Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0977871	02/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Obymar	Carr 420 Km 04 Barrio Voladoras, Moca, 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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of Proficiency testing records, review of Puerto Rico Proficiency Testing records (2018) and laboratory supervisor interview on February 22, 2019 at 9: 40 A.M., it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed from February 2018 to December 2018. 2. The laboratory did not have available the proficiency testing records documentation from February 2017 to December 2017. 3. The laboratory general supervisor confirmed on February 22, 2019 at 9:45 A.M. , that the laboratory did not have available the Proficiency Testing records from February 2017 to December 2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on manufacturer's written instructions, hematology preventive maintenance records review (2017-2018) and laboratory general supervisor interview on February 22, 2019 at 10:15 A.M., it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Cell Dyn 3600 systems. The findings include: 1. The laboratory uses since May 2018 the Cell Dyn 3600 system to perform

	hematology tests. 2. The manufacturer's written instructions establishes that the laboratory must document and perform the daily, weekly preventive maintenance. 3. Review of preventive maintenance records since May 2018 , showed that the laboratory did not perform nor document the daily preventive maintenance (run auto-clean cycle, clean closed sample aspiration needle , clean closed sample tower) the weekly preventive maintenance (clean sample loader and racks, check sample transfer pump tubing) and the monthly preventive maintenance (clean fan filter, run extended auto-clean and replace diluent/sheath filter). 4. The laboratory processed and reported 11,715 hematology patient samples on 2018. 5. The laboratory general supervisor confirmed on February 22, 2019 at 10:30 A.M. that the laboratory failed to follow written instructions for the preventive maintenance of Cell Dyn 3600 systems.
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 review of general immunology quality control records and laboratory general supervisor interview on February 22, 2019 at 11:00 a.m. , it was determined that the laboratory failed to include a negative and positive control material when performed CRP (C-reactive protein) qualitative test. The findingS include : 1. The laboratory performed CRP (C-reactive protein) by agglutination method (Teco). 2. The general immunology quality control records were review from January 2017 to December 2018. 3. The records showed that the laboratory did not include a negative and positive control material the following days: January 22, 2018 - patient identification-101264 November 29, 2018 (patient identification-1042871) 4. The laboratory general supervisor confirmed on February 22, 2019 at 11:00 A.M., that the laboratory failed include a negative and positive control material during 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 review of hematology and general immunology quality control records (2017-2018) and interview with the laboratory general supervisor interview on February 22, 2019 at 11:30 A.M., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory failed to follow written instructions for the preventive maintenance of Cell Dyn 3600 systems. Refer to D5429. 2. The laboratory failed to include a negative and positive control material when performed CRP (C-reactive protein) qualitative test. Refer to D5449.

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 review of hematology and general immunology quality control records (2017-2018) and interview with the laboratory general supervisor interview on February 22, 2019 at 11:30 A.M., it was determined that the laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory failed to follow written instructions for the preventive maintenance of Cell Dyn 3600 systems. Refer to D5429. 2. The laboratory failed to include a negative and positive control material when performed CRP (C-reactive protein) qualitative test. Refer to D5449.