Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2179713	08/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	2955 Brownwood Blvd Ste 110, The Villages, FL	

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 Laboratory Corporation of America on 08/10/2022 - 08/24/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5400- Analytic Systems 493.1250
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with the Technical Supervisor, the laboratory failed to ensure Citrate tubes were spun down per the manufacturer's instructions (See D5411) and failed to record temperatures per the "Operator's Maintenance Checklist" (See D5413) from November of 2020 through August of 2022 on the Sysmex CA-600 Coagulation analyzer.
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: Based on observation, interview with the Technical Supervisor, and record review, the laboratory failed to spin Citrate Tubes per the manufacturer's instructions (MI) for Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) testing for 742 Patients ran from November of 2020 through August of 2022. Findings Included: Review of the MI for the Sysmex CA-600 series coagulation analyzer revealed that to prepare the plasma samples for testing: "2. Centrifuge the blood tube directly after blood collection for 15 minutes at 1500 x g [force] to 2500 x g [force]. Please refer to CLSI [Clinical and Laboratory Standards Institute] guidelines H21-A5 [Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays] for further details." Review of the CLSI guidelines H21-A5 states "To obtain a plasma sample, centrifuge the capped specimen tube at a speed and time required to consistently produce platelet-poor plasma." Observations on 09/10/2022 at 10:00 AM revealed that the laboratory was spinning Citrate Tubes for 10 minutes at 3500 RPM (rotations per minute). Review of MI of the Citrate tubes revealed that the tubes should be ran for 15 minutes at 1500 RCF (relative centrifugal force), which is equal to 3881 RPM. The MI also revealed, "Citrate tubes should be centrifuged at a speed and time to consistently produce platelet-poor plasma." During an interview on 08/10/2022 at 2:30 PM, the Technical Supervisor confirmed that the laboratory was not spinning the Citrate Tubes per the MI, and they were not doing the platelet poor plasma testing to ensure that the plasma specimens for PT and PTT were platelet poor.
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: Based on record review and interview with the Technical Supervisor, the laboratory failed to record the temperatures on the Sysmex CA-600 Coagulation instrument from November of 2020 (11/2020) through August of 2022 (08/2022). Findings Included: Review of the laboratory's "Sysmex CA-600 Operator's Maintenance Checklist" from 11/2020 to 08/2022 revealed that no temperatures were recorded. The maintenance checklist stated that the following temperatures (cooler, detector, probe, and room temperatures) should be checked every day of testing. Review of the temperature section on the maintenance checklists revealed only check marks were documented, and no record of the actual temperature was documented on 458 days out of 458 days of testing from 11/2020 to 08/2022. On 08/10/2022 at 2:30 PM, the Technical Supervisor confirmed that they were not recording the actual temperatures on the maintenance checklist.