Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2087398	(X3) Date Survey Completed 09/11/2024
Name of Provider or Supplier Laboratory Corporation Of America	**Street Address, City, State** 1036 Sharon Drive, Jeffersonville, IN	

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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to ensure one of one personnel (SP-2) met the requirements for a Laboratory Director of a laboratory performing high complexity testing (Adulteration, Teco DX Urinecheck D700) from 04/18/2024 to 09/11/2024.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and

medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview, the laboratory failed to ensure one of one personnel (SP-2) met the requirements for a Laboratory Director of a laboratory performing high complexity testing (Adulteration, Teco DX Urinecheck D700) from 04/18/2024 to 09/11/2024. Findings included: 1. Review of the "Clinical Laboratory Improvement Amendment (CLIA) Application for Certification FORM CMS 116" and the "Laboratory Personnel Report (CLIA) FORM CMS 209", dated 9/7 /2024, indicated the laboratory performed moderate complex testing and SP-2 was the laboratory director. 2. During laboratory tour on 09/11/2024 at 10:23AM, SP-5 (testing personnel) was observed reading the Adulteration Teco DX Urinecheck D700 test strips. 3. The following patients had semi-quantitative test results for the Adulteration Testing: Patient Test Result (PT)s PT#1 Creatinine 50 Potential of Hydrogen pH 7.0 Specific Gravity 1.030 PT#2 Creatinine 50 pH 7.0 Specific Gravity 1.025 PT#3 Creatinine 200 pH 5.0 Specific Gravity 1.030 PT #4 Creatinine 200 pH 7.0 Specific Gravity 1.015 PT#5 Creatinine 100 pH 7.0 Specific Gravity 1.030 4. Distributor websites for Adulteration Teco DX Urinecheck D700 indicated that the test is for forensic use only. 5. Review of the Federal Drug Administration (FDA) data base for CLIA Categorization indicated the Adulteration Teco DX Urinecheck D700 had not been categorized by the FDA and therefore defaults to high complexity testing. 6. Review of personnel records for SP-2 indicated they had a Job Description for moderate complexity laboratory director effective 4/18/2024. SP-2 had a Bachelor of Science in Medical Technology. 7. In an interview on 9/11/2024 at 1:55 PM, SP-1 confirmed that SP-2's highest degree was a Bachelor of Science in Medical Technology. 8. Annual Test volume for Adulteration Teco DX Uricheck D700 is 2,230.