

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 09D2028354	(X3) Date Survey Completed 08/13/2026
Name of Provider or Supplier Laboratory Corporation Of America	Street Address, City, State 2150 Pennsylvania Avenue Suite 1-123, Washington, DC	
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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of the laboratory's procedure, direct observation, and interview with Testing Personnel (TP) #6, the laboratory failed to follow its own written procedure for staining 1 of 1 slide for manual cell identification. Findings Include: a. A review of the laboratory's procedure "Specimen Confirmation-Slide Preparation Procedure" revealed "MANUAL SLIDE PREP ...Allow the smear to air-dry thoroughly before staining." b. On 08/13/2026 at 1:02 PM, patient slide 225-514-0030 for manual cell identification was observed in the laboratory drying on a heat block. c. During an interview on 08/13/2026 at 3:44 PM, TP #6, as listed on the CMS-209, confirmed staff dried the slide on the heat block.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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.

This STANDARD is not met as evidenced by:

Based on the laboratory's temperature records, manufacturer's instructions, and an interview with staff, the laboratory failed to ensure that supplies and equipment were stored and operated according to the manufacturer's instructions for 23 of 23 months (2024-2026). Findings Include: a. On 08/11/2026 at 09:03 AM and 3:31 PM, the following sampling of items were observed in laboratory room 1-122: 1. 6 cases, BD Vacutainer lavender top; lot number 6076404; manufacturer's storage requirements: 4C [degrees Celsius]-25C. 2. 1 Cobas Integra 400 plus; manufacturer's requirements "Environmental conditions ...ambient room temperature 15-32C ...Relative humidity (in operation) Maximum 80%...Minimum 20%". b. During an interview on 8/13/2026 at 3:13 PM, the phlebotomist provided documentation of the room temperature was recorded with the defined range as 18-25C. The phlebotomist stated that the documentation is not provided to laboratory staff for monitoring. c. During an interview on 8/13/2026 at 3:29 PM, Testing Personnel #6, as listed on the CMS-209, confirmed that the laboratory does not review the temperature documentation maintained by the phlebotomist, and the staff used the documentation for room 1-123 for both spaces.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of the laboratory's records, and an interview with Testing Personnel (TP) #6, the laboratory failed to document the evaluation of the manual cell identification and the automated white blood cell (WBC) differential on 2 of 2 occasions in 2025. Findings Include: a. During a laboratory tour on 08/13/2026 at 9:03 AM manual cell identification and automated WBC differential were observed. b. The laboratory was asked to provide records demonstrating the evaluation of the two methodologies, including criteria for acceptable differences in test values in 2025. No documentation was provided. c. During an interview on 08/13/2026 at 2:25 PM, TP #6, as listed on the CMS-209, stated the documentation could not be located. In an email sent 08/17/2026 at 3:31 PM, TP #6 confirmed that "Despite our efforts to locate the Manual Differential to Instrument Differential worksheets, we were unable to identify their current location."

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's records and an interview with Testing Personnel (TP) #6, the laboratory failed to evaluate 34 of 34 patient test results back to the last acceptable quality control (QC) when aspartate aminotransferase (AST) QC exceeded the laboratory's acceptable limits and the laboratory made test system adjustments. Findings Include: a. A review of the laboratory's QC records revealed on 08/12/2026 AST, level 2 QC, did not meet the laboratory's standards for acceptability and staff repeated it. b. A review of the laboratory's "Daily Out of Control Exception Report" revealed that on 08/12/2026 AST level 2 QC exceeded the laboratory's acceptable limits with a written note "Rerun QC after calibration". c. A review of the laboratory's "Corrective Action Log" revealed on 08/12/2026 AST level 2 QC exceeded the laboratory's acceptable limits and "Corrective Action & [and] Results ...Rerun QC after calibration" was documented. d. An interview with TP #6, as listed on the CMS-209, confirmed the last acceptable QC was performed on 08/11/2026, and the laboratory did not evaluate 34 patients tested for acceptability. e. A review of sampled patient test reports revealed the laboratory reported test results for the following patients: 22351400060; 223514000109; 223514000209; 223514000409; 223514000709.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's records, patient test reports, and an interview with Testing Personnel (TP) #6, the laboratory failed to ensure reference intervals were available for 1 of 7 hematology tests. Findings Include: a. A review of a sampling of complete blood count (CBC) patient reports revealed the laboratory reported the automated WBC differential percents reference interval as "Not Estab. [established]" for patient specimens 225-514-0004 and 225-514-0006. b. A review of the laboratory policy "Hematology Reference Intervals" revealed "Note: Differential Percents (5) for Normal Cells are not reported with a RI [reference interval]. This document is only to be used as a point of reference for the lab, regarding normal reference intervals for normal cell %s." c. During an interview on 08/13/2026 at 2:28 PM, TP #6, as listed on the CMS-209, confirmed the findings.