

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2169461	(X3) Date Survey Completed 06/21/2021
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow its policy to assess the competency of all laboratory personnel. Findings include: 1. Review of the laboratory's personnel competency records on 6/21/21 revealed the following: a. The laboratory did not follow the policy in place to assess the competency of the clinical consultant and the technical consultant. b. The laboratory did not have competency documentation for the above laboratory personnel. c. An electronic record of the consultant(s) competency policy revealed they need to be assessed as required. 2. Staff interview with the laboratory director on 6/21/21 at 11:10 AM confirmed the laboratory did not follow its policy in place to assess the competency of the above laboratory personnel and they were not assessed or documented.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document annual competency of testing personnel (TP) to assess the knowledge and skills necessary to</p>

perform moderate complexity laboratory testing. Findings include: 1. Training and competency record review on 6/21/21 revealed the laboratory did not have annual competency documentation for 3 of 4 TP performing moderate complexity tests for 2019 and 2020. 2. Staff interview with the laboratory director (LD) on 6/21/21 at 11:00 AM confirmed the above finding. The LD further stated it is difficult to perform TP competency assessments as the TP are working at multiple locations. 3. The laboratory performs 2 moderate complexity tests per year in the sub-specialty of Endocrinology.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to ensure personnel performing moderate complexity testing had documentation of training appropriate for the testing performed prior to analyzing patient specimens. Findings include: 1. Record review of the testing personnel (TP) training documentation on 6/21/21 revealed the laboratory did not have training documentation for TP#4 performing moderate complexity testing. 2. Record review of the patient test records and proficiency testing (PT) records on 6/21/21 revealed TP#4 was testing patient samples and PT samples from 2019. 3. Staff interview with the laboratory director (LD) on 6/21/21 at 11:30 AM confirmed the above findings. The LD further stated training records for TP#4 were misplaced and not available for review.