Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1010647	04/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kennesaw Pediatrics Pc	3745 Cherokee Street, Suite 401, Kennesaw, 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 April 10, 2019. 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:
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the laboratory tour and an interview with the laboratory lead tech (TP # 3 CMS 209), the laboratory failed to check its testing supply inventory properly for expiration dates before use. Findings include: 1. Laboratory tour revealed seventy (70%) percent of the Microcapilary blood collection tubes (200 ul Ram Scientific) for Bilirubin and C-Reactive Protein (CRP) expired in November 2018. 2. Secondly, thirty (30%) of Urine culture tubes (Uricult by Orion Diagnostics INC) had an expiration date of 03/18/2019. 3. An interview with the laboratory lead tech (TP # 3 CMS 209) at approximately 10:40 am on April 10, 2019 during the tour comfirmed the tubes were expired.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on postanalytic records review and an interview with the laboratory lead tech (TP # 3 CMS 209), the laboratory failed to have test reference ranges reflected on the final laboratory reports. Findings include: 1. Final patient CBC in-house reports did not have "reference ranges" reflected on the reports. 2. An interview with the laboratory lead tech (TP # 3 CMS 209) at approximately 02:30 pm on April 10, 2019 in the break room confirmed in-house patient final reports did not have reference ranges reflected on them.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on Personnel competency records review and an interview with the laboratory's lead tech (TP # 3 CMS 209), the technical consultant (TC) failed to perform annual competencies on all Testing Personnel (TP) in 2018 and 2019 as required. Findings include: 1. 2018 and 2019 competency records review revealed the TC did not perform annual competencies on (TP #s 1 - 15 CMS 209). The competencies were instead performed by the laboratory's lead tech. 2. Annual competencies were not performed by the TC on the two physicians (TP #1 and #15 CMS 209) who performed PPM microscopy in 2018. 3. An interview with laboratory lead tech (TP # 3 CMS 209) on April 10, 2019 in the break room at approximately 02:40 p.m. confirmed annual competencies for the aforementioned testing personnel (TP) were not performed by the Technical Consultant.