Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D0662395	**(X3) Date Survey Completed** 08/24/2023
Name of Provider or Supplier Laboratorio Clinico San Antonio	**Street Address, City, State** 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**
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 Mycoplasma pneumoniae quality control records patient records review (year 2022-2023) and interview with the laboratory director on August 2, 2023 at 12: 15 P.M, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to D5449
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records review (year 2022-2023) and interview with the laboratory director on August 24, 2023 at 10:20 A.M., it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the electrolytes tests processed by the Dimension ExL 200 system. The findings include: 1. The laboratory used the Dimension ExL 200 system to perform routine electrolytes tests. 2. The laboratory performed the electrolytes calibration verification procedures on 12/2021/ 6/2022 and 7/2023. 3. Review of routine chemistry calibration verification records showed that the laboratory did not perform the electrolytes calibration verification procedure on December 2022. (review on August 24, 2023 at 10:25 A.M.) 4. The laboratory processed and reported from December 2022 to June 2023 eightysix electrolytes patient samples. (review on August 24, 2023 at 10:30 A.M.) 5. The laboratory director confirmed on August 24, 2023 at 10:35 A.M., that the laboratory failed to perform , at least every 6 months, the calibration verification procedures for electrolyte tests.
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 General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2022-2023) and laboratory director interview on August 24, 2023 at 11:10 A.M., it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. The findings include: 1. General Immunology (Mycoplasma pneumoniae test) quality control records were review on August 24, 2023 at 11: 10 A.M., from October 2022 to August 2023. 2. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include any control material each day of patient testing since October 2022. (review on August 24, 2023 at 11: 15 A.M.) 3. The laboratory director confirmed on August 24, 2023 at 11: 25 A.M., that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test. 4. The laboratory did not include any control material, when 191 out 191 patient specimen were processed and since October 2022. (review on August 24, 2023 at 11: 25 A.M.)

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 review of General Inmunology quality control records (year 2022-2023) , it was determined that the laboratory director failed to fulfill her responsibilities with the Mycoplasma pneumoniae analytic requirements. Refer to D6020.
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 routine chemistry and Mycoplasma pneumoniae quality control records review (2022-2023) , and interview with the laboratory director on August 24, 2023 at 11:45 A.M., it was determined that the laboratory director failed to follow quality control procedures for the routine chemistry tests and Mycoplasma pneumoniae tests. Refer to D5439 and D 5449.