Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 12D0619283	**(X3) Date Survey Completed** 06/07/2019
Name of Provider or Supplier Diagnostic Laboratory Services Kona 2	**Street Address, City, State** 75-170 Hualalai St B200-201, Kailua Kona, HI	
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	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 review of laboratory preventative maintenance logs and an interview with the laboratory senior testing personnel on 06/07/2019, the lab failed to "perform and document function checks" for the monthly maintenance of the Horizon 755V centrifuge. The findings include: 1) The Centrifuge Preventative Maintenance Log for the year 2019 had no documentation to indicate the performance of the monthly centrifuge RPM maintenance for January 2019 to May 2019. 2) The laboratory senior testing personnel verified that the documentation was not done. 3) The monthly QA review failed to address the missing documentation.