| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D0995491 | 03/27/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pediatric Associates Of Jacksonville Pa | 1102 A1a North Ste #104, Ponte Vedra Beach, FL | |

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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| **D2010** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(2)<br><br>The laboratory must test samples the same number of times that it routinely tests patient samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to test hematology proficiency testing samples the same number of times that it tests patient samples for one proficiency testing event in 2018. The findings include: A record review of 2018 American Proficiency Institute (API) proficiency testing was done on March 27, 2018.. The documentation showed testing of the five proficiency samples was performed twice on March 15, 2018 following tests: White Cell Count, Red Cell Count, Hemoglobin, Hematocrit, Platelet Count, Mean corpuscular volume (MCV), Red cell distribution width (RDW), Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils. HEM-01: 3/15/18 at 12:48 and 12:59 HEM-02: 3/15/18 at 12:51 and 13:01 HEM-03: 3/15/18 at 12:53 and 13:04 HEM-04: 3/15/18 at 12:55 and 13:06 HEM-05: 3/15/18 at 12:57 and 13:08 Interview with the testing person at 11: 00pm confirmed hematology proficiency testing had been performed in duplicate. She verified it was not part of the laboratory's testing procedure to have patient samples tested more than once unless there was a problem with the sample. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed |

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| | by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with laboratory staff, the laboratory failed to maintain complete proficiency testing records for one of three testing events in 2017. The findings include: On March 27, 2018, the laboratory's proficiency testing records were reviewed. The laboratory is enrolled with the API (American Proficiency Institute) proficiency testing program for hematology. During the review of the 2017 proficiency testing records, the error listed below was identified. Testing Event #3 The laboratory did not retain the instrument records for the proficiency specimens that were tested. During an interview with the testing person on 3/27/18 at 11:00 AM, she acknowledged that the 2017 proficiency testing records were incomplete. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the facility failed to perform quality control for complete blood count testing for one of thirty-one days reviewed in March 2017. Findings include: The 3/27/18 record review of the daily quality control printouts showed no quality control was performed on3/15/17. The review of the patient test log showed four patients were tested on that day. The interview with the testing person on 3/27/18 at 10:48am confirmed that quality control testing documentation was missing. |
| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and staff interview, the laboratory failed to follow the facility's protocol for performing quality control at the frequency of controls are run according to facility policy, i.e., 1 normal control, 1 low control and 1 high control each day. The findings include: Record review of the Drew D3 daily quality control |

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| | records revealed that no low control was tested, per facility policy, on: *3/24/2017 *1 /2/2018 * 1/18/2018 There was no documentation included in the quality control results as to why the low control was omitted on the above dates. Interview with the testing person at 10:15am on 3/27/2018 confirmed that there was no low control tested on those dates. |