

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0945814	(X3) Date Survey Completed 12/02/2021
Name of Provider or Supplier Laboratorio Clinico Montellano	Street Address, City, State Carr 14 Km 72 Hm 3, Cayey, 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	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review from August 1, 2021 to August 31, 2021 and interview with the laboratory supervisor on December 2, 2021 at 10:20 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 131 out of 131 patients specimens were tested and reported for of Mycoplasma pneumoniae from August 1, 2021 to August 31, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. 3. On December 2, 2021 at 10:20 AM, review of the Mycoplasma pneumoniae testing records showed that the laboratory did not monitor or document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from from August 1, 2021 to August 31, 2021. 4. The laboratory supervisor confirmed on December 2, 2021 at 10:30 AM, that the laboratory did not monitor or document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. 5. The laboratory processed and reported 131 patient samples for Mycoplasma pneumoniae test from August 1, 2021 to August 31, 2021.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p>

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 reappoints 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 laboratory supervisor interview on December 2, 2021 at 10:20 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 from August 1, 2021 to August 31, 2021. Refer D5405.