

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2195226	(X3) Date Survey Completed 02/08/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 15 Corporate Dr, Ste 2-2, Trumbull, CT	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure daily quality control (QC) was performed and acceptable prior to reporting patient test results for the qualitative detection of human chorionic gonadotropin (hCG) in the subspecialty of endocrinology. Findings include: 1. Record review on 2/8/2023 of the laboratory's 'Stat Lab Serum Qualitative BhCG Quality Control and Patient Log' for June 2022 through February 8, 2023, revealed the following: a. Positive and negative Sure-View hCG-Stat serum controls are utilized. b. Lack of documentation of positive QC results for 3 of 3 patient testing days, specifically, 6/30/2022, 12/12/2022, and 2/6/2023. c. Lack of documentation of negative QC results on 2/6/2023. d. Three patient results were reported on the above testing days. e. Director review and sign off with no corrective action for the lack of documentation of QC. 2. Staff interview on 2/8/2023 at 10:30 AM with the testing personnel #1(TP1) confirmed the above findings. TP1 further commented he/she did not perform QC on the above testing dates.</p>