

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213407	(X3) Date Survey Completed 07/27/2023
Name of Provider or Supplier Pediatric Associates Mont Co	Street Address, City, State 2401 Blueridge Avenue Ste 210, Wheaton, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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: I. Based on review of the procedure and interview with the technical consultant (TC), the laboratory failed to ensure that that units for panic values listed in the procedure were comparable to the units listed on patient results for hematology testing. Findings: 1. The procedure titled "Panic Values" listed the units for white blood cells (WBC) and platelets (PLT) as "cumm." 2. The hematology analyzer reported WBC and PLT as "10^9/l." 3. During the survey on 04/27/2023 at 3:00 PM, the TC confirmed that the units for panic values for WBC and PLT listed in the procedure did not match the units reported by the analyzer. II. Based on review of the hematology instrument</p>

manual, instrument printouts for patient results, and written procedures and interview with the testing person (TP), the laboratory failed to ensure the written procedures included instructions for actions to take when instrument codes were present on patient results. Findings: 1. The Medonic M Series Hematology Analyzer operator's manual (manual) listed analyzer codes that could be present on instrument printouts for patient results and what actions should be taken when the code is present. 2. On 01/13/2023, the results printout for patient accession number 86893 listed the code "DE" next to red blood cell results. The manual stated that the code indicated "Small particle interference" and to "re-analyze sample." 3. On 01/17/2023, the results printout for patient accession number 70591 listed the code "BD" for multiple results. The manual stated that the code indicated "WBC DIFF [white blood cell differential]: High interference between populations" and to "Follow laboratory's protocol for verification of results." 4. The TP stated that actions taken when an instrument code was present on patient results printouts should be documented on the printout. Neither of the patient results printouts included documentation of what actions were taken. 5. The laboratory's procedures did not include instructions for actions to take when instrument codes were present on patient results. 6. During the survey on 07/27/2023 at 3:00 PM, the TP confirmed that the written procedures did not include instructions for what actions to take if instrument codes were present on patient results.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on review of the hematology analyzer guide, observation, and interview with the technical consultant (TC), the laboratory failed to label the opened hematology quality control (QC) material with the expiration date. Findings: 1. The Medonic M Series Hematology Analyzer guide (PN 203129B R03.14.14) stated that for QC materials the "Unopened vial is stable until expiration date on the package" and "Opened vials are stable for 14 days." 2. The opened QC vials stored in the refrigerator were labeled with the opened date, but not the updated opened vial expiration date. 3. During the survey on 07/27/2023 at 3:00 PM, the TC confirmed that the opened QC vials located in the refrigerator were not labeled with the expiration date.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on review of the hematology analyzer guide, package inserts for hematology quality control (QC), and monthly QC summaries and interview with the technical

consultant (TC), the laboratory failed to ensure that hematology QC material was not used beyond the expiration date. Findings: 1. The Medonic M Series Hematology Analyzer guide (PN 203129B R03.14.14) stated "QC material must not be tested beyond the expiration date on the package." 2. The package insert for lot number 223013 listed an expiration date of 06/14/2023. 3. The 06/2023 QC results summaries showed that 223013 was the only lot of QC tested on 06/15/2023. 4. During the survey on 07/27/2023 at 3:00 PM, the TC confirmed that QC lot number 223013 was tested beyond its expiration date.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of the instrument maintenance logs, review of patient test logs, and interview with the technical consultant (TC), the laboratory failed to document monthly and daily maintenance activities performed on the hematology analyzer. Findings: 1. The monthly maintenance form for the hematology analyzer listed two activities to be performed monthly and five activities to be performed daily on dates when patient specimens were tested. 2. Monthly maintenance logs were reviewed for January 2022 through June 2023 (18 months). 3. Two of two monthly maintenance activities were not documented as performed in June 2022, September 2022, January 2023, and May 2023. 4. One of two monthly maintenance activities were not documented as performed in August 2022. 5. Daily maintenance activities were not recorded as performed on the following dates when patient specimens were tested: a. January 4 of 2022 b. February 24 and 25 of 2022 c. March 4, 17, 18, and 31 of 2022 d. April 19, 28, and 29 of 2022 e. May 27, 28, and 31 of 2022 f. July 14, 15, 27, 28, and 30 of 2022 g. August 1, 2, 3, 4, 5, and 12 of 2022 h. October 31 of 2022 i. January 18, 19, 20 of 2023 j. February 3, 24, 27, and 28 of 2023 6. During the survey on 07/27 /2023 at 3:00 PM, the TC confirmed that monthly and daily maintenance activities for the hematology analyzer were not documented as performed.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview with the technical consultant (TC), the TC failed to ensure that competencies were performed in 2022. Findings: 1. The "Laboratory Personnel Report (CLIA)" listed five testing personnel (TP). 2. There were no records documenting the performance of six-month (for TP#2) and annual competencies for 2022. 3. During the survey on 07/27/2023 at 3:00 PM, the TC confirmed that no competencies were performed in 2022.