Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0692483	01/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Associates	7848 Lake Underhill Rd, Orlando, 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 on January 16, 2020. Pediatric Care Group PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on College of American Pathologists (CAP) proficiency testing (PT) records and interview, the laboratory failed to have all testing personnel rotate through the testing of proficiency testing (PT) samples for 5 (2018 1st and 2nd, and 2019 1st, 2nd and 3rd) out of 6 events (2018 1st, 2nd and 3rd, and 2019 1st, 2nd and 3rd). Findings: Review of the CAP PT attestation form showed that Testing Personnel A performed all the PT for 2018 (1st, 2nd) and 2019 (1st, 2nd, 3rd). Review of the CMS-209 form title, "Laboratory Personnel Report (CLIA)" that was signed and dated by the Laboratory Director on 1/15/20, listed 5 testing personnel. Review of competency evaluations showed that there were 2 current employees (A and B) and 3 to 4 former employees who worked in the laboratory in 2018. Review of competency evaluations for 2019 showed that all 5 current employees (A, B, C D, and E) had competency evaluations. During an interview on 1/16/19 at 9:57 AM, the Laboratory Consultant stated that PT for 2018 (1st, 2nd) and 2019 (1st, 2nd, 3rd) was performed by Testing Personnel A and that they should have rotated testing personnel.
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 at least two years of records for laboratory room temperature and humidity logs for 1 (June 2019) out of 24 months reviewed, and the laboratory refrigerator temperature for 1 (November 2019) out of 24 months reviewed. Findings: Review of the "Room Temperature /Humidity Log" revealed that the laboratory was missing the records for June 2019. Review of the "Temperature Log for Refrigerator - Fahrenheit" revealed that the laboratory was missing the records for November 2019. During an interview on 1/16 /20 at 11:28 PM, the Laboratory Consultant acknowledged they were unable to locate the missing documentation.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 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. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the general laboratory system and correct identified deficiencies. Findings: Cross Reference D5221 Based on College of American Pathologists (CAP) proficiency testing (PT) records and interview, the laboratory failed to document corrective action for any score less than 100% for the 1 (2018 3rd event) out of 6 events (2018 1st, 2nd and 3rd, and 2019 1st, 2nd and 3rd). Cross Reference D5291 Based on record review and interview, the laboratory failed to provide documentation showing the laboratory was monitoring, assessing and correcting problems from 1/16/18 to 1/16/20.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on College of American Pathologists (CAP) proficiency testing (PT) records and interview, the laboratory failed to document corrective action for any score less than 100% for 1 (2018 3rd event) out of 6 events (2018 1st, 2nd and 3rd, and 2019 1st, 2nd and 3rd). Findings: Review of the CAP PT records for the 3rd event of 2018 showed no documentation of corrective action taken for the score of 80% for the hemoglobin analyte. During an interview on 1/16/19 at 10:14 AM, the Laboratory Consultant acknowledged that there was no corrective action documented.

D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documentation showing the laboratory was monitoring, assessing and correcting problems from 1/16 /18 to 1/16/20. Findings: Review of laboratory records showed that the laboratory had a "Monthly Quality Assurance (QA) Checklist" and the checklists were not being performed monthly. During an interview on 1/16/20 at 12:40 AM, the Laboratory Consultant acknowledged that the Monthly QA Checklists were not being filled out.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and correct identified problems. Findings: Cross Reference D5415 Based on observation and interview, the laboratory failed to label the hematology quality control vials currently in use with the open date and expiration date. Cross Reference D5437 Based on record review and interview, the laboratory failed to follow manufacturer's instructions by not performing calibrations on the Beckman Coulter Act Diff 2 Hematology analyzer at least twice annually from 7/26/18 to 1/15/20. Cross Reference D5547 Based on record review and interview, the laboratory failed to keep a reagent log listing when the reagents for the Beckman Coulter Act Diff 2 were used from 1/16 /18 to 1/16/20.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory failed to label the hematology

	quality control vials currently in use with the open date and expiration date. Findings: A tour of the laboratory on 1/16/20 at 9:50 AM, revealed that the hematology quality controls vials for low, normal, and high did not have the open date and the new expiration date after the vials were opened. Review of the box containing the controls showed that the new expiration date was recorded on the box and plastic insert holding the controls. During an interview on 1/16/20 at 9:57 AM, Testing Personnel A acknowledged she only wrote the expiration date on the box and the insert, but did not record it on the vials.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow manufacturer's instructions by not performing calibrations on the Beckman Coulter Act Diff 2 Hematology analyzer at least twice annually from 7/26/18 to 1/15/20. Findings: Review of the manufacturer's operations manual showed that calibration should be performed every six months. Review of the laboratory Quality Management Plan noted that "calibration will be performed at the manufacturer's required frequency or every 6 months." Review of the procedure titled "CBC with Automated Three Part Differential by Beckman Coulter Act 2" read "Calibration procedures are to be performed every six months." Review of the calibration records revealed that the hematology analyzer was validated on 7/26/18, and only one record of a calibration performed on 1/15/20 was available for review. During an interview on 1/16/20 at 10:50 AM, the Laboratory Consultant confirmed that the laboratory had performed only one calibration on the analyzer after it was validated.
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have a reagent log listing when the reagents for the Beckman Coulter Act Diff 2 were used from 1/16/18 to 1/16/20. Findings: Review of the quality control documentation showed that the

	laboratory did not have any records indicating when the reagents for the hematology analyzer were used. During an interview on 1/16/20 at 12:59 PM, the Laboratory Consultant acknowledged that the laboratory failed to record the reagents used in the hematology analyzer on a reagent log.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's patient reports failed to list the name and address of the laboratory where the hematology testing was performed for all patients from 7/26/18 to 1/16/20 Findings: The laboratory validated their new Beckman Coulter Act Diff 2 analyzer on 7/26/18. Review of the hematology test results showing the name and address of the location where the testing was done was not on the copy of the instrument printout that was given to patients upon request. During an interview on 1/16/20 at 12:59 PM, Testing Personnel A acknowledged that they gave patients a copy of the hematology analyzers reports and that the reports did not contain the name and address of where the hematology tests were performed.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction in the laboratory. Findings: Cross Reference D6007 Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytic phases of testing. Cross Reference D6016 Based on record review and interview, the Laboratory Director failed to ensure that proficiency testing was performed according to CLIA regulations. Cross Reference D6020 Based on record review and interview, The Laboratory Director failed to ensure that quality control program maintained all quality control documentation. Cross Reference D6021 Based on record review and interview, the Laboratory Directory failed to ensure that the quality assurance program was maintained to ensure quality laboratory services from 1/16/18 to 1/16 /20.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that testing systems used in the laboratory provided quality laboratory services for all aspects of testing performance, including analytic and postanalytic phases of testing. Findings: The Laboratory Director failed to ensure the laboratory Testing Personnel labeled the hematology quality control vials currently in use with the open date and expiration date. (See D5415) The Laboratory Director failed to ensure that the laboratory followed manufacturer's instructions by performing calibrations on the Beckman Coulter Act Diff 2 Hematology analyzer at least twice annually from 7/26 /18 to 1/15/20. (See D5437) The Laboratory Director failed to ensure that the laboratory maintained a reagent log that listed when the reagents for the Beckman Coulter Act Diff 2 were used from 1/16/18 to 1/16/20. (See D5547) The Laboratory Director failed to ensure that the laboratory's patient reports listed the name and address of the laboratory where the hematology testing was performed for all patients from 7/26/18 to 1/16/20. (See D5805)
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that proficiency testing was performed according to CLIA regulations. Findings: The Laboratory Director failed to ensure that all testing personnel rotated through the testing of proficiency testing (PT) samples for 5 (2018 1st and 2nd, and 2019 1st, 2nd and 3rd) out of 6 events (2018 1st, 2nd and 3rd, and 2019 1st, 2nd and 3rd). (See D2007) The Laboratory Director failed to ensure that corrective actions were documented and followed for any score less than 100% for 1 (2018 3rd event) out of 6 events (2018 1st, 2nd and 3rd, and 2019 1st, 2nd and 3rd) for the analyte hemoglobin. (See D5221)
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 record review and interview, the Laboratory Director failed to ensure that quality control program maintained all quality control documentation. Findings: The Laboratory Director failed to ensure quality control documentation for the laboratory's room temperatures and humidity logs for 1 (June 2019) of 24 months reviewed, and the laboratory refrigerator temperature for 1 (November 2019) out of 24 months reviewed for at least two years. (See D3031)
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 record review and interview, the Laboratory Directory failed to ensure that the quality assessment program was maintained to assure quality laboratory services from 1/16/18 to 1/16/20. Findings: The Laboratory Director failed to ensure that the laboratory was monitoring, assessing and correcting problems from 1/16/18 to 1/16/20 by not completing their "Monthly QA Checklist." (See D5291)
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on record review and staff interview, the Technical Consultant failed to provide technical oversight of the laboratory. Findings: Cross Reference D6046 Based on record review and interview, the Technical Consultant failed to assess the competency of Testing Personnel listed on the Laboratory Personnel Report for 2 (A, B) out of 5 (A, B, C, D, E) in 2018, and 4 (B, C, D, E) out of 5 (A, B, C, D, E) in 2019.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of

	all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Consultant failed to assess the competency of Testing Personnel listed on the Laboratory's Personnel Report for 2 (A, B) out of 2 personnel (A, B) that worked in 2018, and 4 (B, C, D, E) out of 5 personnel (A, B, C, D, E) that worked in 2019. Findings: Review of the CMS-209 form title "Laboratory Personnel Report (CLIA)" that was signed and dated by the Laboratory Director on 1/15/20, showed the Laboratory Director served as the Technical Consultant and listed five testing personnel. Review of the 2018 competency assessments showed that Testing Personnel A's competency assessment was signed by the previous Medical Assistant (MA) Supervisor and Testing Personnel B's competency assessment was signed by the current Medical Assistant (MA) Supervisor. Review of the 2019 competency assessments showed that Testing Personnel B, C, D, and E's competency assessment were signed by the current Medical Assistant (MA) Supervisor. Review of the the "State Operations Manual Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services" revealed that personnel must qualify as technical consultants to perform competency evaluations. During an interview on 1/16/20 at 12:26 PM, the Laboratory Consultant acknowledged that the MA supervisors signed the above mentioned competency evaluations and that the MA supervisors were not qualified as technical consultants.