

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D2169461	<b>(X3) Date Survey Completed</b> 03/01/2023
<b>Name of Provider or Supplier</b> Laboratory Corporation Of America Holdings	<b>Street Address, City, State</b> 67 Sandpit Rd, Danbury, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>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.</p> <p>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 quality control performance in the subspecialty of endocrinology. Findings include: 1. Record review on 03/01/2023 of the 'Pregnancy Test, Serum' standard operating procedure quality control section revealed 'testing personnel should perform quality control testing weekly in order to maintain competency'. 2. Record review on 03/01/2023 of the 'quality control and patient log' revealed lack of weekly quality control performance for the month of March, April, June, July, and August of 2021. 3. Staff interview on 03/01/2023 at 10:55 AM with the laboratory director confirmed the above findings. 4. The laboratory performs 2 tests annually in the subspecialty of endocrinology.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, the laboratory failed to follow manufacturer's instructions for specimen storage for human chorionic gonadotropin (HCG) test in the subspecialty of endocrinology. Findings include: 1. Record review on 03/01/2023 of the 'Sure-Vue Serum/Urine hCG-STAT' manufacturer package insert revealed specimen storage requirement at 2 - 8 degrees Celsius for up to 48 hours. 2. Record review on 03/01/2023 of the 'Pregnancy Test, Serum' standard operating procedure specimen requirements section revealed storage requirement at 2 - 8 degrees Celsius for up to 14 days. 3. Record review on 03/01/2023 of the 'On-Site Validation Sure-Vue Stat Qualitative Serum hCG' revealed lack of specimen storage /stability validation for up to 14 days. 4. Staff interview on 03/01/2023 at 10:30 AM with the laboratory director confirmed the above findings and further commented that the storage/stability validation was performed at another laboratory. 5. The laboratory performs 2 tests annually in the subspecialty of endocrinology.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to evaluate testing personnel competency to perform and report accurate test results in the subspecialty of endocrinology. Findings include: 1. Record review on 03/01/2023 of the laboratory's CMS 209 form revealed 2 testing personal (TP) employed to perform human chorionic gonadotropin (HCG) test. 2. Record review on 03/01/2023 of the 'STAT LAB OPERATIONS MANUAL' competency assessment binder revealed lack of annual competency assessment for 1 of 2 TP in the year of 2022. 3. Staff interview on 03/01/2023 at 10:06 AM with the laboratory director confirmed the above findings. 4. The laboratory performs 2 tests annually in the subspecialty of endocrinology.