Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0673285	08/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Gordo	71 Carazo St, Guaynabo, PR	

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
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on Hematology quality control records, backgrounds logs and interview with the laboratory supervisor on August 24, 2023 at 10:50 AM; it was determined that the laboratory failed to take any corrective action prior to patient's testing when the Background counts failed on April 10, 2023. The laboratory processed and reported 30 patient samples. The Findings include: a. The laboratory used Act-5 by Beckman Coulter to performed the hematology test. b. On August 24, 2023 at 10:25 AM the hematology quality control records and background logs was reviewed and showed that the startup of the Backgrounds counts failed on April 10, 2023 and no corrective action was documented. c. On August 24, 2023 at 10:50 AM the laboratory supervisor confirmed that the laboratory failed to tke any corrective action when the background count failed on April 10, 2023 and processed and reported 30 patients.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on Hematology quality control records, backgrounds logs and interview with

	the laboratory supervisor on August 24, 2023 at 10:50 AM; it was determined that the laboratory director failed to ensure that the laboratory personel take any corrective action prior to patient's testing when the Background counts failed on April 10, 2023. The laboratory processed and reported 30 patient samples. Refer to D5431.