Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1060629	05/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	1133 College Ave, Bldg E, Suite 250, Manhattan, KS	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A review of documentation for manual calculation reveal the laboratory failed to periodically verify the accuracy of the International Normalized Ratio (INR) and interview with staff. Finding were as follows: a. At the time of the survey the laboratory failed to produce documentation for the calculation for INR this was confirmed in interview with the Technical Consultant from the CMS form 209 on May 1, 2018 at 10:00 in the office of the Technical Consultant. A review of Citrol coagulation control package inserts and interview with staff revealed the laboratory failed to follow the manufactuer's instructions. Findings were as follows: a. Siemens Dade Ci-Trol coagulation Control Level 1 and Level 3 package insert preparation of the control instructions state, "Add exactly 1 mL of distilled water." b. Interview with Technical Consultant from the CMS form 209 on May 1, 2018 at 09:05 confirmed Ci-Trol controls were prepared using Fisher deionized water, lot 173847. Therefore, the accuracy of the quality control can not be verified.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A review of Temperature and humidity logs and interview with staff revealed the laboratory failed to meet the humidity requirements for the laboratory as the Sysmex XS-1000i hematology analyzer and Sysmex CA-540 coagulation analyzer requires. Findings were as follows: 1. Based upon review of manufacture's operator guide for the Sysmex XS-1000i hematology analyzer, the laboratory failed to meet the humidity requirement of 30% to 85% for the months of January, February, March, and April 2018. 2. Based upon review of manufacture's operator guide for the Sysmex CA-540 coagulation analyzer, the laboratory failed to meet the humidity requirement of 30% to 85% for the months of January, February, March, and April 2018. 3. The documented humidity readings were at or below 25% for January, February, March, and April 2018 and confirmed by Technical Consultant #2 from the CMS 209 form on 05/01/2018 at 10:00 a.m.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with Technical Consultant from the CMS 209 05 /01//2018 at 9:30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).