Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0973194	03/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Pomales	Carr #3 Km 151 Comunidad Coqui, Salinas, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review Proficiency Testing record (years 2020 to 2022), bacteriology patient's testing records, and laboratory supervisor interview, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for Bacteriology throat and ulcer cultures tests when it processed and reported sixteen out of sixteen patient's throat cultures and three out of three patient's ulcers cultures from January 17, 2020 to December 21, 2021. The findings include: 1. The Proficiency Testing records showed no results for Bacteriology throat and ulcer cultures tests since January 17, 2020. 2. On March 15, 2022 at 10:15 AM, the bacteriology patient's testing record showed that the laboratory performed the primary inoculation in patient's throat and ulcer cultures. The laboratory reported at 48 hours the no growth for the ulcer cultures, the normal flora for the throat culture and referred cultures plates to another laboratory for identification and susceptibility tests from January 17, 2020 to December 21, 2021. 3. The laboratory reported sixteen patient's throat cultures as Normal Throat Flora from January 17, 2020 to July 29 to 2021. 4. The laboratory reported three patient's ulcers cultures as No Growth After 48 HR Of Incubation from August 27, 2021 to December 21, 2021. 5. The supervisor confirmed on March 15, 2022 at 10:20 AM, that the laboratory performed the primary

	inoculation for the patients throat and ulcer cultures, reported the no growth results for the ulcer culture, the normal flora results for the throat cultures and referred cultures plates to another laboratory for organisms identification and susceptibility tests since January 17, 2020.
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 2020 to 2022) and interview with the laboratory supervisor, it was determined that the laboratory did not include each day of testing the external positive nor the negative control materials when 132 out of 132 patients specimens were tested and reported for of Mycoplasma pneumoniae patient testing from March 5, 2020 to March 14, 2022. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette method to perform the Mycoplasma pneumoniae qualitative tests since March 5, 2020. 2. On March 15, 2022 at 11:17 AM, review of Mycoplasma pneumoniae quality control record showed that the laboratory did not include each day of testing the external positive nor the negative control materials from March 5, 2020 to March 14, 2022. 3. The laboratory supervisor confirmed on March 15, 2022 at 11:20 AM, that the laboratory failed to include each day of testing the external negative and positive control material . He stated that the laboratory run the external control when it received a new reagent kit on 5/28/2020, 2/15/2021, 9/7 /2021 and 12/8/2021 and always verified the internal control. 4. The laboratory processed and reported 132 patient samples for Mycoplasma pneumoniae qualitative tests from March 5, 2020 to March 14, 2022.
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 review Proficiency Testing record (years 2020 to 2022), bacteriology patient's testing records, General Immunology (Mycoplasma pneumoniae test) quality control records and laboratory supervisor interview, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the Proficiency Testing Program and the analytical system requirements. Refer to D 6088 (The laboratory director failed to ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for for Bacteriology throat and ulcer cultures tests). Refer to D 6093 (The laboratory director failed to establish the quality control procedures for the Mycoplasma pneumoniae test).

D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on review Proficiency Testing record (years 2020 to 2022), bacteriology patient's testing records, and laboratory supervisor interview, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for for Bacteriology throat and ulcer cultures tests. Refer to D 2000 (The laboratory failed to enroll in an HHS approved Proficiency Testing Program for Bacteriology throat and ulcer cultures tests when it processed and reported sixteen out of sixteen patient's throat cultures and three out of three patient's ulcers cultures from January 17, 2020 to December 21, 2021).
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 (Mycoplasma pneumoniae test) quality control records review(years 2020 to 2022) and interview with the laboratory supervisor, it was determined that the laboratory director failed to establish the quality control procedures for the Mycoplasma pneumoniae test March 5, 2020 to March 14, 2022. Refer to D 5449 (The laboratory did not include every day of testing the positive and the negative control materials for Mycoplasma pneumoniae test).