Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1021279	10/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kids First Pediatrics Of Georgia Pc	808 Towne Park Drive Suite 200, Rincon, 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 October 24, 2023. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) provider documents for 2021, 2022, and 2023, and staff interview, the laboratory failed to provide signed attestation statements for event 1 in 2022, and event 1 and 2 in 2023. Findings: 1. A review of the PT documents for 2022 event 1, revealed the laboratory did not provide documentation of a signed attestation statement confirming that PT samples were performed as routine patient samples. 2. A review of the PT documents for 2023 event 1 and 2 revealed the laboratory did not provide documentation of a signed attestation statement confirming that PT samples were performed as routine patient samples. 3. Interview with the Laboratory Director on 10 /24/2023, at approximately 1 pm, in the front office, confirmed that the attestation forms were not provided by MLE so they were not completed.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the Room Temperature (RT) log for years 2022- 2023, and staff interview, the laboratory failed to document corrective action for room temperatures outside of the range as posted on the temperature log. Findings: 1. A review of the RT temperature log for 2022 revealed the laboratory documented temperatures below the posted RT range of 70 to 80 degrees Fahrenheit, 79 times out of the 12 months in 2022 2. Review of the RT temperature log for 2023 through August 2023 (8 months) the laboratory documented temperatures below the posted RT range of 70 to 80 degrees Fahrenheit, 15 times out of 9 months in 2023 3. Interview with the Laboratory Director on 10/24/2023 at approximately 1 pm in the front office, confirmed the aforementioned states.
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 review of the Medical Laboratory Evaluation (MLE) Proficiency Testing (PT) provider documents for 2021- 2023, and staff interview, the Laboratory Director (LD) failed to confirm the laboratory provided a signed attestation statements for event 1 in 2022, and event 1 and 2 in 2023. Findings: 1. A review of the PT documents for 2022 event 1 revealed the LD did not confirm that the laboratory provided documentation of a signed attestation statement stating that the PT samples were performed as routine patient samples. 2. A review of the PT documents for 2023 event 1 and 2 revealed the LD did not confirm that the laboratory provided documentation of a signed attestation statement stating that the PT samples were performed as routine patient samples. 3. Interview with the Laboratory Director on 10 /24/2023, at approximately 1 pm in the front office, confirmed that attestation form was not provided by MLE so they were not completed.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified,

	This STANDARD is not met as evidenced by: Based on review of the Medonic Hematology Analyzer Quality Control (QC) performance documentation and staff interview, the Laboratory Director (LD) failed to have the laboratory testing personnel perform corrective action on June 13, 2023, for the QC being out of range for the Normal and High Control. Findings 1. Review of the QC documents for June 13, 2023, the QC for WBC and RBC for both the NORMAL QC, and the HIGH QC were out of range. There was no documented corrective action performed on this day for five patients that were testing on this day. Two out of three levels were out of range for the analytes WBC, and RBC, the QC was not acceptable. 3. Interview with the LD, on 10/24/2023, at approximately 2 pm, confirmed the above aforementioned statement.