Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0710605	10/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Caribe	Munoz Rivera 35, Rincon, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on refrigerator temperature records review (years 2018-2019) and laboratory general supervisor interview at 11:15 AM on October 22, 2019, it was determined that the laboratory failed to monitor the refrigerator temperature used to storage the hematology controls, routine chemistry reagents and endocrinology reagents. The findings include: 1. On October 22, 2019 at 11:15 AM the laboratory refrigerator temperature records (January 2018 to October 21, 2019) were reviewed. 2. The manufacturer's establishes that hematology controls, routine chemistry and endocrinology reagents must be storage at a temperature between 2-8 C . 3. Review of the refrigerator temperature records showed that the documented temperature was out of range on 21 out of 491 days. Eight days were recorded at 1 C and thirteen at 9 C. 4. The laboratory general supervisor confirmed on October 22, 2019 that the laboratory did not assure the adequate reagent storage temperature during the years 2018 and 2019.
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 2018-2019) and laboratory general supervisor interview on October 22, 2019 at 11:00 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 Horiba Pentra 60 C+ system. The findings include: 1. The laboratory uses a Pentra 60 C+ hematology system for CBC (Complete blood count) patient's tests since April 1, 2018. 2. The manufacturer's instructions establishes that the laboratory must perform the calibration verification procedures each six months. 3. From March 2018 to October 22, 2019, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Pentra 60 C+ hematology system. The calibration verification procedures were done on October 2018 and July 2019. 4. The laboratory processed and reported One thousand thirty seven (1037) Complete blood count (CBC) patient's samples from November 2018 to July 2019. 5. The laboratory general supervisor confirmed on October 22, 2019 that the laboratory did not perform at least every 6 months the calibration verification procedures for the Pentra 60 C+ hematology system.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphillis serology quality control records review (years 2018-2019) and laboratory general supervisor interview at 9:30 AM on October 22, 2019, it was determined that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test by Detector RPR Method for positive and negative reactivity prior to placed it in routine use. The findings include: 1. The laboratory quality control records were review from January 2018 to October 21, 2019. 2. The laboratory received the following reagent kit for Detector RPR Method and no evaluation of their reactivity was performed: Test Lot Expiration Date RPR 9514 3/31/2021 3. The laboratory processed and reported one hundred sixty eight (1682) RPR (Rapid plasma reagin)

	patient's samples since March 4, 2019. 4. The laboratory general supervisor confirmed on October 22, 2019 that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use.
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 and syphillis serology quality control records review (years 2018-2019) and laboratory general supervisor interview at 11:30 AM on October 22, 2019, it was found that the laboratory director did not assure that quality control procedures related to calibration verification and evaluation of new reagents lots were followed. The findings include: 1. The laboratory did not perform, each six months, calibration verification procedures for hematology. Refer to D5437. 2. The laboratory did not evaluate the new RPR reagent kit. Refer to D5471.
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 quality control records review(years 2018-2019) and laboratory general supervisor interview at 11:30 AM on October 22, 2019, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D6177.
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 (years 2018-2019) and laboratory general supervisor interview at 11:30 AM on October 22, 2019, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The testing personnel failed to monitor and take remedial actions when the refrigerator temperature was out of range. Refer to D5413. 2. The testing personnel failed did not followed the manufacturer instructions related to hematology calibration verification procedures. Refer to D5437. 3. The testing personnel did not evaluate new RPR reagent lots. Refer to D5471.