Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0872152	(X3) Date Survey Completed 07/02/2019
Name of Provider or Supplier Laboratory Corporation Of America Holdings	**Street Address, City, State** 1771 Madison Avenue, Lakewood, NJ	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Sysmex Procedure Manual (SPM), Final Report (FR) and interview with the Laboratory Director (LD), the laboratory failed to follow the Sysmex XS-1000i procedure for Hematology tests from 1/8/18 to the date of the survey. The finding includes: 1. The SPM stated White Blood Cell (WBC) counts > 100,000 may cause turbidity and increase the hemoglobin but there was no comment on the FR for WBC counts > 100,000 stating this. 2. Patient ID 1627670016-0 run on 6/11/19 had a WBC result of 124.5 x 10(3)/uL but there was no comment reported on the FR. 3. The LD confirmed on 7/2/19 at 2:40 pm that the laboratory did not follow the SPM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by:

	Based on surveyor review of Manufactures Package Insert, observation of the Quality Control material, and interview with the General Supervisor (GS), the laboratory failed to put open and new expiration dates on Coagulation Control vials used on the Sysmex 620 on the date of the survey. The GS confirmed on 7/2/19 at 2:30 pm the laboratory failed to put open and expiration dates on the control vials.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR), work records and interview with the Laboratory Director (LD), the laboratory failed to ensure test results were transcribed accurately for Atypical Lymphocyte (AL) cells from 1/8/18 to the date of survey. The finding includes: 1. The number of AL observed was not reported on the FR. 2. The LD confirmed on 7/2/19 at 2:10 pm that the laboratory did not transcribe results accurately on the FR.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR) and interview with the Laboratory Director (LD), the laboratory failed to have a Reference Range (RR) for Manual Differential percentage results from 1/8/18 to the date of the survey. The LD confirmed on 7/2/19 at 2:00 pm that the above tests did not have a RR on the FR.