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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>34D2123820           | <b>(X3) Date Survey Completed</b><br><br>05/13/2025 |
| <b>Name of Provider or Supplier</b><br><br>Central Pediatrics & Internal Medicine, Pa                                      | <b>Street Address, City, State</b><br><br>3040 Eastway Drive, Suite A, Charlotte, NC |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
|---------------------------|---|
| <b>D2006</b>              | <p>TESTING OF PROFICIENCY TESTING SAMPLES<br/>CFR(s): 493.801(b)</p> <p>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of the laboratory's policies and procedures, observation, review of 2022, 2023, 2024, and 2025 American Proficiency Institute (API) proficiency testing records, and interview with the technical consultant (TC) 5/13/25, the laboratory failed to test proficiency samples in the same manner that patient specimens are routinely tested. Findings: Review of the laboratory's "PROFICIENCY TESTING POLICY" revealed "... GUIDELINES FOR PROFICIENCY TESTING ... d. All PT samples will be treated in the same manner as patient samples. NOTE: Critical results of PT samples must be verified by repeat testing following the Alert/Critical laboratory protocol. ..." 1. During a tour of the laboratory at approximately 10:15 a.m., the surveyor observed a list of critical values for WBC (white blood cell count), hemoglobin, hematocrit, and platelet count posted on the hematology analyzer. Below the list of critical values was the following statement: "Outside of these range, please repeat test or sent out". Review of 2022, 2023, 2024, and 2025 API proficiency testing records revealed the following proficiency samples with critical hemoglbin results that were not repeated: a. 2022 1st Hematology event - sample HSY-02; b. 2024 3rd Hematology event - sample HSY-14; c. 2025 1st Hematology event - sample HSY-03. 2. Review of 2022, 2023, 2024, and 2025 API proficiency testing records revealed</p> |

that on the 2023 1st Hematology event, the laboratory tested sample HSY-04 twice on 3/21/23 and once on 3/29/23. There was no documentation to indicate why the sample was tested multiple times and on two different days. During interview at approximately 11:05 a.m., the TC confirmed patient specimens are not routinely tested on more than one day.

**D3031**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

This STANDARD is not met as evidenced by:

Based on review of 2022, 2023, and 2024 quality control (QC) and maintenance records, lack of documentation, and interview with the TC 5/13/25, the laboratory failed to retain required analytical system documents for at least two years. Findings: 1. Review of the 2022, 2023, and 2024 Medonic M-Series Hematology analyzer QC logs and Boule Con-Diff Tri-level QC assay sheets revealed missing documentation necessary for ensuring accurate QC ranges and valid expiration dates. There was no assay sheet available for the following Boule Con-Diff Tri-level QC lot numbers: 2231231+, 2231232+, and 2231233+. 2. Review of the 2022, 2023, and 2024 Medonic M-Series Hematology analyzer QC logs and maintenance logs revealed the absence of all QC and maintenance records for June 2024. During an interview at approximately 1:30 p.m., the TC confirmed there were no further records available for review.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, review of 2022, 2023, and 2025 temperature and humidity records, the absence of 2024 records, and interview with the TC 5/13/25, the laboratory failed to monitor and document refrigerator temperature, room temperature, and humidity daily to ensure proper storage of reagents and controls and to ensure accurate and reliable test system operation. Findings: A. Refrigerator temperature Review of manufacturer's instructions for storage of the Boule quality control and calibration material used on the Medonic hematology analyzer revealed a refrigerator storage temperature of 2-10 degrees Celsius. Review of 2022, 2023, and 2025 temperature and humidity records revealed there were no refrigerator temperature records available for: 1. 12 of 12 months in 2022; 2. 12 of 12

months in 2023; 3. 12 of 12 months in 2024. During interview at approximately 11:30 a.m., the TC confirmed the refrigerator temperature records were missing for 2022, 2023, and 2024. B. Room temperature and humidity Review of manufacturer's instructions for the Medonic hematology analyzer revealed a room temperature of 18-32 degrees Celsius and room humidity up to 80% for operation of the analyzer. Review of 2022, 2023, and 2025 temperature and humidity records and the absence of 2024 records revealed the laboratory failed to monitor and document room temperature and humidity: 1. 5 of 23 days in November 2022 - 11/10, 11/21, 11/22, 11/23, 11/25; 2. 12 of 12 months in 2024; 3. 5 of 21 days in January 2025 - 1/2, 1/9, 1/10, 1/17, 1/22. During interview at approximately 11:30 a.m., the TC stated they were unable to locate any temperature and humidity records for 2024. This deficiency was cited on the previous survey 1/24/22.

**D5429**

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

(a)(1) 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 Medonic M-Series Hematology analyzer operator's manual, random review of maintenance records, lack of documentation, and interview with the TC 5/13/25, the laboratory failed to perform required monthly maintenance during months in 2022, 2023, and 2025. Findings: Review of the Medonic M-Series Hematology Analyzer operator's manual, section 8.2 Monthly Cleaning, revealed the statement, "This section describes the cleaning procedure to be used to secure the correct function of the instrument on a monthly basis." Section 8.2 of the operator's manual defined the following monthly maintenance actions: Cleaning and Clot Prevention. The instructions for Clot Prevention explained, "This process will decrease the risk of debris material building up in the instrument system. This should be performed at least once per month or every 1,000 samples." Review of randomly selected Medonic M-Series Hematology analyzer maintenance records revealed lack of monthly maintenance documentation for 7 months from March 2022 to January 2025: 1. No monthly maintenance documented March 2022, May 2022, June 2022, or December 2022; 2. No monthly maintenance documented July 2023 or October 2023; 3. No monthly maintenance documented January 2025. During an interview at approximately 11:15 a.m., the TC said he was aware of the missing documentation and has reminded testing personnel, providing feedback through laboratory review summaries. This deficiency was cited on the previous survey 1/24/22.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Quality Assessment (QA) Plan, review of laboratory policies and procedures, review of laboratory records, review of patient test reports, and interview with the TC, the Lab Director failed to ensure quality

laboratory services through an established quality assessment program. Findings: Review of the laboratory's QA Plan revealed "Patient Test Management and Test Tracking System ... Periodic evaluation of pre-analytical, analytical, and post analytical phases of Patient Test Management and Test Tracking will be performed to assure quality...testing, and reporting in the laboratory." The plan stated reviews are conducted by "Laboratory Director, or Technical Consultant, or qualified staff." The plan described evaluations of various laboratory systems. For example: a. "Proficiency Testing To assure ... the laboratory is enrolled in an approved Proficiency Testing Program (PT) for each regulated analyte ...". The QA plan described review of PT records to ensure PT samples were tested "... using the same procedures/methodologies used for patient testing ...". b. "Quality Control ... Quality control must be run and documented on instruments and test kits as indicated by the manufacturer ... The control logs must clearly indicate the control results for each day of patient testing. ..." The QA plan described daily and monthly review of all quality control results including control package inserts, instrument printouts, QC logs and graphs, and temperature and humidity logs. c. "Instrument Maintenance The laboratory's quality assessment program reviews the control data, instrument calibration, and maintenance of each test method....to assure quality laboratory test results." The QA plan described review of calibration records, maintenance records, problem logs, corrective action reports, quality control, and proficiency testing records and reference ranges to ensure they are appropriate for the patient population and methodology. The "Corrective Action" of each section within the QA Plan stated, "Ensure corrective actions alleviated the problems. Systemic problems may require further training or procedural changes." Review of the laboratory's 2022, 2023, 2024, and 2025 records revealed the Quality Assessment Plan failed to identify and correct the following issues identified during the survey: 1. Proficiency samples not tested in the same manner as patient specimens - see D2006. 2. QC and maintenance records not retained - see D3031. 3. Temperature and humidity not documented - see D5413. 4. Critical maintenance procedures not documented at required frequency - see D5429. 5. Appropriate reference ranges for result interpretation not included on patient test reports - see D6061. During an interview at approximately 2:00 p.m., the TC confirmed that the issues have been noted and his laboratory review notes are copied and provided to the office manager. This deficiency was cited on the previous survey 1/24/22.

**D6061**

**CLINICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1419(c)

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

This STANDARD is not met as evidenced by:  
Based on review of 7 patient test reports, review of corresponding age and gender in patients' medical record, and interview with the Technical Consultant (TC) 5/13/25, the Clinical Consultant failed to ensure age and/or sex specific ranges were available for interpretation of Complete Blood Count (CBC) results. Findings: Patient records were randomly selected based on the patient population. Review of the medical records and their corresponding Complete Blood Count (CBC) test reports revealed the absence of age and/or sex specific normal ranges for 7 of 7 patients. The review of test reports and corresponding medical records included: Patient # 1 = 14 year old female Patient # 2 = 9 year old female Patient # 3 = 5 year old female Patient # 4 = 12 year old female Patient # 5 = 50 year old male Patient # 6 = 4 year old female Patient

# 7 = 2 year old male All seven patient test reports contained identical normal ranges for a CBC. Normal ranges included, for example: White Blood Count (WBC) = 3.5 - 10.0 x 1 billion per liter ( $10^9/L$ ) Hemoglobin (HGB) = 11.5 - 16.5 grams/deciliter (g/dl) Mean Corpuscular Volume (MCV) = 75 - 100 femtoliters (fl) During an interview at approximately 2:00 p.m., the TC said he was unsure whether the Medonic hematology analyzer was capable of reporting more than one normal range. The TC confirmed these reference ranges were the only ranges presented to the ordering provider.