Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 14D2143592	**(X3) Date Survey Completed** 11/20/2019
Name of Provider or Supplier Laboratory Corporation Of America	**Street Address, City, State** 8915 W Golf Rd, Niles, IL	
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**
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of patients' test records and Quality Control (QC) records and interview with testing personnel #1; the laboratory failed to retain QC records documenting all analytic systems activities for its hematology testing as specified. Findings: 1. On November 20, 2019 at 2:30 PM the surveyor reviewed 5 patients' hematology test records from September 2018 through October 2019, along with corresponding QC records. 2. There were no manufacturer's assay information sheets available for the following QC lots: a. Lot 8184 b. Lot 9043 c. Lot 9155 3. On November 20, 2019 at 3:30 PM, testing person #1 confirmed the surveyor's findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless

	the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions and calibration records and interview with testing person #1; the laboratory failed to perform and document calibration verification procedures following the manufacturer's calibration verification instructions: Findings: 1. Sysmex (manufacturer) instructions reads as follows: "Sysmex calibration program is an assisted analyzer calibration in conjunction with the laboratory. The calibration program includes service adjustments not available to the end-user. Calibration of reportable parameters is verified by the laboratory by running quality control after the calibration." 2. Review of Calibration records dated December 14, 2018 revealed that there was no documentation to show the laboratory verified the calibration by running quality control after the calibration. 3. Sysmex worksheets for documenting calibration states, "Certificate of Calibration only valid with customer signature." 4. There was no signature to show that the laboratory validated the calibration performed December 14, 2018. 5. There was no documentation to show that the laboratory performed and documented calibration of its Sysmex hematology analyzer at least every 6 months in 2019. 6. On November 20, 2019 at 3:30 PM, testing person #1 confirmed the surveyor's findings.