Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D2294638	**(X3) Date Survey Completed** 07/16/2025
Name of Provider or Supplier Laboratory Corporation Of America	**Street Address, City, State** 11100 Hefner Pointe Dr, Ste A, Oklahoma City, OK	
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	The initial survey was performed on 07/16/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, laboratory manager, and laboratory quality assurance manager at the conclusion of the survey.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the hematology policy and procedure manual and interview with the laboratory director, the laboratory failed to have a complete written procedure for

	one of one procedure reviewed. Findings include: (1) On 07/16/2025 at 09:30 am, the laboratory director stated the following: (a) CBC (Complete Blood Count) testing was performed using the Sysmex XN-1000 analyzer; (b) Three levels of QC (quality control) materials were tested twice daily each day of patient testing; (c) Beyond Care Quality Monitor (BCQM) was used to set the target values and acceptability of quality control results. (2) A review of the procedure titled, "Sysmex XN-1000 - Automated Hematology Analyzer CBC/Diff" identified the procedure did not include the instructions for changing new lot numbers of quality control materials; (3) The findings were reviewed with the laboratory director who stated on 07/16/2025 at 11: 24 am, the CBC procedure had not included all of the required information.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director, the laboratory failed to label three of three containers with the lot numbers of the contents. Findings include: (1) On 07/16/2025 at 09:32 am, the laboratory director stated the laboratory stained peripheral blood smears to perform manual differential testing; (2) Observation on 07/16/2025 at 09:38 am identified three Coplin jars, appearing to contain materials used to stain peripheral blood smears had not been labeled with the lot numbers; (3) The findings were reviewed with the laboratory director who, on 07 /16/2025 at 09:40 am stated the Coplin jars contained staining materials had not been labeled with the lot numbers.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test method. Findings include: (1) On 07/16/2025 at 09:30 am, the laboratory director stated the laboratory began performing CBC (Complete Blood Count) testing using the Sysmex XN-1000 analyzer on 01/06/2025; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Hemoglobin - 0.0 - 24.6 g/dL (b) Hematocrit - 0.0 - 71.0% (3) Interview with the laboratory director on 07/16/2025 at 11:24 pm confirmed the laboratory was using the

	following manufacturer's reportable ranges: (a) Hemoglobin - 0.1 - 26.0 g/dL (b) Hematocrit - 0.0 - 75.0%