Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0919706	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	1965 S Eagle Rd Ste 130, Meridian, ID	

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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review of maintenance logs and interview with the laboratory director on 11/19/20 the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings include: 1. The laboratory performs estrodiol, progesterone, creatine kinase-MB (CK-MB) and N-terminal pro brain natriuretic peptide(NT proBNP) testing on the Cobas e411. A record review of maintenance logs from the Cobas e411 from 9/1/2018 to 11/19/20, revealed that weekly maintenance was missing in March 2020, April 2020, August 2020 and October 2020. Monthly maintenance was not completed in September 2020, and the two week maintenance was missed once in March and not done at the correct interval in April. Weekly maintenance of cleaning the incubator and aspiration station and cleaning of the sipper probe: March 2-7, 2020 Not performed April 7-11, 2020 Not performed August 3-7, 2020 Not performed September 28- October 2,2020 Not performed Two week maintenance of cleaning the rinse stations and performing the liquid flow cleaning: March 2020 only performed once April 2020 performed on 4/17 and 4/23 Monthly maintenance of replacing the pinch valve tubing: September 2020 not performed. 2. There were not corrective actions documented for the missed maintenance listed above. 3. A review of the quality control (QC) corrective action log for the Cobas e411 revealed that during the week of March 2-7, 2020, when weekly maintenance was not performed, there were three (3) days with documented QC issues. 3/2/2020 estrodiol was out of range 3/4/2020 estrodiol and progesterone were out of range 3/5 /2020 estrodiol and progesterone were out of range 4. The record review of the

	maintenance logs from the Cobas e411 revealed that the laboratory director reviewed and signed the maintenance logs for the Cobas e411 for the months of March 2020, April 2020, August 2020, September 2020 and October 2020. 5. The laboratory reports performing testing 45 patient samples in August, 45 patient samples in September and 22 patient samples in October on the Cobas e411. They were unable to provide the numbers of patients tested on the Cobas e411 for the months of April and March.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review of instrument validations and interview with the laboratory director on 11/19/2020 the laboratory failed to ensure verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. The findings include: 1. A record review of instrument validations following a laboratory move in April of 2019, revealed that the validation for creatine kinase-MB (CK-MB) and N-terminal pro brain natriuretic peptide (NT proBNP) performed on the Cobas e411 was not approved by the laboratory director before implementation of patient testing on 4/29/2020. 2. An interview with the laboratory director on 11/19/2020 at 11:40 confirmed that the laboratory director had not approved the validation for CK-MB and NT proBNP performed on the Cobas e411 before implementation of patient testing. 3. The laboratory reports performing 25 CK-MB and 25 NT proBNP patient tests annually.