Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0956171	01/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Villa Ana Las 400's	Carr 185 Km 158 Bo Las 400'S, Carolina, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory technical supervisor interview on January 3, 2018 at 9:00 a.m., it was found that the laboratory did not perform the technical supervisor (MT # 6296) competence. The findings include: 1.. The laboratory competence evaluation showed that personnel competence must be done every year. 2. The personnel records showed that the last technical supervisor competence was in 2015. The technical supervisor stated the laboratory director did not perform her competence evaluation for the last two years 2016-2017.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review in 2016-2017 and laboratory general supervisor interview on January 3, 2018 at 9:00 a.m., it was determined that laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for general laboratory systems. The findings include: 1.

	The laboratory quality assessment records showed that personnel competence must be performed every year. 2. The laboratory did not evaluate the personnel competence since 2015. Refer to D5209.
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 2016-2017 and laboratory general supervisor interview on January 3., 2018 at 10:00 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 Emerald hematology system. The findings include: 1. The laboratory uses a Cell Dyn Emerald hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions showed that for the Cell Dyn Emerald system establish that the laboratory perform the calibration verification procedures each six months. 3. From January 2016 to December 2017, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Cell Dyn Emerald hematology system. The laboratoy was performed the calibration verification for Cell Dyn Emerald hematology system on May 2016 and March 2017. 4. The laboratory general supervisor stated on January 3, 2018, that the laboratory did not perform at least 6 months the calibration verification procedures for Cell Dyn Emerald 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 2016-2017 and laboratory general supervisor interview on January 3, 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 (each six months) for the hematology tests performed by the Cell Dyn Emerald hematology 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 2016-2017 and laboratory general supervisor interview on January 3, 2018 at 10:30 a.m., it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems for hematology tests. 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) written procedures review, QA recordsin 2016-2017 and laboratory general supervisor interview on January 3, 2018 at 10:30 a.m., it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. The laboratory did not perform the technical supervisor (MT # 6296) competence. Refer to D5291. 2. 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 Emerald hematology system. 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 2016-2017 and laboratory general supervisor interview on January 3, 2018 at 10:30 a.m., it was determined that the general supervisor failed to follow quality control procedures. 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 quality control records review in 2016-2017 and laboratory general supervisor interview on January 3, 2018 at 10:30 a.m., 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 (each six months) for the hematology tests performed by the Cell Dyn Emerald hematology system. Refer to D5437.