Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0883333	10/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	2001 W Orange Grove Rd, Ste 252, Tucson, AZ	

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
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 lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required. Findings include: 1. The laboratory performs Fetal Fibronectin (fFN) testing using a "Rapid fFN for Tli System" test kit under the sub-specialty of Routine Chemistry. On the date of the survey, October 18, 2018, the laboratory's quality control procedure consisted of performing two levels of external control material, once each new lot or shipment of test cassettes is received. 2. No QC documentation was provided for review during the survey to indicate the laboratory performed two levels of control material of different concentrations, each day of patient testing as required since January 1, 2016. 3. During the survey, review of QC records from 2016 through the date of the survey indicated the laboratory performed and documented QC with the number and frequency described above, and as of January 1, 2016, the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for this test kit. 4. The facility personnel confirmed that the laboratory did not perform and document controls as required since January 1, 2016 and confirmed that the laboratory had not implemented an Individualized Quality Control Plan (IQCP) for testing performed on the fFN test. 5. The number of patients

	tested during the time period indicated above could not be determined at the time of the survey.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality control records and control procedures, the laboratory director failed to ensure that quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 for findings.