Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0866459	01/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	10200 Pioneer Blvd, Ste 500, Santa Fe Springs, CA	

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	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 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. This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) result reports and interviews with the laboratory's laboratory director (LD), technical supervisor (TS), and laboratory's testing personnel (TP); it was determined that the laboratory failed to enroll and participate in a proficiency testing (PT) program that meets the criteria in subpart H of 42 CFR part 493 and is approved by HHS. The findings included: 1. The laboratory performed mycology and parasitology procedures and failed to show evidence of enrollment in a PT program for both subspecialties using a CMS approved PT program for the years 2022 and 2023 when the laboratory started testing for mycology procedures (potassium hydroxide- KOH) and parasitology procedures (pinworm, Giardia and Cryptococcus). The laboratory analyzed and reported tests for both mycology and parasitology patient test results during the time of non-enrollment in a proficiency testing (PT) program. 2. The laboratory staff confirmed on January 11, 2024, at approximately 12:00 p. m. that patient test results for mycology and parasitology were reported, yet the laboratory had not enrolled in an accredited PT program for KOH, Giardia, pinworm, and Cryptococcus for the years 2022 and 2023. 3. The laboratory annual testing declaration signed by the LD estimated total volume of mycology to be 66 and parasitology 1,135 tests respectively.

D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of proficiency testing results, quality control, and verification of accuracy results and interview with the laboratory's director (LD) and testing personnel (TP) on January 11, 2024 at approximately 12:00 pm, for those tests performed by the laboratory that are not included in subpart I of this part, the laboratory failed to establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1). Findings include: 1. The laboratory could not provide documentation of verification of accuracy and quality control for potassium hydroxide (KOH), for the years 2022 and 2023. 2. The laboratory could not provide documentation of verification of accuracy for Giardia, Cryptococcus and pinworm testing for the years 2022 and 2023. 3. This deficient practice was verified by interview with the LD and TP on the day of the survey on January 11, 2024. 4. The laboratory reports approximately 1,200 tests annually for KOH, Giardia, Cryptococcus and pinworm.
D2153	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) of the laboratory's proficiency testing (PT) result reports for the third Immunohematology event of 2022 and interview with the laboratory's technical supervisor (TS), it was determined that the laboratory failed to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event was unsatisfactory analyte performance for the testing event. The findings included: 1. CAP reported a score of 80 % for ABO group and Rh (D) type for the 2022 third event (Q3-2022) which was unsatisfactory analyte performance for the testing event. 2. The laboratory TS affirmed that the laboratory attained a score of 80 % for ABO group and Rh (D) type for Q3-2022 event which was unsatisfactory analyte performance for the testing event. 3. The laboratory performed ABO group and Rh (D) type in approximately 871 patient samples monthly.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

	This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's proficiency testing records, policies and procedures, patients' test results records, quality control documentation, and interviews with the laboratory's technical supervisor and testing personnel on January 11, 2024; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D2000, D2003, and D2153.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the deficiency cited (See D2000 and D2003), the laboratory director is herein cited for deficient practice in overall administration to ensure the laboratory is enrolled in proficiency testing for all the analytes patients samples are tested and results reported.