Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	30D0087087	01/30/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of American Holdings	183 Rockingham Rd, Ste 1 East, Windham, NH	

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) (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 review of the laboratory's (lab) procedure manuals, linearity studies, and verification of performance specifications for ammonia and glycosylated hemoglobin A1c (HbA1c), and interview with the Chemistry Technical Consultant (TC1); the procedure manuals for ammonia and HbA1c failed to include the reportable ranges verified by the lab. Findings include: 1. Review on 1/29/2026 of the lab's procedures titled "Ammonia, Plasma" revealed on page 7, paragraph 3, instruction to "Refer to the laboratory's most recent linearity study for the current AMR." Review of the lab's

	procedure titled "Hemoglobin A1c" revealed on page 13, paragraph 7, instruction to "Refer to the laboratory's most recent linearity study for the current AMR". AMR is an abbreviation for analytic measurable range. 2. Review on 1/29/2026 of the lab's linearity summary chart titled "Roche C501 S/N 16Z1-15 Analytic Measurement Range, signed 5/22/2025, revealed the instrument manufacturer's analytic measurement range (AMR) was the same as the lab's reportable range. The lab's in use reportable ranges were defined as: Ammonia: 17.0 - 1703 ug/dL HbA1c: 4.2 - 20.1 % 3. Review on 1/29/2026 of the lab's verification of performance specifications for ammonia and HbA1C revealed the lab conducted testing in December 2024 and the Laboratory Director signed off on the verification on 1/28/2025 for HbA1c and 1/30 /2025 for ammonia. The lab verified the following reportable ranges: Ammonia: 23.77 - 1393.73 ug/dL HbA1c: 4.26 - 17.75 % 4. Interview on 1/29/2026 at 11:45 a.m. with TC1 confirmed the reportable ranges in the procedure manuals for ammonia and HbA1c were in use by the lab and were not verified by the lab during the verification of performance specifications.