| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 21D0213550 | 09/22/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pediatric Associates Of Mont Co | 12520 Prosperity Drive Ste 350, Silver Spring, MD | |

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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| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Note: This is a repeat deficiency. The laboratory was cited during the recertification survey completed on 01/23/2019 for not having a procedure for verifying performance of new hematology quality control (QC) lot numbers by testing them in parallel with current QC lot numbers as well as not having documentation that new QC lot numbers were tested in parallel with current QC lot numbers for performance verification. The laboratory's plan of correction stated that this would be corrected on 04/02/2019. Based on review of the procedure and QC records and interview with the technical consultant (TC), the laboratory failed to have a copy of the approved procedure in the standard operating procedure manual (SOPM) and failed to verify performance of new hematology QC lot numbers by testing them in parallel with current QC lot numbers. Findings: 1. At the time of the on-site survey, the laboratory did not have a copy of the "Parallel QC Procedure" included in the approved SOPM. The procedure was given to the surveyor the day after the on-site survey. 2. The procedure titled |

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| | "Parallel QC Procedure" stated "In order to be in compliance with the manufacturer's recommendations, the new lot of hematology controls must be analyzed along with the current lot of controls." The procedure stated that all three levels of QC from the new lot should be tested in parallel with all three levels of the current lot for one to five days. 3. Instrument printouts of monthly QC results from 03/2020-05/2021 were reviewed, which contained results for five different hematology QC lot number changes. 4. Based on the start and end date of each lot number, the laboratory did not perform parallel testing on three of the five lot numbers found in the QC records (lot numbers 220022, 220082 and 220112). 5. During the exit interview on 09/22/2021 at 1:15 PM, the TC confirmed that the procedure for QC parallel testing was not included in the approved SOPM and that parallel testing to verify the performance of new QC lot numbers was not performed for three of the five lot numbers reviewed. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>I. The laboratory director failed to ensure that the laboratory's plan of correction from the recertification survey completed on 01/23/2019 was implemented. Cross-refer to D5469. II. Based on review of the procedure and monthly quality assurance (QA) review forms and interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the monthly QA reviews were performed and documented in a timely manner. Findings: 1. The procedure titled "Quality Assessment Program" stated "The Quality Assessment program monitors and evaluates the quality of the laboratory services provided. The laboratory director oversees the implementation of the plan and helps identify, then correct problems as they occur and improve services where applicable. Monthly QA reviews are performed to minimize the possibility of recurrent problems." 2. The monthly QA reviews were performed by the TC and assessed instrument performance (quality control, maintenance, and calibration), temperature logs, proficiency testing results, remedial actions taken, personnel competencies, and complaints using a designated form that was to be signed by the TC and the LD upon completion. 3. Monthly QA review forms were reviewed from 09/2019 through 05/2021. 4. The QA review forms for the months of 05/2020 - 08/2020 were signed by the TC on 11/09/2020 and by the LD on 05/28/2021. 5. The QA review forms for the months of 09/2020 - 05/2021 were signed by the TC on 05/30/2021. There was no signature of the LD. 6. As of 09/22/2021, there were no monthly QA review forms completed for 06/2021 - 08/2021. 7. During the exit interview on 09/22/2021 at 1:30 PM, the TC confirmed that the monthly QA reviews were not being performed and documented in a timely manner. |