Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D0658247	**(X3) Date Survey Completed** 06/29/2023
Name of Provider or Supplier Lab Clinico Metabolico	**Street Address, City, State** 1507 Calle Profesor Augusto Rodriguez, Santurce, 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**
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on bacteriology quality control records review and laboratory director interview on June 29, 2023 a t 10:00 a.m. , it was determined that the laboratory failed to include control organism , each day of patient antimicrobial susceptibility test . The findings include: 1. The laboratory performed antimicrobial susceptibility test by the Kirby Bauer method. (reviewed on June 29, 20233 at 10:00 a.m.) 2. The records showed that the laboratory did not include a control organism , when patient specimens were tested for antimicrobial susceptibility tests when specimens antimicrobial susceptibility were tested on 4/22/23 and 4/27/23. (reviewed on June 29, 2023 at 10:10 a.m.) 3. The laboratory performed and reported two patients specimens antimicrobial susceptibility tests for gram negative organism those days.(reviewed on June 29, 2023 at 10:15 a.m.) 4. The laboratory director confirmed on June 29, 2023 at 10:25 a.m. that the laboratory failed to check each day of use the antimicrobial susceptibility tests.
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 bacteriology quality control records review and laboratory director interview on June 29, 2023 at 10:30 a.m. it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. The findings include: 1.The laboratory failed to check each day of testing the antimicrobial susceptibility tests . Refer to D5507.