Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0981282	08/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Kids First Pediatrics	530 North Cobb Street, Milledgeville, 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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on August 8, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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 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 the review of the calibration documents for the Emerald Hematology

	analyzer, and staff interview, the laboratory failed to perform a calibration on the Emerald at least every 6 months. Findings: 1. Review of the calibration documents provided for the Emerald, the laboratory had documentation that the calibration was performed on the following dates: 2/12/2019 12/23/2019 - 10 months 6/10/2020 1/04 /2021 - 7 months 1/13/2021 6/14/2021 The laboratory did not document a calibration on the Emerald from 2/12/2019 and 12/23/2019, a period of 10 months. The laboratory did not document a calibration on the Everald from 6/10/2020 and 01/04 /2021 a period of 7 months. 2. Interview with the Laboratory Director (LD), on August 4, 2021, at approximately 3pm in the conference room, confirmed the aforementioned dates of calibrations on the Emerald Hematology Anaylzer.
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) documents, for the Abbott (Emerald) Hematology analyzer, for 2019, 2020, and 2021, the laboratory was not monitoring the QC to monitor over time the accuracy and precision of the performance that may be influenced by changes in test system performance, environmental conditions, or variance in operator performance. Findings: 1. Review of the QC documents for the Emerald analyzer, it was noted that no Levy Jennings(LJ) graphs had been printed for the years 2019 or 2020, there was one printed for 2021. LJ graphs allows the user to monitor the shifts and trends of the QC values to monitor errors before they actually occur. There was no documentation that this was being performed. 2. Interview with the Laboratory Director, on 08/04/2021,at approximately 2pm, confirmed the aforementioned statement.
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 review of the Quality Control(QC) documents, for the (Emerald) Hematology Analyzer for 2019, 2020, and 2021, as well as staff interview, the Laboratory Director failed to ensure that the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic phases, and postanalytic phases of testing. Findings: 1 Review of the QC documents, for the Emerald showed that there was no Levy Jennings charts printed for each lot number of QC ran on the Emerald for 2019, 2020, and 2021. The Levy Jennings charts demonstrate when QC results are drifting or trending above or below the calculated mean of the range. Monitoring the Levy Jennings charts allows the laboratory to correct errors in the QC before they are out of range. There was no documentation of QC February 16, 2021 thru February 24, 2021. 2 Interview with the Laboratory Director ,on August 8, 2021, in the conference room, in the facility, at approximately 2:30 pm, confirmed the aforementioned findings.
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 review of the Employee training and competency documents for 2019, 2020, and 2021, as well as staff interview, the Laboratory Director fulfilling the Technical Consultant responsibilities failed to perform competency assessments following the six procedure minimal requirements for assessment of competency for all personnel performing laboratory testing. The six procedures are as follows: 1. Direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing. 2. Monitoring the recording and reporting of test results 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. 4. Direct observations of performance of instrument maintenance and function checks, 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples, and 6. Assessment of problem solving skills. Findings: 1. Review of the documents for 2019, 2020, and 2021, competency assessment consisted of a Check sheet with each test listed with a signature page for each procedure. 2. Interviw with the Laboratory Director, on 08/4 /2021, at approximately 2:20pm, in the conference room, confirmed the aforementioned statement.