Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1054938	10/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	7447 Talcott Ave, Ste 1, Chicago, IL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with the technical supervisor (TS); the laboratory failed to attest to the routine integration of PT samples into the patient workload for 2 of 12 PT events reviewed, starting in 2023 through 2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Proficiency Testing Policy", which stated, "14. The proficiency testing attestation statement is signed by the laboratory director or designee and the individual performing the testing." 2. Review of API PT records revealed that the laboratory director and testing personnel failed to sign the attestation statement for testing in routine chemistry for one of six events reviewed in the years of 2023 through 2025. Event: Year: 3 2025 3. Review of API PT records revealed that the laboratory director failed to sign the attestation statement for testing in Hematology for one of six events reviewed in the years of 2023 through 2025. Event: Year: 3 2023 4. Interview with the TS on 10/08/2025, at 11:20 am, confirmed the laboratory failed to attest to the routine integration of PT samples into the patient workload for one of six PT events reviewed for chemistry and one of six PT events reviewed for hematology testing in the years of 2023 and 2025.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the

	manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, review of quality control (QC) results and interview with the technical supervisor (TS), the laboratory failed to maintain control procedures to monitor quality control testing on the integra 400 plus for one of six patient testing dates reviewed. Findings include: 1. Review of the laboratory policy and procedure manual identified the policy, "Creatinine plus ver 2.0", under the section titled "quality control", which stated the following "If control results are out of the specified acceptable ranges, corrective actions must be performed and documented pursuant to the laboratory's quantitative and qualitative quality control procedure. Patient test results may not be reported until successful corrective actions have been completed and documented." 2. Review of QC testing on the integra 400 plus on 01-06-2025 revealed that the results for aspartate aminotransferase (AST), Calcium, Creatine, and Glucose were not within the specified acceptable ranges documented by the laboratory prior to the release of patient test results. Analyte - QC result - Labs acceptable range 1. L3 AST- 205 IU/L - (184-204) 2. L3 Creatinine - 5.69 mg/dL - (5.2-5.5) 3. L3 Glucose - 289.97 mg/dL - (274 - 286) 4. L1 Calcium - 8.96 mg/dL - (8.48 - 8.92) 5. L1 Creatinine - 0.917 mg/dL - (0.82 - 0.9) 3. Interview with the TS on 10-8-2025, at 03:20 pm, confirmed the laboratory failed to ensure that QC results for testing on the integra 400 plus were acceptable prior to the release of patient test results for testing completed on 01-06-25.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of employee competency assessments and interview with the technical supervisor (TS); the laboratory failed to have competency assessments performed semiannually for one of three new testing personnel (TP) responsible for high complexity testing during their first year of patient testing. Findings include: 1. Review of employee competency assessments revealed that one of three new TP (TP #4) failed to have competency assessments performed semiannually as required in their first year of testing patient specimens. 2. An interview with the TS at 9:00 am on 10-8-2025 confirmed that TP #4 failed to have competency assessments performed semiannually as required in their first year of testing patient samples.