

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2266935	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 4401 Wornall Road, Rm B428, Kansas City, MO	
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>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of the policy manual, lack of humidity logs, and interview with the general supervisor (GS) #2, the laboratory failed to follow procedure for monitoring and documenting humidity. Findings: 1. Review of the Humidity Monitoring procedure states, "the monitoring of humidity is required to ensure appropriate storage conditions for specimens and reagents and the proper operating conditions for instruments in the laboratory." 2. Lack of humidity logs confirmed no documentation of humidity September 2022, and to date April 26, 2023 in the specimen processing room housing the cryostats. 4. Interview with the GS #2 on April 26, 2023 at 12:00 PM confirmed the laboratory failed to follow procedure for monitoring and documenting humidity.</p>