

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0993817	(X3) Date Survey Completed 07/08/2025
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 3980 Colonnade Parkway, Birmingham, AL	
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
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on reviews of the American Proficiency Institute (API) Proficiency Testing (PT) records, PT failure investigation records and an interview with the Technical Consultant (TC), the laboratory failed to achieve successful PT evaluations for the pro B-type natriuretic peptide (proBNP), a regulated analyte. The surveyor noted two of the three consecutive testing events had unsuccessful performance from 2023-2024. The findings include: 1. 1. A review of the API PT records revealed the proBNP evaluation scores were unsuccessful for the following events: a) 2023 Chemistry Core Second Event, 20 percent b) 2024 Chemistry First Event, 40 percent 2. A review of the PT Failure (PTF) investigation records revealed the following. A) PTF 8900 date created, June 27, 2023, "QC had been trending high for BNP..." B) PTF 9589 date created, March 1, 2024, "Investigate on-going issue..."; "...instrument performance and pipetting concerns..."; "...calibration fail often..." 3. The TC confirmed the above findings during the exit conference on 07-08-2025 at 1:40 PM.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)</p>

Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on a review of the PathFast Cardiac Biomarker analyzer (PCB) Quality Control (QC) records and an interview with the Technical Consultant (TC), the laboratory failed to monitor the shifts and trends of test performance over time. The surveyor noted there was no documentation of Levey-Jennings (L-J) charts or peer group data comparisons for 19 of the 25 months reviewed from the date of the last survey, 05-13-2023, to the date of the current survey, 07-08-2025. The findings include: 1. A review of the PCB QC records revealed no evidence of L-J charts or peer group data comparisons were available for review for the following months. A) 2023 - July, August, September, November, and December B) 2024 - January through April, August through December C) 2025 - January through May 2. During the exit conference on 07-08-2025 at 1:40 PM, the TC confirmed the above findings.