Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2002044	06/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	2515 Business Center Dr, Pearland, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of patient test reports, and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal ranges when a change of reference intervals was made. The findings were: 1. A review of patient test reports revealed the laboratory changed its reference intervals for platelets from 150 - 379 x 10E3/uL to 150 - 450 x 10E3/uL on May 20, 2019. 2. The laboratory was asked

	to provide documentation of verifying the new reference intervals. No documentation was provided. 3. An interview with the Quality manager on 06/20/2019 at 1345 hours in the conference room revealed the new reference intervals had not been verified. This confirmed the findings.
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's quality control records from May 2018 to May 2019, and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control over time for testing performed on the Abbott Piccolo. The findings were: 1. A review of the laboratory's test menu revealed the following testing was performed on the Abbott Piccolo: a) Chemistries Albumin, Alkaline Phosphatase, Alanine Aminotranserase, Aspartate Aminotransferase, Bilirubin, Blood Urea Nitrogen, Calcium, Carbon Dioxide, Calcium, Creatine, Glucose, Potassium, Total Protein, and Sodium b) Lipids HDL cholesterol, Total cholesterol, and Triglycerides 2. A review of the laboratory's quality control records from May 2018 to May 2019 revealed the laboratory failed to have a mechanism in place to monitor quality control over time to detect any shifts or trends. 3. The laboratory was asked to provide documentation of monitoring quality control over time for the identified tests. No documentation was provided. 4. An interview with the Quality manager on 06/20/2019 at 0954 hours in the conference room revealed the laboratory did not monitor quality control values over time. This confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's

	Individualized Quality Control Plan (IQCP) for chemistry testing and lipid testing performed on the Abbott Piccolo analyzer, and staff interview, it was revealed the laboratory failed to have evidence to support its modification of the frequency of quality control testing. The findings were: 1. A review of the laboratory's test menu revealed the following testing was performed on the Abbott Piccolo: a) Chemistries Albumin, Alkaline Phosphatase, Alanine Aminotranserase, Aspartate Aminotransferase, Bilirubin, Blood Urea Nitrogen, Calcium, Carbon Dioxide, Calcium, Creatine, Glucose, Potassium, Total Protein, and Sodium b) Lipids HDL cholesterol, Total cholesterol, and Triglycerides 2. A review of the laboratory's IQCP performed in January - February 2019 revealed the laboratory modified the frequency of quality control testing from each day of patient testing to every 30 days, with each new shipment, or each new lot. 3. Further review of the IQCP revealed the laboratory's revealed the laboratory only tested quality control material for a period of 10 days from January 21, 2019 to February 1, 2019. Quality control had not been testing each day for 30 days to support the laboratory's IQCP. 4. The laboratory was asked to provide documentation of data to support the frequency of testing as defined by its IQCP. No documentation was provided. 5. An interview with the Quality manager on 06/20/2019 at 0925 hours in the conference room revealed the laboratory only tested quality control for 10 days. This confirmed the findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of patient reports, review of laboratory policies, and staff interview, it was revealed the laboratory failed to provide reference intervals for neutrophils (%), lymphocytes (%), monocytes (%), eosinophils (%), and basophils (%). The findings were: 1. A review of patient test reports revealed 12 of 12 reports did not provide reference intervals for neutrophils (%), lymphocytes (%), monocytes (%), eosinophils (%), and basophils (%). For each result, the notation of "Not Estab." (meaning not established) was listed under the column for reference interval. 2. A review of the laboratory's policy titled "Hematology Reference Intervals" (effective date: 03 June 2019) revealed: "Note: Differential Percents (%) for Normal Cells are not reported with a RI." RI = reference interval 3. The laboratory was asked to provide documentation providing reference intervals to aid providers in the assessment of patient results. No documentation was provided. 4. An interview with the quality manager on 06/20/2019 at 1330 hours in the conference room revealed the laboratory did not provide reference intervals and did not have them defined. This confirmed the findings.
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's installation records for the Abaxis Piccolo chemistry analyzer, personnel records, and staff interview, it was revealed the technical consultant failed to have documentation of assessing competency for 1 of 8 testing personnel performing testing on a new instrument prior to testing on patient samples. Findings include: 1. A review of the laboratory's installation records for the Abaxis Piccolo chemistry analyzer revealed the analyzer was put into service in May 2018. 2. A review of the laboratory's personnel records revealed 1 of 8 testing personnel files did not contain documentation of a competency assessment performed on the new instrument (Abaxis Piccolo chemistry analyzer) prior to reporting patient test results. 3. The laboratory was asked to provide documentation of the technical consultant performing competency assessment of testing person #7 (as listed on the CMS 209 form, signed by the laboratory director on 6/17/19) on the Abaxis Piccolo chemistry analyzer prior to performing patient testing. No documentation was provided. 4. An interview with the QA manager on 6/20/19 at 11:00 in the conference room confirmed competency assessment was not performed for testing person #7 on the new analyzer prior to performing patient testing.