Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0682782	04/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Irizarry Guasch	Calle Emilio Gonzalez #100, Isabela, 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 verification records review, manufacturer's instructions and laboratory director interview on April 6,2018 at 10:40 A.M., it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the Cell Dyn 1700 system. The findings include: 1. The laboratory uses a Cell Dyn 1700 hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that for the Cell Dyn 1700 system, the calibration verification procedures must be perform each six months. 3. From April 2016 to April 2018, the calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn 1700 hematology system. The last calibration verification for Cell Dyn 1700 system was performed on April 2016. 4. The laboratory director confirmed on April 6, 2018 at 10:40 A.M., that the laboratory did not perform at least 6 months the calibration verification procedures for Cell Dyn 1700 system.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review and laboratory director on April 6, 2018 at 11:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment manual showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. 2. From April 2016 to April 2018, the laboratory did not evaluate aspects regarding the analytic system in the following areas: hematology. Refer to D 5437.
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 calibration verification records review and laboratory director interview on April 6, 2018 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5437.