Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2170095	(X3) Date Survey Completed 03/02/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	**Street Address, City, State** 1290 Summer St, Stamford, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow its written policies and procedures for lot-to-lot testing in the subspecialty of endocrinology Findings include: 1. Record review on 03/02/2023 of the 'STAT LAB TECHNICAL MANUAL' revealed 'to verify that new lots of Sure-Vue hCG Stat cartridges and/or Sure-Vue hCG Stat Serum Controls perform as expected prior to using the new lot for patient testing'. 2. Record review on 03/02/2023 of the 'Quality Control and Patient Log' revealed lack of documentation for lot-to-lot verification for the following lot number of hCG quality controls (QC) in use: a. Sure-Vue serum QC lot number 209121. b. Sure-Vue serum QC lot number 109201. 3. Staff interview on 03/02/2023 at 10:30 AM with the laboratory director confirmed the above findings and further commented that he/she was aware that lot to lot verification was not performed. 4. The laboratory performs 2 tests annually in the subspecialty of endocrinology.