Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0254477	09/04/2019
Name of Provider or Supplier	**Street Address, City, State**	
Atlanta Cancer Care - Decatur	2545 Lawrenceville Hwy, Suite 300, Decatur, 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 validation survey performed on September 04, 2019 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.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on hematology maintenance document review and staff interview, the laboratory failed to perform and document maintenance as defined by the manufacturer. Findings include: 1. Horiba hematology analyzer maintenance document review revealed the lack of maintenance logs for the following months in 2017: May through September; November through December. 2. An interview with the laboratory coordinator, in a conference room, on 9/4/2019, at approximately 2:00 p.m, confirmed the aforementioned lack of maintenance documentation for the Horiba Hematology analyzer.
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 quality control (QC) document review and staff interview, the laboratory failed to monitor over time the accuracy and precision of test performance as required. Findings include: 1. Horiba hematology analyzer QC document review revealed there were no Levey-Jennings charts available at the time of survey for 2017 (June through December). 2. Hemochron coagulation analyzer QC document review revealed there were no Levey-Jennings charts available at the time of survey for 2019 thus far. 2. An interview, in a conference room, on 9/4/2019, with the laboratory coordinator, at approximately 2:00 p.m. confirmed the aforementioned lack of Levey-Jennings charts for 2017 and 2019.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP), the laboratory director (LD) failed to ensure policies and procedures were established for monitoring individuals who conduct all phases of laboratory testing as required. Findings include: 1. SOP review revealed the lack of a six-month competency policy and procedure for testing personnel. 2. An interview with the laboratory coordinator in a conference room on 9/4/2019 at approximately 2:00 p.m. confirmed the lack of a six-month competency policy and procedure for testing personnel in the laboratory SOP.