Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0662395	09/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico San Antonio	Avenida Emerito Estrada Rivera #1486, San Sebastian, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on routine chemistry quality control records review (2018-2019) and interview with the laboratory director on September 13, 2019, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for routine chemistry subspecialty . The findings include: 1. The laboratory failed to follow manufacturer's instructions when patient specimens were tested for routine chemistry tests by the Dimension Xpand system. Refer to D 5405. 2. The laboratory failed to verify the performance specifications of the Dimension Xpand routine chemistry system when the laboratory was relocated on May 15, 2019. Refer to D 5421.
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 manufacturer's instructions, routine chemistry and endocrinology quality

	control records review in 2017-2018 and laboratory director interview at 10:30 a.m. on September 13, 2019, it was determined that the laboratory failed to follow manufacturer's instructions when patient specimens were tested for routine chemistry tests by the Dimension Xpand system. The findings include: 1. The laboratory uses Dimension Xpand system to perform routine chemistry and endocrinology patient tests. 2. The manufacturer establishes that two levels of control material (normal and high) must be included each day of testing. 3. Review of routine chemistry quality control records from January 2018 to September 2019, showed that the laboratory did not include the two levels of controls from January 2, 2019 to February 7, 2019. 4. The laboratory processed and reported 8,854 routine chemistry analytes during those days. 5. The laboratory director confirmed that the laboratory failed to follow manufacturer's instructions (regarding testing of control materials) when patient specimens were tested for routine chemistry by the Dimension Xpand system.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: 1. Based on lack of hematology performance specifications records and laboratory director interview at 10:00 a.m. on September 13, 2019, it was determined that the laboratory failed to verify the performance specifications of the Cell Dyn 3200 hematology system when the laboratory was relocated on May 15, 2019. The findings include: a. The laboratory was relocated on May 15, 2019. There were not records of the performance verification of specifications. b. The laboratory director confirmed on September 13, 2019 at 10:00 A.M. that the laboratory failed to perform the performance specifications of the Cell Dyn 3200 system prior to begin to test patient samples for Complete Blood Count hematology tests. c. The laboratory processed and reported 1,084 Complete Blood Count (CBC) since May 15, 2019. 2. Based on lack of routine chemistry performance specifications records and laboratory director interview at 10:00 a.m. on September 13, 2019, it was determined that the laboratory failed to verify the performance specifications of the Dimension Xpand system when the laboratory was relocated on May 15, 2019. The findings include: a. The laboratory was relocated on May 15, 2019. There were not records of the performance verification of specifications. b. The laboratory director confirmed on September 13, 2019 at 10:00 A.M. that the laboratory failed to perform the performance specifications of the Dimension Xpand system prior to begin to test patient samples for routine chemistry tests. c. The laboratory processed and reported 14,288 routine chemistry analytes samples since May 15, 2019.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on hematology and routine chemistry performance specifications records review (2019) and laboratory director interview on September 13, 2019 at 11:30 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems requirements. Refer to D5405, D5421.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on hematology and routine chemistry lack performance specifications records (2019) and laboratory director interview on September 13, 2019 at 11:30 A.M. it was determined that laboratory director failed to ensure compliance with the requirements for hematology and routine chemistry analytic systems. Refer to D5405 and D5421.