Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0895988	10/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Lawrenceville Family Practice Pc	1730 Lawrenceville Suwanee Road, Ste 1, Lawrenceville, 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	Based on a CLIA initail recertification survey performed on October 1, 2020, this facility was found to not be in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory failed to include required preanalytic policies and procedures. Findings include: 1. SOP review revealed the lack of policies and

	procedures for specimen collection for the following: capillary blood, urine, and throat. 2. An interview with Staff #3 (CMS 209) in a doctor's office on 10/1/2020 at approximately 11:00 a.m. confirmed the aforementioned lack of specimen collection policies and procedures in the SOP.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on instrument validation document review and staff interview, the laboratory faired to demonstrate performance specifications comparable to those established by the manufacturer as required. Findings include: 1. Review of validation documentation for the Beckman Coulter DxH900, the AU480 Chemistry analyzer, and the Access 2 Chemistry analyzer revealed the lack of accuracy verification for each instrument before reporting patient test results in 2019. 2. An interview with the technical consultant in the laboratory director's office on 10/1/2020 at approximately 2:00 p.m. confirmed the lack of accuracy documentation for the aforementioned instruments at the time of survey.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure quality assessment programs were established and maintained to identify failures in quality as they occur as required. Findings include: 1. American Proficiency Institute (API) PT 2020 document review revealed the laboratory failed two consecutive Core Chemistry events -- Event One (60 percent) and Event Two (40 percent) -- for the analyte LDL (low- density lipoprotein(cholesterol. 2. An interview with the technical consultant in the doctor's office on 10/1/2020 at approximately 11:30 a.m. confirmed the aforementioned consecutive PT failures.