Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0677377	12/07/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico De Loiza	Pr-3 Km 19, Hm 8 Marginal, Loiza, 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
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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and laboratory general supervisor, it was determined that the laboratory failed to follow the manufacturer's instruction when 1,221 out of 1,510 patient specimen were tested for Mycoplasma by Immuno Card Meridian method from January 2022 to December 2022. The findings include: 1. On December 7, 2022 at 11:06am the manufacturer's instructions was requested. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On December 7, 2022 at 11:10 AM, the Mycoplasma testing records showed that the laboratory did not follow the manufacturer instruction when it processed and report 1,221 out of 1,510 sample specimen with a temperature out of range from January 2022 to December 2022. 3. The laboratory supervisor confirmed on December 7, 2022 at 11: 25 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing of mycoplasma pneumoniae test. 4. The laboratory processed and reported 1,221 out of 1,510 patient specimen for mycoplasma test out of the manufacturer's temperature range from January 2022 to December 2022.
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 Mycoplasma pneumonia test quality control records and interview with the laboratory supervisor; it was determined that the laboratory did not assure that the established quality control program for Mycoplasma pneumonia tests were followed. Refer to D5405.