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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 20D0885112 | (X3) Date Survey Completed 09/07/2022 |
| 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 |
|---------------------------|---|
| D2123 | <p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the CASPER Proficiency Testing (PT) data report 155, lack of PT records and documentation, and staff interviews, the laboratory failed to participate in an approved PT program for Hematology. Findings include: 1. Record review on 9/6/2022 of the CASPER 155 report revealed PT scores of 0% for Hematology (HSY-11 through HSY-15) 2021 Event 3. 2. Record review on 9/6/2022 of the laboratory's American Proficiency Institute performance summary documentation revealed a "Failure to Participate" result in Hematology for PT 2021 Event 3. 3. Staff interview with testing personnel #1 (TP1) on 9/6/2022 at 9:30 AM confirmed the laboratory failed to participate in PT for 2021 Event 3. 4. The laboratory performs approximately 2000 tests annually in the specialty of Hematology.</p> |
| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test</p> |

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, it was determined that the reference ranges for the specialty of Hematology were not included in the laboratory procedure manual. Findings include: 1. Record review of laboratory procedure manual on 9/6/2022 revealed no reference ranges for CBC testing and the statement: "...all laboratory policies and procedures will be reviewed on an annual basis and updated as necessary." 2. Staff interview with testing personnel on 9/6/2022 at 10:30 am confirmed the reference ranges for the testing noted above were not in the laboratory procedure manual. 3. The laboratory performs approximately 2000 tests annually in the specialty of Hematology.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the proficiency testing (PT) data report (CASPER Report 0155D), and PT graded results from the American Proficiency Institute (API) and staff interview, the laboratory director (LD) failed to investigate or take remedial action when the laboratory failed to participate in PT resulting in an unsatisfactory score of 0%. Findings include: 1. Record review on 9/6/2022 of the CASPER Report 0155D revealed the laboratory received a PT score of 0% for the regulated analytes in the specialty of Hematology for 2021 Event 3. 2. Record review on 9/6/2022 of the laboratory's Hematology/Coagulation 2021 API PT records revealed: 2021 Event 3: a. An "Failure to Participate" PT result for "HSY-11 through HSY-15" resulting in a score of 0%. b. Results not signed by the LD with a note, "?Failed to participate" c. An investigation and action plan for the unsatisfactory score was not documented. 3. Record review on 9/6/2022 of the laboratory manual revealed the statement: "If there

are problems with the proficiency testing results, laboratory personnel will investigate the cause of the problem. All troubleshooting and corrective actions must be documented. Retraining of testing personnel will be performed and documented as indicated." 4. Staff interview on 9/6/2022 at 10:00 AM with testing personnel confirmed the above findings. 5. The laboratory performs approximately 2000 tests annually in the specialty of Hematology.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on lack of documentation and interview with testing personnel #1 (TP1) the technical consultant (TC) failed to document annual competency of testing personnel to assess the knowledge and skills necessary to perform moderate complexity laboratory testing in the specialty of Hematology. Findings include: 1. Record review on 9/6/2022 of the CMS form 209 revealed 12 of 12 TP perform moderate complexity testing. 2. During interview with (TP1) on 9/6/2022 at 9:15 AM, TP1 confirmed that the TP were evaluating each other and that competencies are not performed by the TC. 3. The laboratory performs approximately 2,000 tests in the specialty of Hematology per year.