Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0967342	04/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	6130 Harbourside Centre Loop - Suite 101, Midlothian, 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 04/25/23 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 quality control records (QC), policy and procedures (P&P), lack of documentation, daily patient testing logs and interview, the lab failed to follow the established P&P ensuring QC levels were within acceptable range and corrective actions documented on 03/31/22 for the Alanine Aminotransferase (ALT) analyte prior to reporting 22 patients. Dates of record review include 07/01/21 up to date of survey on 04/25/23. Findings include: 1. Review of the daily QC records for the Roche Cobas Integra Plus 400 chemistry analyzer revealed that on 03/31/22, the BioRad Liquicheck Unassayed Chemistry Control Level 1 (L1) was out of acceptable range (Level 2 was within acceptable range) for the ALT analyte. In addition, there was lack of documentation of a rerun of the L1 ALT assay. 2. Review of the P&P, "Alanine Aminotransferase (ALT)" revealed the following statements, "Quality Control, if control results are out of the specified acceptable ranges, corrective actions must be performed and documented pursuant to the laboratory's quantitative and Qualitative Control Procedure. Patient test results may not be reported until successful

	corrective actions have been completed and documented." The inspector requested the corrective action documentation according to the P&P. The documentation was not available for review. 3. Review of the daily patient testing logs via electronic medical record (EMR) revealed that ALT results were reported for 22 patients on 03/31/22. 4. An exit interview with the technical supervisor on 04/25/23 at 1445 confirmed the findings.