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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D0211974 | (X3) Date Survey Completed 02/07/2023 |
| Name of Provider or Supplier Pediatric Associates Mont County | Street Address, City, State 3416 Olanwood Court, Suite 108, Olney, 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 |
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| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the laboratory failed to have all the policies and procedures approved by the current laboratory director listed on the CLIA certificate. Findings: 1. Review of the procedure manual showed that the last time the procedure manual was signed by the laboratory director listed on the CLIA certificate was 02/09/2018. The signature of the clinical consultant was on the procedure manual for 02/12/2018, 12/23/2019, 01/22/2020, and 02/09/2021. 2. During the survey on 08/03/2022 at 12:15 PM, the TP confirmed that the procedure was not signed by the current laboratory director.</p> |
| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the</p> |

range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the calibration records, and phone interview with the technical consultant (TC), the laboratory failed to ensure that calibration verification was performed and documented once every six month for the Medonic hematology analyzer. Findings: 1. The calibration records that were reviewed showed that calibration verification had been performed on 07/18/2022, 11/11/2021, 03/15/2021 and 06/15/2020. 2. The "Technical Consultant Duties and Responsibilities" procedure states that the TC will validate the test performance. CLIA requires calibration verification to be performed once every six months. The records show that twice there was a nine month gap between the performance of the calibration verification. 3. During the phone interview on 08/03/2022 at 12:15 PM, the TC confirmed that the calibration verification procedures were not performed once every six months as required.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on review of the duties and responsibilities, monthly quality assessment (QA) review worksheets, proficiency testing (PT) records, quality control (QC) records, and interview with the testing personnel (TP), the laboratory director (LD) failed to be actively involved in the operation of the laboratory by assuring that the laboratory staff were performing the delegated duties and responsibilities. Findings: 1. The "Clinical Consultant Duties and Responsibilities" procedure identifies a Clinical Consultant (CC) who acts as the assistant lab director. According to the procedure the CC "is actively involved in monitoring the laboratory's Quality Assurance, Quality Control and Proficiency Testing programs." The CLIA regulations do not recognize the position of an assistant lab director under the moderate or high complexity testing personnel requirements. 2. The monthly QA worksheets and QC graphs for 2021 and 2022 were reviewed. The review signatures documented on the QA worksheet included the technical consultant (TC) and CC, but not the LD. 3. During the survey on 08/03/2022 at 12:30 PM, the TP confirmed that the LD does not document review

of the QA worksheets, PT, and QC records. This is done by the CC who is not qualified as a LD (have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407) and does not provide the LD with a documented summary of the QA reviews. The LD delegated duties and responsibilities and failed to ensure that all duties were properly performed on a routine basis by reviewing the monthly summary provided by the TC.

D6021

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

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the evaluation records and phone interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the policies for monitoring the laboratory staff were being followed each year. Findings: 1. The annual evaluation records for 2020 through 2022 were reviewed. The evaluation records were for eight people. Two of eight were missing their annual review for 2020. Three of eight were missing their annual review for 2022. 2. The TC was one of the two laboratory staff that did not receive an annual evaluation in 2020. The LD failed to ensure that the testing personnel and TC received an annual evaluation as required by the policies and procedures. 3. During the phone interview on 08/03/2022 at 12:15 PM, the TC confirmed that the annual evaluations had not been performed as required and that the LD had not performed the annual evaluation of the TC.

D6022

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

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on review of the "Technical Consultant Duties and Responsibilities" procedure, the monthly "Quality Assessment Review" worksheets and phone interview with the technical consultant (TC), the laboratory director (LD) failed to ensure that the TC provided the monthly "Quality Assessment Review" on a monthly basis. Findings: 1. The "Technical Consultant Duties and Responsibilities" procedure states that each month the TC will provide a quality assessment report to the laboratory director for review. The worksheet requires the TC and LD to sign and date each review. 2. The "Quality Assessment Review" worksheets for 2021 and 2022 were reviewed for a total of 19 months. The reports show that the TC was on site 07/22/2022, 03/18/2022,

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| | <p>11/11/2021, and 05/18/2021. The TC and LD signed and dated the reviews on 07/22/2022, 03/18/2022, 11/11/2021, and 05/18/2021. 3. During the phone interview on 08/03/2022 at 12:15 PM, the TC confirmed that the monthly quality assessment reviews were not being performed on a monthly basis.</p> |
| <p>D6033</p> | <p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the testing personnel, the technical consultant failed to evaluate the competency of the testing personnel by performing the monthly review of Levey-Jennings graphs, calibration, maintenance, temperature logs, proficiency testing, and review of patient results (D6049); and failed to ensure that all testing personnel received an annual competency review (D6054). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.</p> |
| <p>D6049</p> | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by: Based on review of the "Technical Consultant Duties and Responsibilities" procedure, monthly quality assessment (QA) worksheets and phone interview with the technical consultant (TC), the TC failed to perform and document the QA on a monthly basis as required by the written procedure. Findings: 1. The "Technical Consultant Duties and Responsibilities" procedure states that the TC will be "Providing monthly Quality Assessment reports." 2. The QA worksheet includes documentation of monthly review of Levey-Jennings graphs, calibration, maintenance, temperature logs, proficiency testing, review of results, and testing personnel review. 3. The QA worksheets for 2021 and 2022 were reviewed for a total of 19 months. The worksheets show that the TC was on site 07/22/2022, 03/18/2022, 11/11/2021, and 05/18/2021. 4. The QA worksheets for 2021 and 2022 failed to include documentation of the proficiency testing kits being received and results submitted; whether remedial action was required for patient results; and when testing personnel were reviewed. 5. During the phone interview on 08/03/2022 at 12:15 PM, the TC confirmed that the monthly QA reports were not being completed on a monthly basis as required by the "Quality Assessment Review" worksheet.</p> |
| <p>D6054</p> | <p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least</p> |

annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the annual evaluation records and phone interview with the technical consultant (TC), the TC failed to ensure that all testing personnel received an annual competency review as required by the procedure manual. Findings: 1. The annual evaluation records for 2020 through 2022 were reviewed. The evaluation records were for eight people. Two of eight were missing their annual review for 2020. Three of eight were missing their annual review for 2022. 2. During the phone interview on 08/03/2022 at 12:15 PM, the TC confirmed that the annual evaluations were not being performed as required.