Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2042736	05/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	1918 Randolph Road, Suite #670, Charlotte, NC	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the TC(technical consultant) 5/10/22, the laboratory failed to discard control materials that had exceeded the expiration date. Findings: During tour of the laboratory at approximately 1:35pm., the surveyor observed the Surevue hCG(human chorionic gonadotropin) serum control set, lot #104211 that had expired 4/30/22, located in the laboratory refrigerator and available for use. At approximately 1:40pm, the TC confirmed the quality control material was expired.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and review of 2020 and 2021 QC(quality control) and patient records 5/10/22, the laboratory failed to perform and document Serum hCG(human chorionic gonadotropin) QC each day of patient

	testing. Findings: The laboratory's "Serum Pregnancy Test" procedure states, "..A positive serum control and a negative serum control must be tested each day patient results are tested. Quality control results must be documented and shown to be within established limits of acceptability before patient samples may be reported..." Review of 2020 and 2021 Serum hCG QC and patient log revealed positive and negative controls were not performed for 3 days in September 2021 when patients were tested: a. 9/27/21- 1 patient tested(MRN# 50386716); b. 9/28/21- 1 patient tested(MRN# 53519890); c. 9/29/21- 1 patient tested(MRN# 70572740).