Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1107161	09/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Borinquen - Dorado	Centro Comercial Plaza Dorada Ave Jose Efron Esq, Dorado, 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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on C-reactive protein (CRP) and Rheumatoid Arthritis (RA) testing records (years 2018 and 2019) review and general supervisor interview on September 11, 2019 at 11:45 AM, it was determined that the laboratory failed to include at least once a day, a negative and a positive control materials, when 5 out of 5 patients specimens were tested for CRP and RA quantitative tests from March 22, 2018 to May 15, 2019. The findings include: 1. On September 11, 2019 at 11:45 AM, the CRP and RA testing records showed that the laboratory did not include at least once a day a negative and a positive control materials when the following 5 patients specimens were tested for CRP and RA quantitative tests from March 22, 2018 to May 15, 2019: Date Test patient specimen 1. 03/22/2018 RA #8149651 2. 04/18/2018 CRP #8201960 3. 04/30/2018 RA #8224798 4. 12/29/2018 CRP #8669761 5. 05/15/2019 CRP #8975445 2. The general supervisor stated on September 11, 2019 at 11:45 AM, that the laboratory performed the quality control procedures each day of testing but, not recorded the controls results those days.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the

	following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on Mononucleosis (MONO) qualitative tests testing records, (years 2018 and 2019), Mono tests reports review and general supervisor interview on September 11, 2019 at 11:45 AM, it was determined that the laboratory failed to document the testing record with the date of testing, patients name, requisition numbers, tests results and the identity of the personnel who performed the test when 2 of 2 patients specimens were tested and reported for MONO qualitative tests from April 30, 2018 to March 27, 2019. The Findings include: 1. The Mono tests reports showed that the laboratory reported the following 2 patients specimens for MONO qualitative tests: a. Patients # 8224619 on April 30, 2018. b. Patients # 8872533 on March 27, 2019. 2. On September 11, 2019 at 11:45 AM, the MONO qualitative tests testing records showed that the laboratory did not document the testing record with the date of testing, patients name, requisition numbers, tests results nor the identity of the personnel who performed the patients specimens for MONO tests on April 30, 2018 and on March 27, 2019. 3. The general supervisor stated on September 11, 2019 at 11: 45 AM, that the laboratory performed the testing procedures for those patients MONO specimens but, not documented the testing records those days.
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 CRP, RA, MONO qualitative tests testing records (years 2018 and 2019), Mono tests reports review and general supervisor interview on September 11, 2019 at 11:45 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for General Immunology from March 22, 2018 to May 15, 2019. Refer to D 5449 (The laboratory did not include at least once a day a negative and a positive control materials when 5 out of 5 patients specimens were tested for CRP and RA qualitative tests from March 22, 2018 to May 15, 2019). Refer to D 5787 (The laboratory did not document the testing record with the date of testing, patients name, requisition numbers, tests results and the identity of the personnel who performed the test when 2 of 2 patients specimens were tested and reported for MONO qualitative tests from April 30, 2018 to March 27, 2019).
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 CRP, RA, MONO qualitative tests testing records (years 2018 and 2019), Mono tests reports review and general supervisor interview on September 11, 2019 at 11:45 AM, it was determined that the general supervisor failed to to perform day-to-day supervision for the personnel that performing testing and reporting the CRP, RA and MONO tests results from March 22, 2018 to May 15, 2019. Refer to D 5449 (The laboratory did not include at least once a day, a negative and a positive control materials when 5 out of 5 patients specimens were tested for CRP and RA qualitative tests from March 22, 2018 to May 15, 2019). Refer to D 5787 (The laboratory did not document the testing record with the date of testing, patients name, requisition numbers, tests results and the identity of the personnel who performed the test when 2 of 2 patients specimens were tested and reported for MONO qualitative tests from April 30, 2018 to March 27, 2019).
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 CRP, RA, MONO qualitative tests testing records (years 2018 and 2019), Mono tests reports review and general supervisor interview on September 11, 2019 at 11:45 AM, it was determined that the testing personnel failed to follow quality control procedures for the CRP, RA and MONO tests from March 22, 2018 to May 15, 2019. Refer to D 5449 (The laboratory did not include at least once a day, a negative and a positive control materials when 5 out of 5 patients specimens were tested for CRP and RA quantitative tests from March 22, 2018 to May 15, 2019). Refer to D 5787 (The laboratory did not document the testing record with the date of testing, patients name, requisition numbers, tests results and the identity of the personnel who performed the test when 2 of 2 patients specimens were tested and reported for MONO quantitative tests from April 30, 2018 to March 27, 2019).