Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1075276	(X3) Date Survey Completed 02/28/2024
Name of Provider or Supplier Laboratory Corporation Of America Holdings	**Street Address, City, State** 801 North Mur-Len, Suite 211, Olathe, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based upon a review of the laboratory procedures and interview with testing personnel (TP) #1 and the quality manager (QM), the laboratory failed to define by written procedure: corrective action to take when calibration and/or control results fail to meet the laboratory's criteria for acceptability that included the evaluation of all patient results since the last acceptable quality control (QC) and/or calibration to determine if previously reported patient results may have been adversely affected. Findings: 1. Review of the procedure for the Sysmex XS1000i hematology analyzer revealed no instruction to evaluate all patient results in the unacceptable test run and

	since the last acceptable QC or calibration. 2. The surveyor asked TP #1 what actions must be taken when QC and/or calibration is not acceptable. TP #1 response did not include the evaluation of previously released patient results. Interview with TP #1 occurred 2/28/24 at 11:05 a.m. 3. The surveyor asked the QM if the instructions for the evaluation of previously reported results since the last acceptable QC and/or calibration was provided in a different procedure. The QM stated she it was not. 4. Interview with the QM on 2/28/24 at 11:40 a.m. confirmed, the laboratory failed to define by written procedure: corrective action to take when calibration and/or control results fail to meet the laboratory's criteria for acceptability that included the evaluation of all patient results since the last acceptable quality control (QC) and/or calibration to determine if previously reported patient results may have been adversely affected.