

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0684520	<b>(X3) Date Survey Completed</b>  02/16/2023
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Caribe	<b>Street Address, City, State</b>  Edificio Medical Ophthalmic Plaza, Bayamon, 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>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 Mycoplasma pneumoniae test quality control records review and laboratory director interview on February 16, 2023 at 10:40 AM, it was determined that the laboratory failed to include each day of testing an external positive and negative control material when ten out of ten patient's specimens were tested and reported for Mycoplasma pneumoniae qualitative tests from October 13, 2022 to October 25, 2022. The findings include: 1. On February 16, 2023 at 10:40 AM, review of Mycoplasma pneumoniae test quality control record showed the following: a. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. b. The laboratory did not include each day of testing the external control materials (positive and negative controls) when patient's specimens were processed for Mycoplasma pneumoniae qualitative tests from October 13, 2022 to October 25, 2022. 2. On February 16, 2023 at 10:50 AM, the laboratory director confirmed that the laboratory did not include each day of testing the external controls when patients specimens were testing for Mycolasma pneumoniae qualitative tests. 3. On February 16, 2023 at 10:55 AM, review the Mycolasma pneumoniae quality control records showed that the laboratory processed and reported ten out of ten patient's specimens for Mycoplasma pneumoniae qualitative tests from October 13, 2022 to October 25, 2022.</p>
<b>D6093</b>	<b>LABORATORY DIRECTOR RESPONSIBILITIES</b>

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 *Mycoplasma pneumoniae* test quality control records review and laboratory director interview on February 16, 2023 at 10:40 AM, it was determined that the laboratory director failed to establish the quality control procedures for the *Mycoplasma pneumoniae* qualitative tests from October 13, 2022 to October 25, 2022. Refer to D 5449 (The laboratory failed to include each day of testing an external positive and negative control material when ten out of ten patient's specimens were tested and reported for *Mycoplasma pneumoniae* qualitative tests from October 13, 2022 to October 25, 2022).