Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 19D2238389	**(X3) Date Survey Completed** 11/08/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	**Street Address, City, State** 7777 Hennessey Blvd, Ste 6000a, Baton Rouge, LA	
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	A Certification survey was performed at Laboratory Corporation of America Holdings, CLIA ID # 19D2238389, on November 8, 2023. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
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 on review of the laboratory's policies and interview with personnel, the laboratory failed to establish complete corrective action procedures for quality control (QC) failures for Chemistry testing. Findings: 1. Review of the laboratory's "Quality

	Control Policy" revealed the laboratory did not include detailed written procedures for QC corrective actions, to include, but not limited to criteria and process for disabling reagent packs. 2. In interview on November 8, 2023 at 2:20 pm, the Laboratory Director confirmed the laboratory's policies did not include written procedures for disabling of reagent packs.
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 observation by surveyor, review of calibration verification records, and interview with personnel, the laboratory failed to perform calibration verification procedures at least every six (6) months for the Architect c4000 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on November 8, 2023 at 9:28 am revealed the laboratory utilizes the Architect c4000 analyzer for Chemistry testing. 2. In interview on November 8, 2023 at 11:05 am, the Laboratory Director stated the laboratory performs calibration verifications for the Chemistry analyzer every six (6) months. 3. Review of the laboratory's calibration records revealed the laboratory did not have documentation of performance of calibration verifications for the following dates: December 2022 4. In further interview on November 8, 2023 at 11:05 am, the Laboratory Director stated there was a delay performing the calibration verification.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

	This STANDARD is not met as evidenced by: Based on observation by surveyor, review of records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5439.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.