Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0902571	05/31/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates Inc	400 N Hiatus Rd Ste 105, Pembroke Pines, FL	

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 conducted from May 16, 2024 to May 31, 2024. PEDIATRIC ASSOCIATES INC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories. Cited the following Condition: D6168 - Testing Personnel 493.1487
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. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to retain records for Quality Control (QC) for one out 25 days reviewed during November 2023. Findings included: 1-Review of Quality Control/Quality Assurance (QA) logs for November 2023 revealed that the high control was repeated on 11/17/2023 and the testing personnel documented the identified problem as "High Control out of range" with corrective action as "remix, re-run still out of range, Laboratory Lead aware." 2-Review of the monthly printout tables revealed there were three QC lots in use: - Lot 2230751 (Level 1) Levy Jennings Graph for Medonic hematocrit (HCT) parameter did not have runs recorded for 11/17/2023. - Lot 2230752 (Level 2) Monthly QC Control Summary Report did not have runs recorded for 11/17/2023. - Lot 2230753 (Level 3) Monthly QC Control Summary Report had one run 11/17/2023 at 14:21 with HCT 53.2H (flagged high), hemoglobin (HGB) 17.3H (flagged high). All other parameters were within range. Record for repeat run was not provided. 3- Based on interview on 5/16/2024 at 4:36 PM the office manager acknowledged that the LIS was down on that day. Additional email confirmation from 5/20/24 at 5:06 PM stated "For the QC, we unfortunately did not find adequate documentation for 11/17/2023."

D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to obtain two out of three levels of hematology control on 11/17/2023 as required for the Complete Blood Counter (CBC) quantitative analyzer Medonic M Series. The laboratory failed to provide the number of patient tested and results released on 11/17/2023. Findings: Review of the Quality Control records for three levels of Quality Control (QC) during November 2023 revealed the following: - Monthly QC Summary report for lot 2230752+ did not have a run recorded for 11/17/2023 out of the 23 listed. - Monthly QC Summary report for lot 2230753+ had one run recorded for 11/17/2023, but the hemoglobin (HGB) and hematocrit (HCT) parameters were flagged high (H). - Levy Jennings (LJ) Graph for Medonic Level 1 Lot 22307-51 hematocrit (HCT) parameter has no entry for 11/17/2023 out of the 18 points recorded on the graph. Based on interview on 5/16/2024 at 4:36 PM the laboratory staff provided LIS printout of the QC that was available and stated that the LIS was down that day. Additional email confirmation from 5/24/24 at 3:41 PM from office manager (MG) stated "Unfortunately, yes patients were tested for CBC that day."
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview with laboratory manager, the laboratory failed to verify the education of one out of five testing personnel. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)

(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory manager, the laboratory failed to verify the education of one (TP1) out of five (TP1, TP2, TP3, TP4, TP5) testing personnel. Findings included: - Review of the CMS-209 form signed and dated by the laboratory director on 5/16/2024 revealed that there were five testing personnel (TP1, TP2, TP3, TP4, TP5). - Review of the employee file TP1 revealed that employee holds an associate degree in Radiology. There were no high school diploma and no transcripts for the associate degree on file. - Interview with TP1 at 5:01 PM confirmed that transcript were not available and would be emailed. - Email notification from laboratory manager on 5/22/2024 at 1:29PM confirmed that employee had requested transcripts for the associate degree. As of 5/31/2024 documents had not been received.