Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0667290	02/23/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Negron	Box 429 Calle Rodriguez Serra 16, Sabana Grande, 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 quality control records review in 2016-2018 and laboratory director interview on February 23, 2018 at 10:00 AM, 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 Coulter Act diff 2 system. The findings include: 1. The laboratory uses a Coulter Act diff 2 hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that the laboratory perform the calibration verification procedures at least once every six months. 3. Review of records from January 2016 to January 2018, the records showed that the laboratory did not perform at least every six (6) months the calibration verification procedures for the Coulter Act diff 2 hematology system. The laboratoy was performed the calibration verification for Coulter Act diff 2 hematology system on

	July 2016 and May 2017. 4. The laboratory director stated on February 23, 2018, that the laboratory did not perform at least 6 months the calibration verification procedures for Coulter Act diff 2 hematology 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 in 2016-2018 and laboratory director interview on February 23, 2018 at 10:00 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 finding includes: 1.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 Coulter Act diff 2 system. Refer to D5437.
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 in 2016- 2018 and laboratory director interview on February 23, 2018 at 10:00 AM , it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5437.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review in 2016-2018 and laboratory director interview on February 23, 2018 at 10:00 AM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.
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 in 2016-2018 and laboratory director interview on February 23, 2018 at 10:00 AM, it was determined that the general supervisor failed to follow quality control procedures. The finding includes: 1. The laboratory general supervisor 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 Coulter Act diff 2 system. Refer to D5437.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on hematology quality control records review in 2016-2018 and laboratory director interview on February 23, 2018 at 10:00 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. 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 Coulter Act diff 2 system. Refer to D5437.