Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0999144	11/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	1010 S Ponds Drive, Webster, 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(s) at the exit conference. The facility representative(s) were 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.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) Chemistry proficiency testing records from 2017 and 2018, and confirmed in interview, the laboratory failed to attain a satisfactory score of at least 80% for the analyte Total Bilirubin (Tbili). The findings were: 1. A review of the laboratory's API from 2017 and 2018 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes Tbili on 1 of 5 events: 2018 Event 3 Tbili (40%) lab result acceptable result CH-12 3.0 1.8 - 2.8 CH-13 4.2 2.5 - 3.8 CH-15 3.5 2.1 - 3.2 2. An interview with the quality assurance manager on 11/13/18 at 0940 hours in the office confirmed the above findings.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a

	proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing records, and confirmed in interview, the laboratory failed to document remedial action for PT failures for the analyte Total Bilirubin. Findings were: 1. Review of the 2018 API proficiency testing records revealed the laboratory failed to attain an 80% for the analyte Total Bilirubin for 1 of 3 testing event for Chemistry. Cross refer to D2087 2. Review of the laboratory Proficiency Testing Failure quality assessment record for the API 3rd event revealed "since all QC [quality control] were in range and no reported instrument issues, no patient impact was expected." 3. Review of the 2018 API 3rd event quality assessment records revealed no documentation of the patient remedial action. Refer to patient alias list. 4. An interview with the quality assurance manager on 11/13/18 at 1000 hours in the office confirmed the above findings.