

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0658003	<b>(X3) Date Survey Completed</b>  05/03/2022
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Lugo	<b>Street Address, City, State</b>  Barcelo Num 10 Suite 101, Barranquitas, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5405</b>	<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 general supervisor, it was determined that the laboratory failed to follow the manufacturer's instruction when 34 out of 34 patient specimen were tested for Mycoplasma by Immuno Card Meridian method from November 4, 2021 to February 24, 2022. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On May 3, 2022 at 1:20 PM, the Mycoplasma testing records showed that the laboratory did not follow the manufacturer instruction when it processed the following patients specimens: Testing Temperature Date processed 1. 11/04/2021 20 C. 2. 11/05/2021 20 C. 3. 11/08/2021 20 C. 4. 01/19/2022 20 C. 5. 01/24/2022 20 C. 6. 01/28/2022 20 C. 7. 02/04/2022 20 C. 8. 02/07/2022 20 C. 9. 02/11/2022 20 C. 10. 02/24/2022 20 C. 3. The laboratory supervisor confirmed on May 3, 2022 at 1:25 PM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 34 out of 34 patient specimen for mycoplasma test out of the manufacturer's temperature range from November 4, 2021 to February 24, 2022.</p>
<b>D5449</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on General Immunology (Mycoplasma pneumoniae test) testing records review (year 2021 to 2022) and interview with the laboratory supervisor it was determined that the laboratory did not include an external positive and negative control material each day of patient testing when 23 out of 28 patients specimens were tested and reported for of Mycoplasma pneumoniae from January 19, 2022 to February 24, 2022. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. On May 3, 2022 at 12:45 PM, the Mycoplasma pneumoniae testing record was reviewed and showed that the laboratory performs and reported patient sample from January 19, 2022 to February 24, 2022. The laboratory did not include an external positive and negative control material each day of testing. 3. The laboratory Supervisor confirmed on May 3, 2022 at 1:00 PM, that the laboratory failed to include an external negative and positive control material each day of patient testing . She stated that the laboratory run the external controls with new open box or new lot of reagent. 4. The laboratory processed and reported 23 out of 28 patients specimens for Mycoplasma pneumoniae from January 19, 2022 to February 24, 2022.

**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 laboratory supervisor interview on May 3, 2022 at 1:20 PM, 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 November 04, 2021 to February 24, 2022. Refer D5405

**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 general immunology (Mycoplasma pneumonia IgM) quality control records and interview with the laboratory supervisor on May 3, 2022 at 1:35 PM, it was determined that the laboratory director did not make sure to include a external positive and a negative control material each day of patient testing for Mycoplasma pneumonia tests. The finding includes: 1. The laboratory did not include a external positive and a negative control material when performed Mycoplasma pneumoniae IgM each day of patient testing. Refer to D5449.