

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2048770	(X3) Date Survey Completed 12/07/2022
Name of Provider or Supplier Laboratorio Clinico Villa Ana Ii	Street Address, City, State Urb Valencia I, Calle Casul # 148, Juncos, 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 reviewed (year 2021-2022) and laboratory technical consultant interview on December 7, 2022 at 11:10 A.M. , it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2022 to November 14, 2022. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. (review on December 7, 2022 at 10:56 a.m.) 2. On December 7, 2022 at 11:00 AM, the Mycoplasma testing records showed that the laboratory establishes a room temperature from 20 to 25 C in the worksheet year 2022. 3. The laboratory did not follow the manufacturer instruction when it processed mycoplasma patients specimens at 21 C , 44 days of 204 days. (review on December 7, 2022 at 11:02 a.m.) 4. The laboratory technical consultant confirmed on December 7, 2022 at 11:10 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 5. The laboratory processed and reported 230 patient specimen for mycoplasma test out of the manufacturer's temperature range from January 3, 2022 to November 14, 2022. (review on December 7, 2022 at 11:13 a.m.)</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on Mycoplasma pneumoniae quality control records review (year 2021-2022) and laboratory technical consultant interview on December 7, 2022 at 11:00 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5405 (failed to follow the manufacturer's instruction when patient specimen were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2022 to November 14, 2022.)

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on Mycoplasma pneumoniae testing records reviewed (year 2021-2022) and laboratory technical consultant interview on December 7, 2022 at 11:00 A.M., it was determined that the laboratory testing personal failed to follow the manufacturer's instruction when patient specimen were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2022 to November 14, 2022. Refer to D5405.