

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0967342	(X3) Date Survey Completed 05/08/2025
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 6130 Harbourside Centre Loop - Suite 101, Midlothian, VA	
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
D0000	An announced CLIA recertification survey was conducted at Laboratory Corporation of America on May 7-8, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies cited are as follows:
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for high 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 a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's personnel files, laboratory's policies and procedures, lack of documentation, and an interview, the Technical Supervisor (TS) failed to follow the established laboratory policy to perform a six month Hematology and Chemistry competency evaluations for three (3) of five (5) testing personnel in calendar year 2023 until the dates of the survey on May 7-8, 2025. The findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified one Technical Supervisor (TS), one General Supervisor and 5 testing personnel (TP) responsible for high complexity Hematology and Chemistry testing. 2. Review of the laboratory's policies and procedures revealed a policy, "Training and Competency Assessment Policy", with the following statement, "Competency...4. "For non-waived test systems, all the above six elements must be assessed following initial training, six months after initial training, then annually (unless any are not applicable to the test system)..." 3. Review of the laboratory's personnel files revealed TP C was hired on January 9, 2023 with an initial competency record completed on January 30, 2023. The surveyor requested to review a semi-annual competency</p>

assessment for TP C completed in July 2023. The laboratory provided competencies completed on December 11, 2023 and December 30, 2024. (See Personnel Code Sheet.) 4. Review of the laboratory's personnel files revealed TP D was hired on August 14, 2023 with an initial competency record for TP D completed on October 30, 2023. The surveyor request to review a semi-annual competency assessment for TP D completed in April 2024. The laboratory provided competencies completed on July 1, 2024 and December 5, 2024. (See Personnel Code Sheet.) 5. Review of the laboratory's personnel files revealed TP E was hired on April 24, 2023 with an initial competency record for TP E completed on July 28, 2023. The surveyor requested to review a semi-annual competency assessment for TP E completed in February 2024. The laboratory provided competencies completed on June 7, 2024 and December 5, 2024. (See Personnel Code Sheet.) 6. In an exit interview with the Technical Supervisor on May 8, 2025 at 9:00 AM, the above findings were confirmed.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory's personnel files, laboratory's policies and procedures, lack of documentation, and interview, the technical supervisor (TS) failed to follow their established policy and perform annual competency assessment evaluations for one (1) of five (5) testing personnel responsible performing high complexity Hematology and Chemistry testing in calendar year 2023. The findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified one Technical Supervisor, one General Supervisor and five testing personnel (TP) responsible for high complexity Hematology and Chemistry testing. 2. Review of the laboratory's personnel files revealed TP B was hired on May 23, 2022 with an initial competency record for TP B completed on June 14, 2022 and semi-annual competency performed on November 4, 2022. The surveyor requested to review an annual competency assessment for TP B completed in 2023. The laboratory provided competencies completed on January 12, 2024 and December 30, 2024 for review. (See Personnel Code Sheet.) 3. Review of the laboratory's policies and procedures revealed a policy, "Training and Competency Assessment Policy", with the following statement, "Competency...4. "For non-waived test systems, all the above six elements must be assessed following initial training, six months after initial training, then annually (unless any are not applicable to the test system)..." 4. In an exit interview with the Technical Supervisor on May 8, 2025 at 9:00 AM, the above findings were confirmed.