

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0658157	<b>(X3) Date Survey Completed</b>  09/10/2021
<b>Name of Provider or Supplier</b>  Lab Clinico Central De La Montana	<b>Street Address, City, State</b>  Centro De Salud Integral En Naranjito Carr Pr-164, Naranjito, 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>D5014</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.1208</p> <p>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review from January 1, 2021 to September 9, 2021 and interview with the laboratory director and general supervisor on September 10, 2021 at 10:35 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to : 5449- The laboratory did not include positive and negative control material.</p>
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations 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.</p> <p>This STANDARD is not met as evidenced by: Based on General Immunology (Mycoplasma Pneumoniae test) quality control records review from January 1, 2021 to September 9, 2021, interview with the</p>

laboratory director and general supervisor on September 10, 2021 at 10:35 AM , it was determined that the laboratory failed to include a negative and positive control material when performed Mycoplasma pneumoniae test by Immuno Card method. The findings include : 1. The laboratory performed Mycoplasma pneumoniae test by Immuno Card method. 2. Review of the Mycoplasma pneumoniae quality control logs, showed that the laboratory did not include a negative and positive control material each day of testing from January 1, 2021 to September 9, 2021. 3. The laboratory performed and reported 1,660 patient samples from January 1, 2021 to September 9, 2021. 4. The laboratory director and general supervisor confirmed on September 10, 2021 at 10:35 AM, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumoniae test by Immuno Card method.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on general immunology (Mycoplasma pneumoniae) quality control records review from January 1, 2021 to September 9, 2021, laboratory director and general supervisor interview on September 10, 2021 at 10:35 AM, it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. Refer to D 5449.

**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 director and general supervisor on September 10, 2021 at 10:35 AM, it was determined that the laboratory director did not make sure to include a 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 positive and a negative control material when performed Mycoplasma pneumoniae IgM each day of patient testing. Refer to D5449.

**D6144**

**GENERAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on general immunology (*Mycoplasma pneumoniae*) quality control records review from January 1, 2021 to September 9, 2021 and laboratory general supervisor interview on September 10, 2021 at 10:35 AM, it was determined that the general supervisor failed to ensure compliance with the requirement for analytic systems. The finding includes: 1. The laboratory did not include a positive and a negative control material when performed *Mycoplasma* IgM each day of patient testing. Refer to D5449.