Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D0658211	**(X3) Date Survey Completed** 10/27/2021
Name of Provider or Supplier Lab Clinico Bacteriologico Lorimar	**Street Address, City, State** 21 Severo Arana St Suite 1, San Sebastian, 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**
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on hematology calibration records reviewed (years 2019-2021) and laboratory director interview on October 27, 2021 at 10:00AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer's (each six months) for the hematology tests performed by the Cell Dyn Ruby hematology system. The findings include: 1. The laboratory uses a Cell Dyn Ruby hematology system for CBC (Complete blood count) patient's tests since December 30, 2020. 2. The manufacturer's instructions establishes that the laboratory must perform the calibration verification procedures each six months. 3. From January 2021 to October 26, 2021, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn Ruby hematology system. The calibration verification procedures were done on December 30, 2020. 4. The laboratory processed and reported three hundred thirty three (333) Complete blood count (CBC) patient's

	samples from January 2021 to October 26, 2021. 5. The laboratory director confirmed on October 27, 2021 that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn Ruby hematology system.
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 hematology quality control records review (years 2020-2021) and laboratory director interview at 10:00 AM on October 27, 2021, it was found that the laboratory director did not assure that quality control procedures related to calibration and calibration verification were followed. The finding includes: 1. The laboratory did not perform, each six months, calibration verification procedures for hematology. Refer to D5437.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on hematology quality control records review (years 2020-2021) and laboratory director interview at 10:00 AM on October 27, 2021, it was determined that the general supervisor did not assure that quality control procedures related to calibration and calibration verification were followed. Refer to D5437.