

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213550	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Pediatric Associates Of Mont Co	Street Address, City, State 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of the "Parallel QC [quality control] Procedure", parallel testing log book for the Medonic M-series (hematology analyzer) and interview with the office manager (OM), the laboratory failed to perform parallel testing of the QC materials with each new lot as required by the manufacturer. Findings: 1. The "Parallel QC Procedure" states that the old QC lot and the new QC lot are to be tested on the same day and compared prior to switching to the new lot of QC materials. 2. The records in the parallel testing log book from September 2023 through October 2024 were reviewed. 3. The records from 12/4/2023 included documentation that stated the testing person had forgotten to compare the previous QC materials with the new controls. A note placed on the new "For Medonic M-series with barcode reader" worksheet stated that the comparison was done using the old QC results from the previous day and not the day that the new QC was started. The only records attached to the worksheet were the results of the new lot of QC materials. 4. The records from 4/15/2024 included documentation stating that the testing person had forgotten to test the old and new QC materials on the same day. There were no QC records attached to the "For Medonic M-series with barcode reader" worksheet. 5. During the survey on 11/13/2024 at 11:45 AM, the OM confirmed that the parallel testing on the hematology analyzer had not been performed as required by the manufacturer.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p>

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual and interview with the office manager (OM), the laboratory director failed to specify in writing, the responsibilities and duties of each person engaged in the performance of the pre-analytic, analytic and post analytic phases of testing, that identifies which examination and procedure each individual is authorized to perform, and whether supervisory or director review is required prior to reporting patient test results. Findings: 1. The procedure manual included the duties and responsibilities of the laboratory director, technical consultant, medical laboratory technician (qualified with a 2 year degree), and nursing- lab responsibilities (which only included waived testing). The procedure did not include duties and responsibilities for testing personnel and/or medical assistance that qualified with only a high school diploma and medical assistant certificate. 2. According to the OM, QC and QA records are sent to the technical consultant (TC) on a monthly basis. The duties and responsibilities of the laboratory director and TC fail to include written instructions for what records are to be reviewed, when these records are to be emailed for review, and the turnaround time for the evaluation of these records. 3. During the survey on 11/13/2024 at 11:45 AM, the OM confirmed that the laboratory's procedure manual did not specify in writing the duties and responsibilities of the qualified laboratory testing personnel and the timely evaluation of QC and QA records.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:

Based on review of the monthly quality assessment (QA) review worksheets and interview with the office manager (OM), the technical consultant (TC) failed to ensure that monthly QA records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented. Findings: 1. The monthly QA review worksheets from September 2023 through September 2024 were reviewed. 2. The monthly QA worksheet for September 2023 was completed on 10/11/23; October 2023 was completed on 11/30/23; November 2023 was completed on 11/30/23; December 2023 was completed on 01/25/24; January 2024 was completed on 02/27/24; February 2024 was completed on 03/25/24; March 2024 was completed on 04/15/24; April 2024 was completed on 05/29/24; May 2024 was completed on 06/25/24; June 2024 was completed on 07/11/24; July 2024 was completed on 08/15/24; August

2024 was completed on 09/24/24; and September 2024 was completed on 10/31/24. October 2024 had not been completed yet. 3. The monthly reviews were performed 11 to 31 days after the end of the month. QA evaluations were not being reviewed in a timely manner to ensure accurate and reliable test results. 4. The TC failed to provide oversight and follow-up with the testing personnel when they failed to perform the parallel testing of the quality control materials with each new lot as required by the manufacturer. The failure to perform parallel testing was not noted in the monthly QA reviews. Cross refer to Tag D5411 for details. 5. During the survey on 11/13/2024 at 11:45 AM, the OM confirmed that monthly QA records were reviewed in a timely manner to ensure that problems were identified and corrective actions implemented.