Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2132919	04/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America, Holdings	1120 First Colonial Road - Suite 100, Virginia Beach, VA	

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	An announced CLIA recertification survey was conducted at Laboratory Corporation of America, Holdings on April 3, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiency cited is as follows:
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a laboratory tour, review of procedures, maintenance logs, and interviews, the laboratory failed to document function checks for centrifuge revolutions per minute (rpm) for one (1) urinalysis centrifuge in calendar year 2018. Findings include: 1. During a tour at approximately 12:00 PM, the inspector noted one (1) McKesson Unico-LX centrifuge, serial number (SN) LT-1601948, in use for urine microscopic sample preparation. The LD and primary testing personnel stated: "We have Merco come in annually to document the urine centrifuge calibration speed. We calibrate the timer mechanism". 2. Review of the laboratory Standard Operating Procedure (SOP) manual revealed a Microscopic Examination of Urine procedure that stated: "spin aliquot of urine for 5 minutes at 1500 rpm". 3. Review of the equipment maintenance documentation revealed no records of calibration verification for the stated

	requirement of 1,500 rpm in calendar year 2018. The inspector requested to review the 2018 centrifuge maintenance documentation. No documentation was available for review. 4. In an exit interview with the Laboratory Director and testing personnel at approximately 1:30 PM, the above findings were confirmed.