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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 20D0885112 | (X3) Date Survey Completed 11/19/2024 |
| Name of Provider or Supplier Pediatric Associates Of Lewiston Pa | Street Address, City, State 33 Mollison Way, Lewiston, ME | |
| 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 |
|---------------------------|---|
| D2009 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview with the laboratory director (LD), the LD and testing personnel (TP) failed to sign the attestation sheets for the American Proficiency Institute (API) proficiency testing (PT) samples in the specialty of Hematology. Findings include: 1. Record review on 11/19/2024 of the laboratory's PT attestation sheets for API Hematology surveys revealed the following: a. Events 2 and 3 2023, and Events 1, 2, and 3 2024; Not signed by the LD. b. Events 1 and 3 2023, and Events 1, 2, and 3 2024; Not signed by TP. 2. Staff interview on 11/19/2024 at 9:30am with the LD confirmed the above findings. 3. The laboratory performs 500 tests annually in the specialty of Hematology.</p> |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the laboratory failed to ensure controls were within their expiration date before use in the specialty of Hematology. Findings include: 1. Record review of</p> |

laboratory 2023 corrective action documentation for the Medonic M Series Hematology analyzer on 11/19/2024 revealed the following: a. "12/8/23 CBC CONTROLS RUN... Controls run using the expired reagents, controls passes. As there were no recent variances of concern, they machine continued to be used". b. Backordered Items form: "11/27/2023... Medonic M-Series Hematology Tri-Level Control... 501-605" and "12/08/2023... Medonic M-Series Hematology Tri-Level Control... 501-605". 2. Record review of laboratory quality assurance policy on 11/19/2024 revealed: "QC material must not be tested beyond the expiration date on the package." 3. Staff interview with the LD on 11/19/2024 at 10:30am confirmed the above findings. 6. The laboratory performs 500 tests annually in the specialty of Hematology.

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 lack of documentation and interview with testing personnel #1 (TP#1), the laboratory failed to document routine maintenance and function checks on the Medonic M Series Hematology analyzer. Findings include: 1. Record review of the laboratory's Medonic maintenance documentation on 11/19/2024 revealed no monthly maintenance recorded for August, November, and December 2023 and February 2024. 2. Record review of the laboratory's policy and procedure manual on 11/19/2024 revealed: "Instrument Maintenance (Cleaning) is performed monthly and semi-annually according to the manufacturer's instructions, utilizing the Boule Cleaning Kit." 3. Interview with TP#1 on 11/19/2024 at 9:00am confirmed the above findings. 4. The laboratory performs 500 tests per year in the specialty of Hematology.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of the PT graded results from the American Proficiency Institute (API) and staff interview, the laboratory director (LD) failed ensure that all proficiency testing reports received were reviewed. Findings include: 1. Record review on 11/19/2024 of the laboratory's API Proficiency Testing Performance Evaluation reports revealed no documented review of Event 2 2023 and Event 1 2024 by the LD or designee. 2. Staff interview on 11/19/2024 at 10:00am with the LD confirmed the above findings. 3. The laboratory performs 500 tests annually in the specialty of Hematology.

D6050

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iv)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical consultant (TC) failed to perform direct observation of performance of instrument maintenance and function checks for all testing personnel (TP). Findings include: 1. Record review on 11/19 /2024 of the laboratories TP competency documentation 2023-2024 revealed 10 of 15 TP did not have direct observation of performance of instrument maintenance and function checks documented. 2. Staff interview with the laboratory director on 11/19 /2024 at 9:30am confirmed the above findings. 4. The laboratory performs 500 tests annually in the specialty of Hematology.