Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0667291	11/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Griselle	Calle 1 D 2 Urb Villa Maria, Manati, 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 general supervisor interview on November 5, 2021 at 9:56 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 59 out of 64 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from September 1, 2021 to September 23, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On November 5, 2021 at 9:56 AM, the Mycoplasma testing records showed that the laboratory tested patient's specimens for Mycoplasma by Immuno Card Meridian method and the temperature was out of range from September 1, 2021 to September 23, 2021. 3. The general supervisor confirmed on November 5, 2021 at 9:56 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 59 out of 64 patients specimens for mycoplasma test by Immuno Card Meridian method from September 1, 2021 to September 23, 2021.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently,

	and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and general supervisor interview on November 5, 2021 at 9:56 AM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the that the laboratory did not follow the manufacture's instructions for the temperature of processing on September 2021. Refer D5405.