Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0959085	(X3) Date Survey Completed 04/20/2023
Name of Provider or Supplier Laboratory Corporation Of America Holdings	**Street Address, City, State** 4950 Essen Lane, Fifth Floor, Baton Rouge, LA	
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
D0000	A Certification survey was performed at Laboratory Corporation of America Holdings, CLIA ID # 19D0959085. Laboratory Corporation of America was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803: CONDITION: Successful participation 42 CFR 493.1403: CONDITION: Laboratories Performing Moderate Complexity Testing, Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records, CASPER 155D

	report, and interview with personnel, the laboratory failed to achieve a score of at least 80% for total bilirubin for two of three consecutive events, resulting in an initial unsuccessful performance. Refer to D2096.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(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. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, CASPER 155D report, and interview with personnel, the laboratory failed to achieve a score of at least 80% for total bilirubin for two (2) of six (6) consecutive events reviewed for 2021 and 2022 resulting in an initial unsuccessful participation. Findings: 1. Review of the CASPER 155D report, American Academy of Family Physicians (AAFP) proficiency testing records for 2021, and American Proficiency Institute (API) proficiency testing records for 2022 revealed the laboratory achieved the following unsatisfactory scores: AAFP Module 619, MultiCHEM 21 +, 2021-C, total bilirubin, score: 40% API 2022 Chemistry-Core 2nd Event, total bilirubin, score: 60 % 2. In interview on April 20, 2023 at 9:20 am, the Technical Consultant confirmed the laboratory did not achieve proficiency testing scores of at least 80% for the identified events for total bilirubin.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records, CASPER 155D report, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, CASPER 155D report, and interview with personnel, the Laboratory Director failed to ensure proficiency testing samples were satisfactory as required. Refer to D2096.