Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0663075	01/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Las Lomas	1700 Ave J T Pinero Esq San Patricio, Rio Piedras, 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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Chlamydia/Gonorrhoeae quality control records review and interview with the laboratory director on January 28, 2021 at 12:07 PM, it was determined that the laboratory failed to comply with the analytic system requirements of bacteriology for the Chlamydia/Gonorrhoeae qualitative tests . The finding includes: 1. The laboratory did not include each day of testing a negative and a positive control materials when 34 out of 34 patients specimens were tested and reported for qualitative Chlamydia /Gonorrhoeae from July 20, 2020 to September 22, 2020 by the Gen XPERT system. Refer to D 5449.
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 Chlamydia/Gonorrhoeae quality control records review and interview with

	the laboratory director on January 28, 2021 at 12:07 PM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 34 out of 34 patients specimens were tested and reported for qualitative Chlamydia/Gonorrhoeae from July 20, 2020 to September 22, 2020 by the Gen XPERT system. The findings include : 1. On January 28, 2021 at 12:07 PM, the Chlamydia/Gonorrhoeae quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials when 34 out of 34 patients specimens were tested and reported for Chlamydia/Gonorrhoeae from July 20, 2020 to September 22, 2020 by the Gen XPERT system. 2. The laboratory includes the negative and the positive control materials when it placed in routine use the following BOX lots numbers Gen XPERT Chlamydia/Gonorrhoeae reagents kit: a. BOX lot 100018175 on July 20, 2020. b. BOX lot 1000203116 on August 13, 2020. 3. The laboratory director confirmed on January 28, 2021 at 12:07 PM, that the quality control records showed that the laboratory did not include the negative and the positive control materials each day of qualitative Chlamydia/Gonorrhoeae testing, instead the laboratory includes a negative and a positive control materials when it places in routine use every new BOX lot or new shipping of the Chlamydia /Gonorrhoeae Gen XPERT reagents Kit. 4. The laboratory tested and reported 34 out of 34 patients specimens patients specimens for qualitative Chlamydia/Gonorrhoeae tests from July 20, 2020 to September 22, 2020 by the Gen XPERT system.
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 Chlamydia/Gonorrhoeae quality control records review and interview with the laboratory director on January 28, 2021 at 12:07 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system of bacteriology for the Chlamydia/Gonorrhoeae qualitative tests . The finding includes: 1. The laboratory director failed to comply with the analytic system requirements of bacteriology for the Chlamydia/Gonorrhoeae qualitative tests Refer to D 6093.
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 Chlamydia/Gonorrhoeae quality control records review and interview with the laboratory director on January 28, 2021 at 12:07 PM, it was determined that the laboratory director failed to comply with the analytic system requirements of bacteriology for the Chlamydia/Gonorrhoeae qualitative tests . The finding includes: 1. The laboratory failed to comply with the analytic system requirements of bacteriology for the Chlamydia/Gonorrhoeae qualitative tests. Refer to D 5002.