Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2125016	06/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America Holdings Inc	1022 North 1st Street Suite 500, Alabaster, AL	

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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review API (American Proficiency Institute) proficiency testing records, a review of the Proficiency Testing Guidelines policy (Policy and Procedure Manual), and an interview with the laboratory's representative (the former Technical Consultant), the surveyor determined the laboratory failed to review and evaluate the performance of two proficiency testing events in 2018, to verify the accuracy of testing of d-Dimer (tested on the PathFast). This affected two of six testing events reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records revealed the laboratory was enrolled in testing for d-Dimer, proBNP and Troponin I, non-regulated CLIA analytes. 2. Further review of the proficiency testing records revealed the laboratory failed to obtain the participants' data summaries to evaluate the results of d-dimer testing for Chemistry Events #2 and #3 of 2018. The surveyor's review of these results revealed six of ten of the d-dimer results were not graded by API. 3. A review of the laboratory's Proficiency Testing Guidelines, signed by the Laboratory Director, gave instructions to the designated laboratory personnel responsible to review the proficiency testing for unacceptable results, trends and peer comparisons. The instructions included the designated laboratory personnel or Laboratory Director should review proficiency testing evaluations, including graded and non-graded results, regulated and non-regulated challenges, educational challenges, and challenges not graded, due to lack of consensus.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)

	The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review API (American Proficiency Institute) proficiency testing records, a review of the Proficiency Testing Guidelines policy (Policy and Procedure Manual), and an interview with the laboratory's representative (the former Technical Consultant), the surveyor determined the laboratory failed to verify the accuracy of testing of d-Dimer (tested on the PathFast), when the results were returned by API, as not graded/scored. This affected three of six testing events reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records revealed the laboratory was enrolled in testing for d-Dimer, proBNP and Troponin I, non-regulated CLIA analytes. 2. Further review of the proficiency testing records revealed the following results for d-Dimer, which were returned as not graded by API: a) Chemistry Event #3, 2017: Specimens CM11, CM14 and CM15 were not graded by API. The laboratory printed the data summary, but failed to document evaluation of the results to determine the laboratory's accuracy of reporting. The laboratory had reported greater than five (>5 FEU/ml) for each of the above listed specimens. The surveyor reviewed the data summary and determined API indicated the majority of PathFast users reported greater than 5. However, the peer group was very small (limited). b) Chemistry Event #1, 2018: Specimens CM02, CM03 and CM05 were not graded by API. The laboratory printed the data summary, but failed to document evaluation of the results. c) Chemistry Event #1, 2019: Specimen CM01, CM03, CM04 and CM05 were not graded by API. The laboratory failed to evaluate to verify its accuracy of reporting d-Dimer results. 3. The surveyor's review of the proficiency testing records (the data summary and result sheets) revealed scores reported as greater than 5.000 were determined by API as acceptable, but results indicated as >5 were not graded. Also, the results of the PathFast users were almost double the results of the other participants. 4. A review of the laboratory's Proficiency Testing Guidelines, signed by the Laboratory Director, gave instructions to the designated laboratory personnel responsible to review the proficiency testing for unacceptable results, trends and peer comparisons. The instructions included the designated laboratory personnel or Laboratory Director should review proficiency testing evaluations, including graded and non-graded results, regulated and non-regulated challenges, educational challenges, and challenges not graded, due to lack of consensus.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the initial tour observation of the laboratory, a review of calibration verification records, a review of the policy and procedure manual, and an interview with the laboratory's representative (the former technical consultant), the surveyor determined the laboratory failed to perform calibration verifications for analytes (Troponin I, proBNP and d-Dimer) run on the PathFast Chemistry analyzer, at least every six months. This affected the survey review period of July 2017 - June 2019. The findings include: 1. During the initial tour of the laboratory on June 25, 2019, Testing Personnel (TP) #1 stated the test menu included the Troponin I, proBNP and d-Dimer run on the PathFast. 2. A review of the calibration verification records for the PathFast revealed the verifications, performed after the installation date (March 2017) of the analyzer, were done on 11/29/17, eight months after the previous calibration verification. After 11/29/17, the verification was not done until 12/20/2018, nearly one year after the previous calibration verification. 3. A review of the policy and procedure manual revealed each analyte tested on the PathFast were routinely calibrated with only two calibrations, run in duplicate. 4. During an interview on June 25, 2019 at 4:30 PM, the former Technical Consultant (TC) stated a calibration verification was missed in 2018. The former TC further stated no standing order had been arranged, however, the dates to order the calibration materials had been added to a calendar.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records for Chemistry, a review of policies and procedures, a review of patients' test reports (reviewed by testing personnel), and an interview with the laboratory's representative (the former Technical Consultant), the surveyor determined the laboratory failed to ensure at least two levels of quality control were acceptable on 11/03/17, prior to testing patient specimens and reporting the results for Troponin I. This affected one day of twenty-four months of quality control testing reviewed by the surveyor. The findings include: 1. A review of the quality control records for Chemistry revealed on November 3, 2017, of the two levels of quality control tested for Troponin I, only one level was documented as acceptable. Level III was out-of-range, and repeat testing had not been documented. 2. In an interview on June 25, 2019 at 2:57 PM, the former technical consultant (TC) stated two levels of external quality control were run each day of patient testing for proBNP, Troponin I and d-Dimer. 3. On June 25, 2019 at the exit of the survey, at

	approximately 5:00 PM, Testing Personnel #1 provided the one patient test report (Troponin I) that she said was tested on November 3, 2017, when the laboratory failed to have at least two levels of acceptable quality control.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of temperature logs, a review of Biorad's requirements for the Liquichek quality control (QC) material, and an interview with the laboratory's representative (the former technical consultant) and Testing Personnel (TP) #1, the surveyor determined the laboratory failed to implement and document corrective actions, when the freezer temperatures were found unacceptable for the storage of the Biorad Liquichek QC. This affected at least twenty-one days over a period of three months in 2019. The findings include: 1. A review of the temperature logs revealed an established range of minus twenty to minus seventy (-20 to -70 degrees Celsius) for freezer #2. In March of 2019, the laboratory staff documented temperatures of -18 and -19 for at least 8 days; 10 days in April and 3 days in May. There was no corrective actions taken for these temperatures which were warmer than the acceptable range of -20 to -70 degrees Celsius. 2. A review of the Quality Control Manual for the PathFast revealed Liquichek QC material (Freezer #2) should be stored frozen at minus twenty (-20) or below. The Biorad instructions indicated the QC material should be stable until the expiration date when stored unopened at -20 to -70 degrees Celsius. Once opened and tightly capped, the QC could be stored at 2 - 8 degrees Celsius, up to fifteen days. 3. At 4:30 PM on June 25, 2019, TP #1 and the former Technical Consultant confirmed the temperatures recorded on the above mentioned days were warmer than the acceptable minus twenty to minus seventy (-20 to -70). The staff further confirmed the contents of freezer #2 included the Biorad QC material.