

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473674	(X3) Date Survey Completed 10/26/2023
Name of Provider or Supplier Pediatric & Adolescent Care	Street Address, City, State 2000 S Wheeling Ave, Suite 300, Tulsa, OK	
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
D0000	The recertification survey was performed on 10/26/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, technical consultant #1, and technical consultant #2 during an exit conference performed at the conclusion of the survey.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #2, the laboratory failed to evaluate the accuracy of testing when proficiency result had not been graded by the proficiency testing program for one of three Clinical Microscopy events reviewed in 2022 and 2023. Findings include: (1) A review of Clinical Microscopy proficiency testing records for 2022 and 2023 identified the following for one of three events: (a) First 2023 Event (CM-A 2023) - One of one result had not been graded by the proficiency testing program for Urine Sediment ID (sample USP-02). There was no documentation to prove the laboratory performed a self-evaluation of the non-graded result. (2) The records were reviewed with technical consultant #1 and technical consultant #2 who stated on 10/26/2023 at 10:40 am, the laboratory had not performed a self-evaluation to evaluate the non-graded result.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of records, written policies and procedures, and interview with technical consultant #1, technical consultant #2, and testing person #3, the laboratory failed to follow their written policy for labeling hematology specimens for CBC for nine of 12 patient specimens. Findings include: (1) On 10/26/2023 at 10:20 am, testing person #3 stated the following: (a) The laboratory performed CBC testing on the Medonic M series analyzer; (2) Observation of the specimen refrigerator on 10/26/2023 at 10:20 am identified the following: (a) Nine EDTA whole blood specimens in an emesis basin in the refrigerator labeled with the patient's last name and a unique identification number; (3) A review of the policy titled, "Technical Procedures" stated, "All specimens will be labeled with 2 patient identifiers: Patient's legal first and last name, date of birth (DOB). All specimens will be labeled with the date and time of collection. All specimens will be labeled with the phlebotomist's or collectors initials."; (4) Interview with testing person #3 on 10/26/2023 at 10:20 am confirmed the following: (a) Nine of 12 blood samples in the refrigerator were labeled with the last name and unique identifier only; (5) The findings were reviewed with technical consultant #1 and technical consultant #2 who stated on 10/26/2023 at 10:30 am, the laboratory had not followed their policy for labeling the patient specimens.

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 a review of records, manufacturer's instruction manual, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Medonic M-series analyzer during the review period of 09/01/2022 through 09/30/2023. Findings include: (1) On 10/26/2023 at 10:30 am, technical consultant #1 and technical consultant #2 stated CBC (Complete Blood Count) testing was performed using the Medonic M-series analyzer; (2) A review of the manufacturer's instruction manual titled, "Medonic M-series User's Manual", Chapter 8, section 8-2 required the following monthly maintenance procedures: (a) Monthly Cleaning (Hypochloride) (b) Clot Prevention (Enzymatic) (3) A review of maintenance logs from 09/01/2022 through 09/30/2023 identified monthly maintenance had not been documented as performed between: (a) 11/02/2022 and 01/04/2023 (b) 03/28/2022 and 05/31/2022 (4) The records were reviewed with technical consultant #1 and technical consultant #2 who stated on 10/26/2023 at 01:26 pm, maintenance procedures had not been documented as performed as stated above.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

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.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with technical consultant #1 and technical consultant #2, the laboratory failed to verify the stated value of control materials before they were put into use for three of six lot numbers. Findings include: (1) On 10/26/2023 at 10:30 am, technical consultant #1 and technical consultant #2 stated the following: (a) CBC (Complete Blood Count) testing was performed using the Medonic-series analyzer; (b) Three levels of QC (quality control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records for six control lot numbers identified no evidence the provided ranges were verified before the lot numbers were put into use for three of six lot numbers as follows: (a) Low control lot #2230601, Normal control lot #2230602, and High control lot #2230603 put into use on 07/28/2023. (3) The findings were reviewed with technical consultant #1 and technical consultant #2 who stated on 10/26/2023 at 11:57 am the manufacturer's ranges had not been verified before the above lot numbers had been put into use.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of patient reports, the complete blood count technical procedures manual, and interview with technical consultant #1 and technical consultant #2, the laboratory failed to make appropriate reference ranges available for three of three patient CBC reports. Findings include: (1) On 10/26/2023 at 1:00 pm, technical consultant #1 stated the Medonic M Series analyzer was used to perform CBC (Complete Blood Count) testing, to include mean corpuscular hemoglobin (MCH) and mean corpuscular hemoglobin concentration (MCHC) values; (2) A review of the procedure titled "Complete Blood Count" listed the laboratory's acceptable reference ranges for three distinct patient populations; (a) Range 1 - Patients between age two to six months. Acceptable values were as follows, "MCH 26.0-32.0 pg, MCHC 32.0-36.0 g/dL"; (b) Range 2- Patients between age seven months to two years. Acceptable values were as follows, "MCH 23.0-28.0 pg, MCHC 31.0-36.0 g/dL"; (c) Range 3 -

Patients between three years to 12 years. Acceptable values were as follows, "MCH 25.0-29.0 pg, MCHC 31.0-35.0 g/dL". (3) A review of one patient test report for each patient age range was reviewed and revealed the following; (a) Range 1 - Patient report stated the normal MCH as 25.0-34.0 pg, and MCHC as 30.0-37.0 g/dL; (b) Range 2 - Patient report stated the normal MCH as 25.0-34.0 pg, and MCHC as 30.0-37.0 g/dL; (c) Range 3 - Patient report stated the normal MCH as 25.0-34.0 pg, and MCHC as 30.0-37.0 g/dL. (4) The reports and the policy were reviewed with technical consultant #1 and technical consultant #2, who stated on 10/26/2023 at 01:00 pm, the laboratory had not updated the age-specific normal reference ranges in the laboratory's computer information system.