Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1086433	09/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Kids First Pediatrics Of Georgia Pc	101 Little Neck Road Building 2 Suite A, Savannah, 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 September 10, 2018. 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:
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 proficiency testing (PT) records from Medical Laboratory Evaluation (MLE)) and staff interview, the laboratory failed to retain documentation signed by the testing personnel (TP) and laboratory director (LD) attesting to routine integration of samples into the patient workload for the 1st testing event of 2018. Findings include: 1. Review of 2018 attestation statements for PT from MLE in the speciality of hematology for complete blood counts (CBC) revealed no documentation of the attestation statement for the 1st event of 2018 . 2. Interview with the laboratory director and testing personnel # 1, (see CMS 209) on September 10, 2018 at 1 pm in the doctor's office confirmed the attestation statement for the 1st event of 2018 is not available.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and staff interview, the laboratory failed to test PT samples for event 2 of 2017 the same number of times it routinely tests patient samples. Findings include: 1. Review of raw data for PT samples from event 2 of 2017 revealed all 5 samples were tested 3 times. 2. Interview with testing personnel # 1(see CMS 209) and the laboratory director on September 10, 2018 in the doctor's office at 1 pm confirmed the samples were testing multiple times and patient samples are routinely tested only once.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation of specimens during a tour of the laboratory, review of the laboratory's policy and procedure manual and staff interview, the laboratory failed to follow established policies and procedures to ensure positive identification of patient specimens through specimen collection and labeling. Findings include: 1. Observation of specimens during a tour of the laboratory revealed 8 of 10 urine specimens not labeled according to the laboratory's policy. Three specimens were labeled with the patient's first name only. One specimen was labeled with Room # 3, one specimen was not labeled with any identifying information and two specimens were labeled with the patient's first and last name. 2. Review of the laboratory's procedure for labeling specimen containers revealed urine specimens should be labeled with the patient's name, chart number and date of collection. 3. Review of the laboratory's specimen rejection policy revealed insufficient or no identification on specimens is cause for rejection. 4. Interview with the laboratory director and testing personnel # 1 (see CMS 209), on September 10, 2018 at 12 pm in the doctor's office confirmed specimens were not labeled correctly and improper labeling is a reason for rejection.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of maintenance charts for the Emerald Cell Dyn and Medonic hematology analyzers and staff interview, the laboratory failed to document maintenance required by the manufacturer. Finding Include: 1. Review of 2017 maintenance charts for the Emerald Cell Dyn revealed no documentation of the required monthly maintenance for February, March, April, October and December of 2017. 2. Review of 2018 maintenance charts for the Medonic hematology analyzer which was put into use in April 2018, revealed no documentation of the required daily

	and monthly maintenance for April, May, June, July and August 2018. 3. Interview with the laboratory director and testing personnel # 1 (see CMS 209) on September 10, 2018 in the doctor's office at 2 pm confirmed documentation of the required maintenance is not available.