

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0673282	<b>(X3) Date Survey Completed</b> 11/08/2022
<b>Name of Provider or Supplier</b> Laboratorio Clinico Barbosa	<b>Street Address, City, State</b> Ave Barbosa #315, Hato Rey, 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>D3039</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(5)</p> <p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records and laboratory testing personnel interview on November 8, 2022, it was found that the laboratory did not retain nor perform the evaluations of the Quality Assessment Program in order to monitor and evaluate the laboratory activities (pre-analytic, analytic and post-analytic systems) since year 2021. The findings include: 1. On November 8, 2022 at 11:43 AM, showed that the laboratory did not have any document related to the QA program for year 2021 nor year 2022. No QA procedure manual was found at the facility. 2. The laboratory testing personnel stated on November 8, 2022 at 11:55 AM, that the laboratory did not have available the Quality Assessment documentation in the laboratory since January 2021.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in</p>

493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from January 3, 2022 to November 8, 2022 and laboratory testing personnel interview on November 8, 2022, it was determined that the laboratory failed to follow the manufacturer's instruction when 22 out of 377 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from January 3, 2021 to November 8, 2022. The findings include: 1. Review manufacturer's instructions on November 8, 2022 at 10:42 AM, showed that the manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. Review of Mycoplasma testig records on November 8, 2022 at 10:45 AM, showed that the laboratory establishes to perform the test procedures at room temperature from 15C to 30C. 3. On November 8, 2022 at 10:45 AM, the Mycoplasma testing records showed that the laboratory tested the patient's specimens over the room temperatures establishes (26C) on January 26, 2022 (two patient's), January 27, 2022 (one patient), March 1, 2022 (one patient), March 11, 2022 (one patient), April 6, 2022 (one patient), April 12, 2022 (two patient's), April 22, 2022 (one patient), May 18, 2022 (two patient's), May 24, 2022 (three patient's) , May 25, 2022 (three patient's), May 26, 2022 (one patient), August 19, 2022 (two patient's), September 26, 2022 (two patient's). 4. The laboratory testing personnel confirmed on November 8, 2022 at 11:05 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 5. The laboratory processed and reported 22 out of 377 patients specimens for mycoplasma test by Immuno Card Meridian method from January 3, 2022 to November 8, 2022.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from January 3, 2022 to November 8, 2022 and laboratory testing personnel interview on November 8, 2022 at 11:47 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the manufacturer's instructions for monitor and documented the room temperature when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. The finding includes: 1. The laboratory did not follow the manufacturer's instructions for

monitor and documented the room temperature from January 3, 2022 to November 8, 2022 when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. Refer to D5403.

**D6070**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:  
Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review and laboratory testing personnel interview on November 8, 2022 at 11:48 AM, it was determined that the testing personnel failed to follow the manufacturer's instruction when patient's were tested for Mycoplasma by Immuno Card Meridian Method from January 3, 2022 to November 8, 2022. Refer to D5403.