Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2130214	12/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
University Cancer & Blood Center, Llc - Covington	4182 Hwy 278 Ne, Covington, 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 December 11, 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:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) documents and staff interview, the laboratory failed to ensure PT samples were examined by testing personnel (TP) who routinely perform moderate-complexity testing in the laboratory as required. Findings include: 1. American Proficiency Institute (API) PT document review revealed Staff #4 (CMS 209) performed all testing of PT samples for Hematology/Coagulation 2018 PT events (1, 2, and 3). 2. An interview with the technical consultant in the front office area on 12/11/2019 at approximately 1:00 p.m. confirmed the aforementioned lack of TP rotation for the 2018 Hematology/Coagulation PT events.
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 review of hematology analyzer documents and staff interview, the laboratory failed to perform required validation of the performance specifications of the hematology analyzer after moving the instrument. Findings include: 1. Sysmex XP-300 document review revealed instrument validation was not performed after the instrument was moved in November of 2019. 2. An interview with the technical consultant in the front office area on 12/11/2019 at approximately 1:00 p.m. confirmed the lack of Sysmex validation in November of 2019 after moving the instrument.