

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1071092	(X3) Date Survey Completed 10/30/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 1803 S Ridgeview, Suite 100, Olathe, KS	
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
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the CMS 209 personnel form, lack of testing personnel (TP) competency documentation and interview with the site manager, the technical consultant (TC) failed to evaluate and document competency on one of seven moderate complexity TP for 2023. Findings: 1. Request was made for annual competency documentation for TP #5 which was due for completion on 7/26/23. No documentation of the annual competency assessment for TP #5 was made available at the time of survey. 2. Interview with site manager on 10/30/23 at 10:35 a.m. confirmed, the TC failed to evaluate and document competency on one of seven moderate complexity testing personnel for 2023.</p>
D6053	<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 semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS 209 personnel form, TP competency, and interview with the site manager, the TC failed to evaluate by direct observation at least semiannually during the first year the individual tests patient specimens for one of one TP.</p>

Findings: 1. Review of the site's CMS for 209 for personnel revealed four new testing personnel since last survey of which only one had been working more than six months: TP #5. 2. Review of the six month competency records for TP #5 revealed the evaluation was performed on 1/26/23. The signature of the TC was made on 2/9/23. No documentation of direct observation by the TC of routine patient test performance and performance of instrument maintenance was present on the competency. 3. Interview with the site manager on 10/30/23 at 10:35 a.m. confirmed, TC failed to evaluate by direct observation at least semiannually during the first year the individual tests patient specimens for one of one TP.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of the CMS 209 form, personnel records, and interview with the site manager, the laboratory failed to have educational credentials required to qualify one of seven TP to perform moderate complexity testing prior to reporting patient results (refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on the review of the CMS 209 form, lack of educational credentials, and interview with the site manager, the laboratory failed to have the educational credentials to qualify one of seven TP to perform moderate complexity laboratory testing prior to reporting patient results. Findings: 1. The CMS 209 form provided at survey listed seven moderate complexity TP. 2. No documentation of educational credentials for TP #7 was available for review at the time of survey. 3. TP #7 worked from 5/2022 to 8/2022. 4. Request was made for patient test results released by TP #7. The site manager and TP #1 were unable to provide documentation that TP #7 did or did not perform patient testing as their electronic documents that contained this information had a current 90 day look back storage. Records did show that TP #7 performed quality control and proficiency sample testing. TP #7's training records revealed patient test results. 5. Interview with the site manager on 10/30/23 at 11:35 a.

m. confirmed the laboratory failed to have the educational credentials to qualify one of seven TP to perform moderate complexity laboratory testing prior to reporting patient results.