

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2157358	(X3) Date Survey Completed 07/18/2024
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 2500 Horton Boulevard, Wilson, NC	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies/procedures, absence of Centrifuge Maintenance standard operating procedure (SOP), review of 2021, 2022, 2023, and 2024 Centrifuge Maintenance Records, and interview with the technical consultant (TC) 07/18/2024, the laboratory failed to establish a protocol for Centrifuge Maintenance and the laboratory failed to perform and document revolutions per minute (RPM) checks and timer checks for Centrifuge Maintenance Records for 9 of 14 quarters from May 05, 2021 to July 18, 2024. Findings: Review of "Technical Standard Operating Procedures Table of Contents," revealed "...11. Centrifuge Maintenance SOP...", but no SOP available for review during the survey. The laboratory did not have a procedure for centrifuge maintenance that provided instructions for performing RPM and timer checks including the frequency and what to do if the checks were not acceptable. Review of 2021, 2022, 2023 and 2024 "Centrifuge Maintenance Records" logs revealed RPM and timer checks were to be performed quarterly. Review of 2021, 2022, 2023, and 2024 "Centrifuge Maintenance Records" logs revealed the checks were not performed for: 1. 2021 (May 05 to December 31) - 2 of 3 quarters 2. 2022 - 3 of 4 quarters 3. 2023 - 3 of 4 quarters 4. 2024 (January 01 to July 18) - 1 of 3 quarters During interview with TC at approximately 12:15 p.m., TC stated she is the</p>

only person that performs quarterly timer checks and RPM checks. TC stated she was aware items were missed.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, various quality and maintenance log reviews, and interview with technical consultant (TC) 07/18/2024, testing personnel (TP) failed to follow laboratory policy for making changes to laboratory records. Findings: Review of 2021 (May 05 to December 31), 2022, 2023, and 2024 (January 01 to July 18) laboratory logs revealed TP failed to follow the "Correction of Laboratory Records" policy. Examples: 1. On the August - September 2021 "Patient Services Temperature Monitoring Log," room temperature on 08/10/2021 and refrigerator temperature on 09/07/2021 were written over instead of crossed out and re-written. 2. April 02 to April 04, 2021 "Facility/Department Disinfection Schedule," the daily disinfection original data is not legible. 3. Week 5 of JUN 2022 "Centrifuge Maintenance Record" log has more than a single line through the correct data. 4. Week 5 of NOV 2023 "Centrifuge Maintenance Record" log does not have the correct information written next to or above the crossed out data. 5. On the 2024 "Centrifuge Maintenance Record," the year 2024 was written over instead of crossed out and re-written. 6. On March 25, 2024, "Freezer Temperature Range..." log, original data entry is not visible. 7. On the April 2024 "Ambient Temperature Range..." log, date entered for "Thermometer Calibration Exp. Date..." was written over instead of crossed out and re-written. During interview with TC at approximately 2:39 p.m., the TC confirmed that testing personnel failed to follow the "Correction of Laboratory Records" policy. She stated nonblack and blue ink, different colors have been used on lab records. Write overs have been used on records too, and she's told staff not to do this.