

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1060629	(X3) Date Survey Completed 02/12/2019
Name of Provider or Supplier Laboratory Corporation Of America Holdings	Street Address, City, State 1133 College Ave, Bldg E, Suite 250, Manhattan, KS	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of observation of 2 of 2 pipettes and interview with the general supervisor, the laboratory failed to define and perform a function check to verify the accuracy of the pipettes. Findings: 1. Observation of the 100 microliter and 20 microliter, Eppendorf pipettes located in the laboratory available for use showed no function check since 2017. 2. Interview with the general supervisor on February 12, 2019 at 1:00 PM confirmed, the laboratory failed to define a protocol and perform a function check to verify the accuracy of the volumes of 2 of 2 pipettes.</p>