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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>51D0236407        | <b>(X3) Date Survey Completed</b><br><br>03/11/2025 |
| <b>Name of Provider or Supplier</b><br><br>Upc-Pediatrics Associates   | <b>Street Address, City, State</b><br><br>7 Chenoweth Drive Ste A, Bridgeport, WV |   |
| 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>  |
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| <b>D0000</b>              | A routine recertification survey was conducted at UPC-Pediatrics Associates on March 11, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.   |
| <b>D5403</b>              | <p>PROCEDURE MANUAL<br/>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, 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.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of written policies and procedures, manufacturer instructions for the Beckman Coulter DxH520, lack of documentation, and interview with testing</p> |

personnel (TP1) the laboratory failed to establish the process to (b)(3) resolve parameters flagged for review (R) on complete blood count (CBC) results from the DxH520 hematology analyzer. Findings: 1. Review of the DxH520 analyzer manufacturer instructions revealed a table of error codes, flags, and an explanation of possible causes for each one, stating to resolve parameters flagged for review (R) to follow the process established by the laboratory. 2. Review of hematology and general laboratory policies and procedures revealed no established process for resolving CBC patient results flagged for review (R) from the DxH520 analyzer. No policy could be located. 3. During an interview with TP1, 3/11/2025 at approximately 10:30 AM, TP1 stated there was no written process for how to handle CBC parameters flagged for review (R).

**D5781**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on review of written policies and procedures, Beckman Coulter DxH520 hematology analyzer manufacturer instructions, complete blood count (CBC) patient reports, lack of documentation, and interview with testing personnel (TP1), the laboratory failed to document the resolution of hematology parameters flagged for review (R) by the DxH520 analyzer for 12 of 49 patient CBCs in February 2025. This is a repeat deficiency. Findings: 1. Review of the DxH520 manufacturer instructions revealed a table of error codes and flags and an explanation for each one, stating to resolve the error codes to follow the process established by the laboratory. 2. No written policy or procedure for how to resolve CBC parameters with a review flag (R) could be located. See D5403. 3. Review of 49 February 2025 patient CBC results revealed 12 patient results released with a parameter review flag (R) and no documentation of the review could be located (E4354312, E3040246, E4074340, E4471922, E4351935, E4182018, E4361537, E4408523, E4183897, E4120854, E4446623, E2740941). 4. During an interview with TP1, 3/11/2025 at approximately 10:30 AM, TP1 stated there was no written process for how to handle (R)review flags and confirmed the 12 CBC results had no documentation of the required review. This is a repeat deficiency. The laboratory was cited during the recertification survey 5/25 /2023 for a failure to document the resolution of error codes on patient CBC results from the AcTDiff hematology analyzer. The current DxH520 hematology analyzer in the laboratory was put into use in January 11, 2024.

**D5813**

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

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test

result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:

Based on review of hematology policies and procedures, Beckman Coulter DxH520 analyzer reports, Critical & Panic Value Log book, lack of documentation, and interview with testing personnel (TP1), the laboratory failed to document date, time, test results, and person to whom the critical results were reported for one of 49 complete blood count (CBC) reports released. Findings: 1. Review of hematology "Procedure for Reporting Critical & Panic Values" revealed the critical value is to be "documented in critical & panic value log book by the testing personnel" after the ordering physician is notified of the value. 2. Review of 49 CBC patient results from February 2025 identified one patient result that was released with a critical value flag (E4354312). Review of the laboratory Critical & Panic Log book revealed no documentation that the authorized person was notified of the critical value (hgb 8.93). 3. During an interview with TP1, 3/11/25 at 11:36 AM, TP1 stated no documentation for the notification of this critical value to the ordering physician could be located.