Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 01D0993817	**(X3) Date Survey Completed** 06/26/2019
Name of Provider or Supplier Laboratory Corporation Of America Holdings	**Street Address, City, State** 3980 Colonnade Parkway, Birmingham, 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 of API (American Proficiency Institute) proficiency testing records and an interview with the laboratory's representative (the former technical consultant), the surveyor determined the laboratory failed to review and evaluate the results of Chemistry Event #3, 2017. The laboratory failed to obtain the results of the event. This affected one of seven proficiency testing events reviewed by the surveyor. The findings include: 1. A review of the proficiency testing records revealed the laboratory had not obtained the results to Chemistry Event #3, 2017. Hence, no review nor evaluation had been performed to determine the laboratory's accuracy of testing. 2. On June 26, 2019 at 1:45 PM, after review of the records, the former Technical Consultant (TC) stated she could not find the results for the above named event; so she printed the results. The surveyor reviewed the results, which indicated specimens CM11, CM14 and CM15 were not graded by API, due to a limited peer group.
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 a review of calibration verification record, policies and procedures, 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. A review of the calibration verification records for the PathFast revealed the verifications, performed since the previous survey (January 25, 2017) were done on 7/13/17 for all three analytes. The calibration verification on Troponin I was due in July (previously done on 1/19/2017); and proBNP and d-Dimer were due in May of 2017 (previously done on 11/29/2016). Following the 7/13/2017 calibration verifications, the studies were again performed on 1/09/2018; 11/21 and 11 /27/2018, ten months after the previous calibration verification; and 5/28 and 5/29 /2019. 2. 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. 3. During an interview on June 26, 2019 at 3:44 PM, the former Technical Consultant (TC) stated she got off track with the performance of the calibration verifications, and has since realized she needs to delegate some of the responsibilities.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the personnel records, a review of the proficiency testing records, and an interview with the laboratory's representative (the former technical consultant), the surveyor determined the laboratory director failed to verify the testing personnel's educational credentials, prior to allowing the personnel to perform moderate complexity testing on patients' specimens and report the results. This affected two [Testing Personnel (TP) #3 and #4] of four testing personnel reported on

	the Laboratory Personnel Report for CLIA (CMS form #209). The findings include: 1. A review of the personnel records for TP #3 and TP #4 (new testing personnel since the previous survey on 1/25/2017) revealed no educational credentials/records. A training record for TP #3 was documented and dated 9/06/17; and 2/05/2019 (PathFast) for TP #4. An unidentified type of assessment, dated 12/14/2018 was included in TP #4's file (see interview at paragraph 2). 2. During an interview on June 26, 2019 at 2:46 PM, the former technical consultant (TC) confirmed no educational credentials were included in the personnel files of TP #3 and #4. The former TC also stated she believed TP #4 was hired the last part of 2018. 3. A review of the proficiency testing records for 2018 and 2019 revealed TP #3 and #4 had participated in proficiency testing performance. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the laboratory's representative (the former technical consultant), the surveyor determined the Technical Consultant failed to perform semiannual competency assessments on two (Testing Personnel #1 and #3) of four testing personnel listed on the Laboratory Personnel Report (CMS form #209). The findings include: 1. A review of the personnel records revealed Testing Personnel (TP) #1 was initially trained on September 6, 2017. TP #1's competency was not assessed until September 20, 2018, one year following the initial training. The laboratory failed to perform a semi-annual competency assessment on TP #1. 2. TP #3 was initially trained on September 6, 2017. The personnel did not have a competency assessment (annual) performed until December 3, 2018, greater than one year after initial training. The Technical Consultant (TC) failed to perform a semi-annual competency assessment for TP #3, during the first year of employment. 3. At 2:46 PM on June 26, 2019, the former TC confirmed the missing evaluations. The former TC further explained she experienced some personal issues during the time the evaluations were due.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the laboratory's representative (the former technical consultant), the surveyor determined the Technical Consultant failed to perform an annual competency assessment on Testing Personnel (TP) #2, one of four testing personnel listed on the Laboratory Personnel Report (CMS form #209). The findings include: 1. A review of the personnel records revealed TP #2 was hired on September 6, 2016 and complete the initial training on December 30, 2016. An annual competency assessment was performed on December

	13, 2018. The Technical Consultant (TC) failed to perform an annual competency assessment on TP #2 in 2017. 2. At 2:46 PM on June 26, 2019, the former TC confirmed the missing evaluation. The former TC further explained she experienced some personal issues during the time the evaluation was due.