymphs %: Specimens FH16-06, FH16-07, and FH16-10." d. "Test: Lymphs Absolute: Specimens FH16-07." e. "CMS performance Summary for Analytes Regulated Under the Clinical Laboratory Improvement Amendments of 1998" revealed the following: i. "Regulated Analyte: WBC Differential" ii. "Proficiency Event: 2, 2025" iii. "Test Event: FH16-B" iv. "Score: 2/5; 40 %" v. "Performance Interpretation: Unsatisfactory" 3. Staff interview on 7/23/2025 at 11:20 AM with the Technical Consultant (TC) confirmed the above findings. The TC further stated that the laboratory performed the PT using the "QC mode" as advised by the Beckman coulter technical services and obtained an unsatisfactory score. He/she further</p>

commented that the laboratory has stopped reporting the WBC differentials on patient samples as of 06/02/2025. 4. The laboratory performs 4150 complete blood counts 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 surveyor observation, record review and staff interview, it was found that the laboratory's established standard operating procedure (SOP) manual lacked clear documentation regarding the selection of test results for patient medical record when hematology tests required repeat testing to verify flagged test results in the specialty of Hematology. Findings include: 1. Surveyor observation on 07/23/2025 at 11:00 AM of the laboratory revealed a "Beckman Coulter DxH" instrument in use for testing Complete Blood Counts (CBC). 2. Record review on 07/23/2025 of the laboratory's "Patient Result Binder" revealed the following: a. Instrument printout for each patient CBC testing performed daily. b. Patient tests were repeated to verify the flags generated by the instrument. c. Two of two patients with repeat results revealed the following: i. Patient #1 (PT#1): Printout- 1: "Run Date: Time: 12/03/2024 08:48 AM" and Printout- 2: "Run Date: Time: 12/03/2024 08:50 AM". ii. Patient #2 (PT#1): Printout- 1: "Run Date: Time: 12/02/2024 01:44 PM" and Printout- 2: "Run Date: Time: 12/02/2024 01:53 PM". 3. Record review on 07/23/2025 of the PT#1 final CBC test report revealed "printout # 1" results entered in patient's medical records. 4. Record review on 7/23/2025 of the PT#2 final CBC test report revealed "printout # 2" results entered in patient's medical record. 5. Record review on 07/23/2025 of the laboratory's established standard operating procedure manual revealed lack of documentation to include the criteria to select one of the two instrument printouts to be entered in patient medical records when the patient sample was repeated for verification of instrument flags. 6. Staff interview on 07/23/2025 at 10:11 AM with the Technical Consultant (TC) confirmed the findings above. The TC further stated that he/she uses her judgement looking at the values of both the printouts to enter results in the patients' medical records. 7. The laboratory performs 4150 CBC annually in the specialty of Hematology.