

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0671891	<b>(X3) Date Survey Completed</b>  10/06/2025
<b>Name of Provider or Supplier</b>  Pediatric Assoc Of Western Ct Llc	<b>Street Address, City, State</b>  41 Germantown Rd, Ste 201, Danbury, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish policies and procedures to assess competency for the regulatory responsibilities of the clinical consultant (CC) and the technical consultant (TC) in the specialty of hematology and subspecialty of bacteriology. Findings include: 1. Record review on 10/06/2025 of the laboratory's personnel competency files revealed the lack of competency assessment documentation for the regulatory positions of CC and TC. 2. Staff interview on 10/06/2025 at 9:30 AM with the TC confirmed the above finding. The TC further commented that he/she was unaware of the regulatory requirement for competency assessment for the CC and TC positions. 3. The laboratory performs 16,205 complete blood counts annually in the specialty of hematology and 2,501 throat cultures annually in the subspecialty of bacteriology.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>(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,</p>

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 establish and follow a complete written policies and procedures for complete blood counts (CBC) prior to patient testing in the specialty of hematology. Findings include: 1. Record review on 10/06/2025 of the laboratory's CBC policies and procedures revealed lack of documentation of the following procedural steps: a. Criteria for specimen acceptability and rejection. b. Step by step performance of the procedure including test calculations and interpretation of results. c. Calibration and calibration verification procedures. d. Control procedures to include type of control, identity, number and frequency of testing controls, control limits and criteria to determine acceptable control results. e. Corrective action to be taken when calibration and control results fail to meet acceptable criteria. f. Limitations in the test methodology including interfering substances. g. Reference intervals. h. Imminently life-threatening test results, or panic or alert values. i. Pertinent literature references. j. Actions to be taken if the instrument and/or lab information system becomes inoperable. 2. Staff interview on 10/06/2025 at 11:30 AM with the technical consultant confirmed the above findings. 3. The laboratory performs 16,205 CBC tests annually in the specialty of hematology.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to define and provide evidence of monitoring and documenting humidity requirements in the specialty of hematology. Findings include: 1. Surveyor observation on 10/06/2025 at 10:30 AM of the laboratory work bench area revealed a DxH 500 Hematology analyzer in use. 2. Record review on 10/06/2025 of the laboratory's maintenance records for 2024 and 2025 revealed lack of documentation of humidity levels for the laboratory area. 3. Record review on 10/06/2025 of the

'DxH 500 Hematology analyzer' operators manual revealed an acceptable relative humidity requirement of up to 80% (non-condensing) while operational. 4. Staff interview on 10/06/2025 at 11:00 AM with the laboratory's technical consultant (TC) confirmed the above findings. The TC further commented that he/she was unaware of this requirement. 5. The laboratory performs 16,205 complete blood counts annually in the specialty of hematology.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to ensure age specific normal ranges and units of measurement are printed by the laboratory information system on the patient test report for complete blood counts (CBC) in the specialty of hematology. Findings include: 1. Record review on 10/06/2025 of a CBC test report for patient #1 revealed lack of documentation of the following: a. Age specific normal ranges. b. Units of measurement. 2. Staff interview on 10/06/2025 at 12:15 PM with the technical consultant confirmed the above findings. 3. The laboratory performs 16,205 complete blood counts annually in the specialty of hematology.

**D6046**

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

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the Technical Consultant failed to follow the laboratory's established policies and procedures to document the competency assessment of Testing Personnel (TP) that perform moderate complexity testing in the specialty of hematology. Findings include: 1. Record review on 10/06/2025 of the laboratory's 'Competency assessment of Laboratory Testing Personnel' forms for 11 of 11 TP's in 2024 and 12 of 12 TP's in 2025 revealed lack of documentation of the following: a. 'Assessment method'. b. 'Assessment date'. c. 'Technical Consultant /Laboratory Director signature and date'. 2. Record review on 10/06/2025 of the laboratory's 'Technical Consultant Job Description' policies and procedures revealed the following duty 'Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently'. 3. Staff interview on 10/06/2025 at 11:

30 PM with the technical consultant confirmed the above findings. 4. The laboratory performs 16,205 complete blood counts annually in the specialty of hematology.

**D6061**

**CLINICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1419(c)

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Clinical Consultant failed to follow the laboratory's established policies and procedures and ensure age specific reference ranges and units of measurements are included on the patient test report for complete blood counts (CBC) in the specialty of hematology. Findings include: 1. Record review on 10/06/2025 of a CBC test report for patient #1 revealed lack of documentation of the following: a. Age specific normal ranges. b. Units of measurement. 2. Record review on 10/06/2025 of the laboratory's 'Clinical Consultant Job Description' policies and procedures revealed the following duty 'Ensure that reports of test results include pertinent information required for specific patient interpretation'. 3. Staff interview on 10/06/2025 at 12:15 PM with the technical consultant confirmed the above findings. 4. The laboratory performs 16,205 complete blood counts annually in the specialty of hematology.