

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2028103	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 7 McDowell Street, Suite 300, Asheville, NC	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of manufacturers' instructions, review of the laboratory's 2024 and 2025 temperature logs, and interview with the TS (technical supervisor) 7/22/25, the laboratory failed to define an acceptable freezer temperature range for storage of the VALIDATE linearity material and failed to ensure freezer temperatures were within manufacturer's specified acceptable limits for storage of the VALIDATE linearity material. Findings: During a tour of the laboratory at approximately 1:00 p.m., the surveyor observed VALIDATE linearity material (examples: GC1 Test Set, Fertility 1 and 2 Test Sets, GC3 Test Set, GC4 Test Set) stored with BIO-RAD Liquichek quality control material (examples: Liquichek Unassayed Chemistry Control Level 1 and Level 2, Liquichek Pediatric Control Level 2) in a small white freezer in the chemistry area. Review of manufacturer's instructions for the VALIDATE GC1 Calibration Verification / Linearity Test Kit revealed "... STORAGE AND STABILITY The VALIDATE GC1 Calibration Verification / Linearity Test Kit is stored at -10 to -25 degrees C (Celsius). ... Test kits are stable until the expiration date printed on the bottle and storage container when handled according to instructions. ..." Review of manufacturer's instructions for the BIO-RAD Liquichek Immunoassay Plus Control Levels 1, 2 and 3 revealed</p>

STORAGE AND STABILITY This product will be stable until the expiration date when stored unopened at -20 to -70 degrees C. ..." Review of the laboratory's 2024 and 2025 temperature logs revealed an acceptable freezer temperature range of -20 to -70 degrees C which was not consistent with the manufacturer's specified range of -10 to -25 degrees C for storage of the VALIDATE linearity material. Documented freezer temperatures were outside the manufacturer's specified range of -10 to -25 degrees C for 193 of 208 days of testing from 1/1/24 to 10/31/24 and 150 of 173 days of testing from 12/1/24 to 7/22/25: 1. January 2024 - 22 of 23 days 2. February 2024 - 21 of 21 days 3. March 2024 - 21 of 21 days 4. April 2024 - 18 of 22 days 5. May 2024 - 19 of 22 days 6. June 2024 - 20 of 20 days 7. July 2024 - 21 of 22 days 8. August 2024 - 21 of 22 days 9. September 2024 - 18 of 18 days 10. October 2024 - 12 of 17 days 11. November 2024 - temperature logs missing 12. December 2024 - 19 of 21 days 13. January 2025 - 23 of 27 days 14. February 2025 - 19 of 20 days 15. March 2025 - 21 of 21 days 16. April 2025 - 21 of 27 days 17. May 2025 - 19 of 21 days 18. June 2025 - 18 of 21 days 19. July 2025 - 11 of 15 days. During interview at approximately 1:40 p.m., the TS confirmed that freezer temperatures were frequently outside the acceptable limits for storage of the VALIDATE linearity material during 2024 and 2025. The TS stated they were unable to locate the temperature logs for November 2024.