Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2037156	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Tiago	Urbanizacion San Feliz Calle 1 , A-2, Corozal, 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
D2061	VIROLOGY CFR(s): 493.831(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (2016 to 2018) and laboratory general supervisor interview on May 18, 2018 at 10:30 A.M., it was determined that the laboratory failed to report the proficiency testing results within the time frame established by the program. The finding includes: 1. Proficiency testing records were reviewed from February 2016 to February 2018. 2. The deadline of the third testing event report of virology tests (Influenza A& B) was December 23, 2016. 3. The laboratory did not report the third testing event of virology within the time frame established by the Proficiency Testing Program. 4. The laboratory general supervisor confirmed that the laboratory did not report the virology proficiency testing results of the third testing event within the time frame established by the Proficiency Testing Program.
D2071	SYPHILIS SEROLOGY CFR(s): 493.835(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (2016 to 2018)

	and laboratory general supervisor interview on May 18, 2018 at 10:30 A.M., it was determined that the laboratory failed to report the proficiency testing results within the time frame established by the program. The finding includes: 1. Proficiency testing records were reviewed from February 2016 to February 2018. 2. The deadline of the third testing event report of syphilis serology tests was December 23, 2016. 3. The laboratory did not report the third testing event of syphilis serology within the time frame established by the Proficiency Testing Program. 4. The laboratory general supervisor confirmed that the laboratory did not report the syphilis serology proficiency testing results of the third testing event within the time frame established by the Proficiency Testing Program.
D2081	GENERAL IMMUNOLOGY CFR(s): 493.837(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (2016 to 2018) and laboratory general supervisor interview on May 18, 2018 at 10:30 A.M., it was determined that the laboratory failed to report the proficiency testing results within the time frame established by the program. The finding includes: 1. Proficiency testing records were reviewed from February 2016 to February 2018. 2. The deadline of the third testing event report of general immunology tests (rheumatoid factor and c reactive protein) was December 23, 2016. 3. The laboratory did not report the third testing event of general immunology within the time frame established by the Proficiency Testing Program. 4. The laboratory general supervisor confirmed that the laboratory did not report the general immunology proficiency testing results of the third testing event within the time frame established by the Proficiency Testing Program.
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 general supervisor interview on May 18,2018 at 11:00 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 3200 system. The findings include: 1. The laboratory uses a Cell Dyn 3200 hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions establishes that for the Cell Dyn 3200 system, the calibration verification procedures must be perform each six months. 3. From 2016 to May 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 calibration verification for Cell Dyn 1700 system was performed on October 2016, March 2017 and January 2018. 4. The laboratory general supervisor confirmed on May 18, 2018 at 11:00 A.M., that the laboratory did not perform at least 6 months the calibration verification procedures for Cell Dyn 3200 system.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review and laboratory general supervisor interview on May 18, 2018 at 11:00 AM, it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2061, D2071 and D2081.
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 calibration verification records review and laboratory general supervisor interview on May 18, 2018 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements 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 3200 system. Refer to D5437.
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 calibration verification records review (2016 to 2018) and laboratory general supervisor interview on May 18, 2018 at 11:30 AM, it was determined that the general supervisor failed to ensure compliance with the requirements 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 3200 system. Refer to D5437.