

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2289400	(X3) Date Survey Completed 12/09/2025
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 10310 West Markham Suite 195, Little Rock, AR	
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 a review of 2025 temperature and humidity records, laboratory instrumentation manuals, and interview with laboratory staff, the laboratory failed to document daily humidity in one of three rooms. Survey findings include: A. A review of laboratory instrumentation manuals revealed performance specifications of a maximum of 80% relative humidity for the Hologic ThinPrep Imaging System Workstation and 90% for the Hologic ThinPrep Imaging System Imaging Station (ThinPrep Imaging System Technical Information Reference Guide, MAN-02144, Rev. 008). B. Through a review of temperature and humidity records for 2025 it was revealed the laboratory failed to document humidity on one (of three) ThinPrep stations for 12 of 12 months for 2025 C. In an interview, at 09:39am on 12/9/2025, the General Supervisor (as listed on entrance/exit interview form) confirmed the laboratory humidities were not documented on days the laboratory was in operation.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for</p>

high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Through a review of personnel files, lack of documentation, and interviews with laboratory staff, it was determined the general supervisor failed to be evaluated for competency at least semiannually in the first year of testing. Survey findings follow:

A. A review of General Supervisor records revealed that the Laboratory Directory, listed on the form CMS-209, had other personnel approval within the employee training documented "AP Competency - Supervisor/Manager 2025". No competency evaluation performed by the current Laboratory Directory. B. In an interview, at 1:09 p.m. on 12/9/2025, General Supervisor, as listed on the form CMS-209, confirmed the competency was not signed by the Laboratory Directory.