

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2028521	(X3) Date Survey Completed 12/06/2023
Name of Provider or Supplier Pediatric Associates, Pc	Street Address, City, State 2863 Johnson Ferry Road, Suite 100, Marietta, GA	
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	A recertification survey was performed on December 6, 2023. The facility was found to be NOT in compliance with the CLIA conditions and standards for specialties /subspecialties for 42 CFR. Conditions: 493.1230 General Laboratory Systems 493.1441 Laboratory Director
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) provider documents and staff interview the laboratory failed to receive acceptable scores on the Specialty Hematology, analytes- White Blood Cell, Red Blood Cell, Hemoglobin, Hematocrit, Platelet Count, and differential for 2022 (event 1 and 2). The laboratory must verify the accuracy of any analyte, specialty, or subspecialty performed in the laboratory at least twice a year. REFERENCE: D-5215</p>
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</p>

for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB) Proficiency Testing (PT) provider documents and staff interview, the laboratory failed to receive acceptable scores on the Specialty- Hematology, Analytes-White Blood Cell, Red Blood Cell, Hemoglobin, Hematocrit, Platelet Count, and differential in 2022 (event 1 and 2). The laboratory must verify the accuracy of any analyte, specialty, or subspecialty performed in the laboratory at least twice a year. Findings: 1. Review of 2022 AAB PT (event 1) results revealed the laboratory did not submit results for evaluation due to not receiving PT samples. The laboratory received event 2 samples at an unacceptable temperature. 2. The laboratory received unacceptable results for two consecutive PT events. The laboratory was unable to verify the accuracy of testing for the Speciality, Hematology, in 2022. 3. Staff interview with testing personnel #5, (CMS 209, Testing Personnel List), on December 6, 2023, at approximately 1:20 pm in the file room, confirmed the above aforementioned statements.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the Quality Control(QC) documentation for months December 2021- November 2023, performed on the Sysmex XP300 hematology analyzer, and staff interview, the Laboratory failed to provide legible printouts for review during the survey. Findings: 1. Review of the QC documents for December 2021- September 2022, revealed the QC printouts were illegible. Observation of the printer revealed the printer was not printing all of the information. The dates and QC results were not legible on the right side of the prinout. 2. Review of QC documents for October 2022 - March 2023 revealed the results were legible and acceptable. 3. Review of the QC documents for April 2023-November 2023 revealed the printouts were illegible. 4. Interview with testing personnel #5 (CMS 209 Testing Personnel Report) on December 6, 2023, at 1:30 pm, in the file room, confirmed the aforementioned statements.

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 American Association of Bioanalysts (AAB) proficiency testing (PT) documents, on the Sysmex, and staff interview, the laboratory director failed to document review of results for the PT test reports performed 2022 - 2023. Findings: 1. Review of AAB PT evaluation reports for 2022 and 2023 revealed that the laboratory director failed to document review of the results for 2022 (events 1 and 3) and 2023 (events 1, 2, and 3). 2. Interview with staff #5, on December 6, 2023, at approximately 1:15 pm, in the file room, confirmed the aforementioned statements.

D6020

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 program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of the Quality Control(QC) documentation for December 2021 - November 2023, performed on the Sysmex XP300, on the hematology analyzer, and staff interview, the Laboratory Director failed to assure the quality of laboratory services. The QC documents were illegible for 18 months out of the 24 months reviewed during the survey process. There was no documentation that the laboratory director reviewed QC documents. Findings: 1. Review of the QC documents for December 2021 - September 2022, the printouts were not legible. Observation of the printer revealed that the printer was not performing optimally. The dates as well as QC results were not legible on the right half of the printout. . 2. Review of the QC documents for October 2022 -March 2023 were legible and were acceptable. 3. Review of the QC documents for April 2023 - November 2023 were illegible.. 4. Interview with testing personnel #5 (CMS 209 Testing Personnel Report) on December 6, 2023, at 1:30 pm in the file room, confirmed the aforementioned statements.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have

successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on review of the employee records for 8/8 testing personnel listed on the (CMS 209 Laboratory Personnel Report form (CMS 209), and staff interview, the laboratory failed to have a copy of the educational documents for all the testing personnel (TP) listed on the CMS 209. Findings: 1. Review of the employee records for the 8/8 testing personnel revealed there were 3 new hires (TP-3, TP-7, TP-8) since the last survey that did not have educational documents in their employee records. 2. Interview with TP-5 on the CMS 209, on December 6, 2023 at approximately 1:30 pm, confirmed the aforementioned statement.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the Quality Control documents for the Sysmex XP300, from November 2021- November 2023, the testing personnel education documents, American Association of Bioanalyst (AAB) Proficiency Testing(PT)documents, the Laboratory Director (LD) failed to provide overall oversight for the laboratory. REFERENCE: D6018, D6020, D6065