

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2009357	(X3) Date Survey Completed 12/27/2024
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 663 Lanier Park Drive, Gainesville, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 27, 2024. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) proficiency testing (PT) documents and staff interview in the specialty of Hematology, the laboratory failed to verify the accuracy of a non-regulated analyte by successfully passing two(2) (PT) events in 2024. Findings: 1.) Review of 2024 (API) (PT) documents revealed in the specialty of Hematology, the laboratory received a score of 20% for RDW-CV (Hem - 5S)/ 20%RDW-SD (Hem - 5S) in event #1 and a 0% score of the same analytes in event #2 of 2024 resulting in "Unsuccessful" notation by PT agency. 2.) An interview with the technical consultant (TC) (TP #2 CMS 209) on 12/27/2024 at approximately 1:00 PM confirmed the above findings and indicated that corrective action was done and event #3 had a 100% score.</p>