

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0909008	<b>(X3) Date Survey Completed</b>  05/19/2022
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Rolon	<b>Street Address, City, State</b>  Road 490 Km 0 2 Hato Arriba, Arecibo, 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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on quality control log sheet review ( year 2021-2022 ) and laboratory general supervisor interview , it was determined that the laboratory failed to include a positive and a negative quality control when performed Mycoplasma pneumoniae . The findings include: 1. The laboratory performed Mycoplasma pneumoniae by Immunocard System. 2. On May 19, 2022 at 12:00 p.m., the quality control review showed that the laboratory did not include a positive and a negative control when performed and reported Mycoplasma patient samples the following days: 3/9/2022, 4 /13/2022, 4/27/22022, 5/10/2022 and 5/11/2022. 3. On May 19, 2022 at 12: 15 p.m., the general supervisor stated that the laboratory establishes to run a positive and a negative control each day of testing for Mycoplasma testing. 4. The laboratory processed and reported 68 patient samples those days.</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on Mycoplasma Pneumoniae quality control log sheet review ( year 2021-2022 ) and laboratory general supervisor interview on May 19, 2022 at 12: 15 P.M., , it was determined that the laboratory director did not assure that the technical supervisor put in place a quality control procedures for Mycoplasma pneumoniae test performed at the laboratory. Refer to D5401.

**D6117**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:  
Based on mycoplasma pneumoniae quality control log sheet review ( year 2021-2022 ) and laboratory general supervisor interview on May 19, 2022 at 12:15 p.m. , it was determined that the technical supervisor did not assure that establishes quality control procedures were followed by the testing personnel. Refer to D5401.