Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2137534	05/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings	205 Hospital Drive Suite Q, Mc Kenzie, TN	

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
D2100	ENDOCRINOLOGY CFR(s): 493.843(c) (c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on direct observation, review of patient test reports, review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, review of a patient activity report, and staff interview, the laboratory failed to participate in PT for the 2025 Event One for the regulated endocrinology analytes of Estradiol, Follicle Stimulating Hormone (FSH), Luteinizing Hormone (LH) and Progesterone. The findings include: 1. Laboratory observation on 05/19/25 at 8:30 a.m. revealed the Roche Cobas e411 used for performing patient testing for multiple analytes, including Estradiol, FSH, LH, and Progesterone. 2. A review of patient test reports revealed the laboratory began testing for the four analytes in January 2025 (patient specimen identification numbers 020-670-0020-0 for Estradiol, LH, and Progesterone on 01/20 /25, 020-670-0015-0 for Estradiol and Progesterone on 01/20/25, and 021-670-0035-0 for Estradiol and FSH on 01/21/25). 3. A review of the laboratory's API PT records revealed the laboratory did not participate in API PT Event One for the Estradiol, FSH, LH, and Progesterone analytes. 4. A review of a patient activity report revealed that approximately 137 Estradiol, 85 FSH, 53 LH, and 76 Progesterone tests were performed from the first patient testing date on January 20, 2025, until the survey date

	on 05/19/25. 5. The general supervisor confirmed the survey findings during an interview on 05/19/25 at 10:30 a.m. when he stated that the laboratory was enrolled and performed the testing for 2025 Event One, but failed to submit the results for the new analytes to the PT program.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: CITATION ONE: Based on direct observation, review of the laboratory procedure manual, review of quality control records, lack of documentation, patient test records, staff interview, and electronic mail communication, the laboratory failed to ensure the quality control (QC) procedure for establishing ranges for the N-terminal pro b-type natriuretic peptide (NT pro-BNP) was followed and failed to ensure the ranges used for the NT pro-BNP and FSH analytes were capable of detecting immediate errors as they occurred. The findings include: 1. Laboratory observation on 05/19/25 at 8:30 a. m. revealed the Roche Cobas e411 instrument used for performing multiple analytes including NT-proBNP and FSH. 2. A review of the laboratory procedure titled "Target Mean, Standard Deviation, and Quality Control Rule Selection revealed the following for "Evaluation of New QC Material": "For most non-hematological tests: Analyze at least 20 data points from 20 or more separate runs (preferably on separate days). Performing at least 20 determinations per analyte will give a reasonable estimate of a between run target value accuracy and SD (precision). If assayed materials are used, the laboratory established mean must be within the range provided by the manufacturer of the QC material. The SD should be within the expected precision for the test (see previous control data.) The manufacturer's stated values are only to be used as a guide to the laboratory. The package insert will often state that the lab mean should fall within the manufacturer's limits. The historic CV may be used to obtain the new lot SD. Multiply the new mean by the historic CV% (based on previous control data), see below." 3. A review of the laboratory's QC records for the NT-proBNP analyte revealed the following: The current QC lot numbers used for NT-proBNP were 87871 (Level 1) and 87873 (Level 3) (Biorad Cardiac Markers-Assayed). The manufacturer's package insert stated that the range provided by Biorad represented a +/- 3SD range. The package insert +/- 3 SD range for Level 1 (87871) was 59.2 to 76.0 pg/ml. The expected range programmed into the Cobas e411 was a range of 43.34 - 90.36 pg/ml. 4. A review of the laboratory's QC records for the FSH analyte revealed the following: The current QC lot numbers used for FSH were 85381 (Level 1) and 85383 (Level 3) (Biorad Immunoassay Plus Control-Assayed). The manufacturer's package insert stated that the range provided by Biorad represented a +/- 3SD range. The package insert +/- 3 SD range for Level 1 was 5.62 - 7.39. mIU /ml. The expected range programmed into the Cobas e411 was a range of 5.29 - 8.29 mIU/ml. The package insert +/- 3 SD range for Level 3 was 32.9 - 43.3. mIU/ml. The

	expected range programmed into the Cobas e411 was a range of 31.02 - 49.02 mIU /ml. 5. On the survey date, the laboratory could not provide documentation that the QC ranges for the NT pro-BNP analyte were established using historic QC data from previous lots. 6. A review of patient test reports and an activity report revealed that the first patient FSH was reported on 01/21/25 for patient 021-670-0035-0. Approximately 85 patients were reported since testing began, during the period when the FSH QC ranges were in use. 7. The general supervisor confirmed the survey findings during an interview on 05/19/25 at 3:30 p.m. 8. Review of an electronic mail communication received on 05/21/25 at 2:39 p.m. revealed that QC lot 87871 was put into use on 09/20/24 for the NT-proBNP analyte. Word Key: pg/ml=picogram per milliliter mIU/ml=milli-International Units per milliliter CV=Coefficient of Variation SD=Standard Deviation CITATION TWO: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to review quality control (QC) data for shifts or trends for the analytes performed on the Cobas e411 for January, February and March 2025. 1. Laboratory observation on 05/19/25 at 8:30 a. m. revealed the Roche Cobas e411 instrument used for performing Troponin T, NT pro-BNP, Creatine Kinase-MB, Estradiol, FSH, Free Thyroxine, quantitative serum human chorionic gonadotropin, LH, Progesterone, Prostate Specific Antigen, and Thyroid Stimulating Hormone. 2. There was no documentation that the laboratory reviewed the QC data for the analytes performed on the Roche Cobas e411 instrument for shifts and trends using data generated from the instrument for January, February, or March 2025. 3. During an interview on 05/19/25 at 3:30 p.m., the laboratory supervisor stated the laboratory entered the daily QC results from the Cobas e411 into the Biorad Unity system and those reports were used for cumulative quality control review. He further stated that the cumulative data from the instrument was not reviewed to detect shifts and trends. This confirmed the survey findings.