

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0655059	(X3) Date Survey Completed 12/07/2021
Name of Provider or Supplier Laboratory Corporation Of America Holdings, Inc	Street Address, City, State 1447 York Court, Burlington, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of specimen logs, review of patient test report (TTD-02, specimen ID #083-125-0007-0), and interview with the AVP - Quality Director 12/7/21, the laboratory received and tested a proficiency sample from a sister facility for Lyme IgG /IgM Line Blot testing. Review of specimen logs and patient test report (TTD-02, specimen ID #083-125-0007-0) revealed the laboratory tested a proficiency sample transferred from a sister laboratory for Lyme IgG/IgM Line Blot testing. The proficiency sample TTD-02 was submitted as a patient specimen with a partial name, and the laboratory failed to recognize the specimen as a proficiency sample. The proficiency sample was tested by the laboratory and the results were reported 4/1/21 (see D2013).</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p> <p>The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally</p>

referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on review of policies and procedures, review of specimen logs, review of patient test report (TTD-02, specimen ID #083-125-0007-0), review of 2021 CAP (College of American Pathologists) proficiency testing records, and interview with the AVP - Quality Director 12/7/21, the laboratory received and tested a proficiency sample from a sister laboratory. Findings: The "Proficiency Testing Policy" (Document Number: LC-BN-QA-CORP-DOC-0012 Revision: 5, effective 7/22/20) states on page 4 "21. Interlaboratory communication about proficiency testing samples is prohibited until after the deadline for submission of data to the PT provider. 22. Proficiency testing specimens are prohibited from referral to another laboratory or acceptance from another laboratory or client. This applies even if the second laboratory is in the same health care system. Report incidents of referral to the National Office of Quality for reporting to CMS and/or CAP. ..." The policy "Proficiency Testing Management Process (Document Number: LC-BN-QA-PRO-5 Revision: 3, effective 10/27/20) states on page 7 "... 8.7 Proficiency Testing Referrals - Distributive Testing ... 8.7.4 The CMS prohibition on referral to another laboratory includes situations where two testing locations are involved in providing test results as occurs in distributive testing. ... 8.7.6 Should the laboratory identify the receipt of PT samples from another laboratory, they are to notify ... QM so the incident can be reported according to regulatory guidelines. Review of the "Shipping Container History" log revealed the laboratory received a proficiency sample from a sister laboratory 3/27/21. The proficiency sample from the 2021 CAP TTD-A survey was submitted as a patient specimen labeled with "TTD-02" and a partial patient name. The laboratory failed to recognize the specimen as a proficiency sample, and the sample was processed as a patient specimen. Review of the patient test report for the proficiency sample TTD-02 revealed the Lyme Total Antibody Test was performed at the sister laboratory and the Lyme IgG and IgM Line Blot testing was performed by the laboratory. Results of the Lyme IgG and IgM Line Blot testing for TTD-02 were reported 4/1/21. Review of 2021 CAP proficiency testing records revealed the laboratory was also enrolled and participated in the 2021 CAP TTD-A survey. The laboratory tested their 2021 CAP TTD-A proficiency samples 3/23/21, and the results were finalized and reported 3/25/21. During interview at approximately 11:15 a.m., the AVP - Quality Director stated that the laboratory was informed of the accidental referral of a proficiency sample by the sister facility that sent the sample. She confirmed that the laboratory was notified by the sister facility after the proficiency sample had already been tested. She stated the laboratory has information technology systems in place to detect and flag proficiency samples submitted as patient specimens and they are working on improving the systems. She stated that because the sample was submitted as a specimen with a partial patient name, the laboratory's systems

	<p>were unable to identify it as a proficiency sample and it was not flagged. She also stated the laboratory requires annual proficiency testing training for accessioning personnel, testing personnel, supervisors, managers, and directors which includes information about proficiency testing referral.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of specimen logs, review of patient test report (TTD-02, specimen ID #083-125-0007-0), and interview with the AVP - Quality Director 12/7/21, the laboratory director failed to provide overall management and direction for the laboratory. The laboratory director failed to ensure proficiency testing samples were tested as required under subpart H (see D6089).</p>
<p>D6089</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of specimen logs, review of patient test report (TTD-02, specimen ID #083-125-0007-0), and interview with the AVP - Quality Director 12/7/21, and the deficiency cited at D2013, the laboratory director failed to ensure proficiency samples were tested as required under subpart H. Findings: The laboratory director failed to ensure the laboratory's systems were effective to prevent the laboratory from testing a proficiency sample transferred from a sister laboratory for Lyme IgG/IgM Line Blot testing. The proficiency sample TTD-02 was submitted as a patient specimen with a partial name, and the laboratory's information technology systems failed to flag it. The laboratory tested the proficiency sample and reported the results 4/1/21.</p>