Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658083	06/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Y De Referencia Del Este	303 General Valero Avenue, Fajardo, 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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Immuno Concepts ANA HEp-2000 manufacturer's instruction, antinuclear antibody (ANA) quality control records (years 2018 and 2019) and interview with testing personnel (MT-1 and MT-2) on June 18, 2019 at 12:30 PM, it was determined that the laboratory failed to meet the requirements of the General Immunology (Ana tests). Refer to D 5405- The laboratory failed to follow manufacturer's instruction when performed ANA test on December 14, 2018, December 27, 2018, December 28, 2018 and June 7, 2019.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on antinuclear antibody test (ANA) manufacturer's instruction review, antinuclear antibody test quality control records review (year 2018-2019) and laboratory testing personnel interview (MT-1 and MT-2) on June 18, 2019 at 10:30 A. M., it was determined that the laboratory failed to follow manufacturer's instruction

	when performed the ANA test . The findings include: 1. The laboratory performed ANA test by Hep-2000 Colorzyme ANA-Ro test system . 2. The manufacturer's instruction establishes that a positive, negative and Phosphate buffered saline powder (PBS) controls should be run in the wells provided for quality control on each slide. The kit provided a substrate slides with ten wells. 3. The antinuclear antibody quality control records showed that the following days the laboratory performed ANA test patient samples and did not include controls materials on each slide: December 14, 2018- 28 patient samples December 27, 2018 -17 patient samples December 28, 2018- 6 patient samples June 7, 2019- 30 patient samples 4. All patient result were reviewed and found that these results were negative for antinuclear antibody. 5. The laboratory testing personnel (MT-1 and MT-2) confirmed on June 18, 2019 at 12:00 P.M, that the laboratory included a positive, negative and PBS controls) with each day of testing instead with each slide.
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(year 2018-2019) and testing personnel (MT-1) on June 18, 2019 at 9:30 A.M, 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 aspects regarding: failed to follow manufacturer's instruction when performed the ANA test . Refer to D5405.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on General Immunology quality control records review (year 2018-2019) and interview with the laboratory testing personnel (MT-1) on June 18, 2019 at 11:30 A. M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements for General Immunology. The finding includes: 1. The laboratory director failed to ensure compliance with the General Immunology requirements. Refer to D6093.
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 General Immunology quality control records review (year 2018-2019) and laboratory testing personnel (MT-1) interview on June 18, 2019 at 12:30 P.M, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5405.
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 General Immunology quality control records review (year 2018-2019) and testing personnel (MT-1) interview on June 18, 2019 at 12:00 P.M., it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results. Refer to D 5405.
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 antinuclear antibody test (ANA) manufacturer's instruction review, antinuclear antibody test quality control records review (year 2018-2019) and laboratory testing personnel interview (MT-1 and MT-2) on June 18, 2019 at 10:30 A. M., it was determined that the laboratory testing personnel failed to follow manufacturer's instruction when performed the ANA test . Refer to D5405.