Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0865451	03/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Post Center Clinical Laboratory	60 North Post St Edif Post Ctr Of 105, Mayaguez, 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
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 in 2016-2017 and laboratory general superviso interview on March 9, 2018 at 10:00 AM, it was determined that the laboratory failed to report the general immunology proficiency testing results withim the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2016 to July 2017. 2. The deadline of the first testing event report of general immunology tests was May 2017. 3. The laboratory did not report the first testing event of general immunology within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event. 4. The laboratory general supervisorr confirmed on March 9, 2018 at 10:00 A.M. that the laboratory did not report the general immunology proficiency testing results of the first testing event within the time frame established by the Proficiency Testing Program.
D2127	HEMATOLOGY CFR(s): 493.851(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 reviewed (2016-2017) and laboratory general supervisor interview on March 9, 2018 at 10:00 A.M., it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2016 to July 2017. 2. The return deadline of the second testing event report of hematology tests was July 29, 2016. 3. The laboratory did not report the second testing event of hematology within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event. 4. The laboratory general supervisor confirmed on March 9, 2018 at 10:00 A.M. that the laboratory did not report the hematology proficiency testing results of the second testing event within the time frame established by the Proficiency Testing Program.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of hematology statistical parameters from August 1, 20117 to September 13 2017, review of patient data log for year 2017 and interview with the laboratory general supervisor on March 9, 2018 at 11:10 AM, it was found that the laboratory did not evaluate nor define the statistical values of the lot number of the commercial control material used by the Excell Drew 3 hematology instrument. The findings include: 1. The laboratory uses Excell Dree 3 for hematology patient's samples tests. 2. The laboratory did not have statistical data (Levy-Jennings, control value mean and limits) of the control materials used from August 1, 2017 to September 13, 2017. 3. The patient data log from August 1, 2017 to September 13, 2017, showed that the laboratory performed one hundred fifty (150) Complete Blood Count (CBC) patient's samples. 4. The laboratory processed and reported one hundred fifty (150) CBC's patient's samples those days. 5. The laboratory general supervisor confirmed on March 9, 2018 at 11:10 AM that the laboratory failed to evaluate, monitor and take remedial actions for the statistical data (Levy-Jennings) those days.
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 general supervisor interview on March 9, 2018 at 11:10 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 did not evaluate nor define the statistical values of the lot number of the commercial control material used by the Excell Drew 3 hematology instrument from August 1, 2017 to September 13, 2017. Refer to D5469.
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 testing records review in 2016-2017 and laboratory general supervisor interview on March 9, 2018 at 10:00 AM, it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2081 and D2127.
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 from January 2016 to March 8, 2018 and laboratory general supervisor interview at 11:10 AM on March 9, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5469.
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

	general supervisor interview at 11:10 AM on March 9, 2018, 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 general supervisor interview on March 9, 2018 at 11:10 AM, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory did not evaluate nor define the statistical values of the lot number of the commercial control material used by the Excell Drew 3 hematology instrument. Refer to D5469. 2. The laboratory failed to report the hematology proficiency testing results within the time frame established by the Puerto Rico proficiency program. Refer to D2127. 3. The laboratory failed to report the general immunology proficiency testing results within the time frame established by the Puerto Rico proficiency program. Refer to D2081.