

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D0250796	(X3) Date Survey Completed 09/09/2026
Name of Provider or Supplier Labcorp Of America Holdings	Street Address, City, State 3825 Faber Place Drive, North Charleston, SC	
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 onsite CLIA recertification survey was conducted on September 9, 2026 at the laboratory of Laboratory Corporation of America of North Charleston. The laboratory was found to be out of compliance with conditions of participation for the Clinical Laboratory Improvement Amendments (CLIA) of 1988 found at 42 CFR Part 493 Listed below is the deficiency cited as a result of the 09/09/2026 recertification survey:
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i) (A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to document the twice annual accuracy assessment of the Laboratory Information System (LIS) for 2 out of 3 years reviewed (2024,2025,and 2026). Findings included: 1. A review of policy and procedure (Quality Management Plan), reveals the lack of requirement for twice annual accuracy assessment for the LIS. 2. Review of laboratory quality indicators reveals the laboratory lacks documentation of twice annual accuracy assessments of the LIS for the following years: a. 2025 - performed once on 7/9/2025 b. 2024 - performed once on 9/30/2024 3. In an interview with the General Supervisor (GS) on 09/09/2026 at 2:00pm in the laboratory conference room, the findings were confirmed.