Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0866459	09/20/2021
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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure and test records of random patients' samples for the years of 2019, 2020 and 2021, and interview with the laboratory technical supervisor on September 20, 2021 at 3:15 pm, the laboratory failed to follow written policies and procedures to reject the heparinized blood sample for QuantiFERON-TB Gold test. The findings include: 1. The laboratory did QuantiFERON-TB Gold test on blood samples collected in tubes containing heparin. The laboratory procedure describes the sample stability at room temperature for 12 hours after collection. However, the laboratory never recorded or tracked the sample collection and receiving times, and when interviewed the processing staff #1 was unaware of this timing requirement. Therefore, the laboratory might had performed test on compromised blood samples and rendered inaccurate patient test results causing potential harm to the patients. 2. The laboratory technical supervisor on September 20, 2021 at 3:15 pm, affirmed that the laboratory never recorded or tracked the sample collection and receiving times. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/22/2021, stated that the laboratory performs 26,211 tests in mycobacteriology, annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a)

	The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure and test records of random patients' samples for the years of 2019, 2020 and 2021, and interview with the laboratory technical supervisor on September 20, 2021 at 2:05 pm, the laboratory failed to establish a procedure for an ongoing mechanism to monitor, identify and correct problems regarding missing samples. The findings include: 1. The laboratory's problem resolution and investigation forms showed that samples # 20073554 and 20039366 were missing lavender specimen. The laboratory did investigations to find the missing samples but was unable to locate the samples. However, it resolved the problem by re-collecting the samples. The laboratory's investigation could not identify the reason of missing samples. The laboratory must establish policies or procedures to ensure proper accountability or tracking of patient specimens from time of collection to receipt by the laboratory and throughout the accessioning, testing, and reporting processes. When the laboratory discovers an error or identifies a potential problem, actions must be taken to correct the situation. This correction process involves identification and resolution of the problem, and development of policies that will prevent recurrence. A missing sample might have serious negative outcome in patient care. 2. The laboratory technical supervisor on September 20, 2021 at 2:05 pm, affirmed that the laboratory could not identify the cause of the missing samples. 3. The laboratory's testing declaration form, signed by the laboratory Director on 9/21 /2021, stated that the laboratory performs 225,147 tests in hematology, annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patients' test records for the years of 2019, 2020 and 2021, and interview with the laboratory technical supervisor and sample processing staff #1 on September 20, 2021 at 3:15 pm, the laboratory director failed to ensure laboratory staffs are performing the test methods as required for accurate and reliable results. The findings include: See D5311.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy and procedure, patients' test records for the years of 2019, 2020 and 2021, and interview with the laboratory technical

	supervisor on September 20, 2021 at 2:05 pm, the laboratory director failed to assure the quality of laboratory services provided in the pre-analytic phase of testing. The findings include: See D5391.