| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0967013 | 11/07/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pediatric Associates Of Johns Creek Pc | 4310 Johns Creek Parkway, Suite 150, Suwanee, GA | |

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 |
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| **D0000** | A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on November 07, 2025. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited: |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory procedure manual (SOP) and interview with lab lead, the laboratory director failed to provide an updated step by step procedure |

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| | manual for the Cell-dyn Emerald analyzer in the specialty of Hematology by the day of survey 11/07/2025 as required by CLIA Regulation 493.1251(b). Findings: 1.) A review of current SOPs confirmed the lack of step by step standard procedure manual for complete blood count (CBC) testing for the Cell-Dyn Emerald hematology analyzer by the day of survey 11/07/2025. 2.) There were no protocools for critical value alerts, specimen collection, handling and transportation for staff in training. Parts of the SOPs were written in #2 pencils. 3.) Interviews with the laboratory director and lab lead (TP#2 CMS 209) in the review room on 11/07/2025, at approximately 12:30 p.m confirmed the above findings. |