

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0671002	(X3) Date Survey Completed 10/27/2021
Name of Provider or Supplier Laboratorio Clinico Van Scoy	Street Address, City, State Ave Don Pelayo Aa-4 Hacienda Del Norte, Toa Baja, 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, Mycoplasma testing records and laboratory director interview on October 27, 2021 at 10:12 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when eight out of eight patient's specimens were tested for Mycoplasma by Immuno Card Meridian method on March, 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 October 27, 2021 at 10:12 AM, the Mycoplasma testing random records showed that the laboratory did not monitor or record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method on March 2021 3. The laboratory director confirmed on October 26, 2021 at 10:12 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported eight out of eight patients specimens for mycoplasma test by Immuno Card Meridian method on March 2021.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <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</p>

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 director interview on October 27, 2021 at 10:12 AM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the that the laboratory follow the manufacture's instructions for the temperature of processing on March 2021. Refer D5405.