Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2023996	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	4730 Puddledock Road - Suite 100, Prince George, VA	

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	An announced CLIA Recertification survey was conducted at the Laboratory Corporation of America Holdings on 12/16/21 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), quality control (QC) records, lack of documentation, patient records and interview, the lab failed to follow the established policy of performing three levels of Complete Blood Count (CBC) QC materials on 06/07/21 reporting 27 patients. Findings include: 1. Review of P&P revealed the following statement, "Sysmex XS-1000iC Quality Control" "Frequency of Controls Use and Review: Three levels of Sysmex e-Check Whole Blood Controls must be run at the beginning of each shift before patient's samples are tested." 2. Review of daily QC records from 10/01/19 up to 12/16/21 for the Sysmex XS 1000iC hematology analyzer revealed lack of documentation of the performance of three levels of the e-Check QC materials on 06/07/21. 3. Review of the ONCO electronic medical record (EMR) revealed 27 patient CBCs assayed and reported on 06/07/21. 4. An exit interview with the technical supervisor on 12/16/21 at approximately 12:00 PM confirmed the findings.