Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0705479	10/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corp Of America Holdings	119 Mountain View Road, Mars Hill, NC	

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
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 2020 and 2021 chemistry calibration records and calibration verification records, and interview with General Supervisor (GS) 10/6/21, the laboratory failed to perform 1 of 2 calibration verifications every 6 months as required. Findings: The laboratory began testing on the Integra 400+ chemistry analyzer in June of 2020. 1. Review of 2020 and 2021 chemistry calibration records revealed the laboratory performs 2 point calibrations on all analytes tested on the

	Integra 400+ chemistry analyzer. 2. Review of 2020 and 2021 chemistry calibration verification records revealed the laboratory performed 3 point calibration verifications for all analytes in December of 2020. The laboratory failed to perform the 3 point calibration verifications due in June of 2021. The calibration verifications were not performed until 9/12/21, approximately 3 months later. 3. Interview with GS at approximately 2:30 p.m. confirmed the laboratory failed to perform 3 point calibration verifications every 6 months as required. She stated the calibration verifications due in June of 2021 had been overlooked until September.