

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D1102872	<b>(X3) Date Survey Completed</b> 11/10/2021
<b>Name of Provider or Supplier</b> Laboratorio Clinico Metropolis	<b>Street Address, City, State</b> Carr-Pr-860, Km 0, Hm 9, Hg -25, Carolina, 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>D3009</b>	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on COVID 19 test report, Puerto Rico Department of Health (PRDOH) COVID 19 state reporting requirement and laboratory director interview on November 10, 2021 at 10:38 AM, it was determined that the laboratory did not follow the state COVID 19 test reporting requirements. The findings include: 1. The PRDOH requires that all COVID 19 tests report must be informed within 24 hours of the final report, to the Bio Portal platform. 2. The laboratory used the Healgen rapid test for antibody (IgG / IgM) test kit, CareStart COVID 19 for antigen test kit and Id Now (Abbott) for molecular COVID 19 test. 3. The test report records showed that 31 out of 31 days from September 22, 2021 to November 8, 2021. The laboratory did not report the SARS-CoV-IgG / IgM patients results in the required frequency (24 hrs) by the Bio Portal: Date Patients Date tested specimens reported 09/22/2021 2 09/27/2021 09/23/2021 1 09/27/2021 09/24/2021 2 09/27/2021 09/25/2021 3 09/27/2021 09/27/2021 1 10/04/2021 09/30/2021 1 10/04/2021 10/02/2021 5 10/04/2021 10/04/2021 1 10/11/2021 10/05/2021 2 10/11/2021 10/06/2021 1 10/11/2021 10/09/2021 5 10/11/2021 10/11/2021 1 10/18/2021 10/12/2021 1 10/18/2021 10/12/2021 1 10/18/2021 10/13/2021 2 10/18/2021 10/14/2021 2 10/18/2021 10/15/2021 1 10/18/2021 10/16/2021 9 10/18/2021 10/18/2021 3 10/26/2021 10/19/2021 1 10/26/2021 10/20/2021 1 10/26/2021 10/22/2021 2 10/26/2021 10/23/2021 5 10/26/2021 10/25/2021 3 10/26/2021 10/28/2021 1 11/09/2021 10/30/2021 2 11/09/2021 11/02/2021 4 11/09/2021 11/03/2021 1 11/09/2021 11/04/2021 1 11/09/2021 11/05/2021 2 11/09/2021 11/06/2021 2 11/09/2021 Total of report greater than 24 hours: 70 reports. 4. The test report records showed that 18 out of 21 days from December 8, 2020 to February 17, 2021. The laboratory did not report the SARS-CoV- antigen patients results in the required frequency (24</p>

hrs) by the Bio Portal: Date Patients Date tested specimens reported 09/13/2021 12 09/22/2021 09/14/2021 12 09/22/2021 09/15/2021 9 09/22/2021 09/16/2021 2 09/22/2021 09/17/2021 13 09/22/2021 09/18/2021 13 09/22/2021 09/20/2021 6 09/22/2021 09/22/2021 9 09/27/2021 09/23/2021 8 09/27/2021 09/24/2021 12 09/27/2021 09/25/2021 12 09/27/2021 09/27/2021 9 10/04/2021 09/28/2021 7 10/04/2021 09/29/2021 14 10/04/2021 09/30/2021 7 10/04/2021 10/01/2021 10 10/04/2021 10/02/2021 15 10/04/2021 10/04/2021 6 10/11/2021 10/05/2021 7 10/11/2021 10/06/2021 13 10/11/2021 10/07/2021 14 10/11/2021 10/08/2021 9 10/11/2021 10/09/2021 17 10/11/2021 10/11/2021 7 10/18/2021 10/12/2021 9 10/18/2021 10/13/2021 12 10/18/2021 10/14/2021 10 10/18/2021 10/15/2021 11 10/18/2021 10/16/2021 26 10/18/2021 10/18/2021 11 10/26/2021 10/19/2021 14 10/26/2021 10/20/2021 7 10/26/2021 10/21/2021 7 10/26/2021 10/22/2021 3 10/26/2021 10/23/2021 9 10/26/2021 10/26/2021 3 11/09/2021 10/27/2021 5 11/09/2021 10/28/2021 5 11/09/2021 10/29/2021 14 11/09/2021 10/30/2021 14 11/09/2021 11/01/2021 11 11/09/2021 11/02/2021 4 11/09/2021 11/03/2021 4 11/09/2021 11/04/2021 5 11/09/2021 11/05/2021 18 11/09/2021 11/06/2021 8 11/09/2021 Total of report greater than 24 hours: 660 reports. 5. The test report records showed that 17 out of 17 days from December 12, 2020 to January 19, 2021. The laboratory did not report the SARS-CoV- molecular (ID NOW) patients results in the required frequency (24 hrs) by the Bio Portal: Date Patients Date tested specimens reported 09/22/2021 9 no fecha de envi 09/23/2021 7 no fecha de envi 09/24/2021 13 no fecha de envi 09/25/2021 5 no fecha de envi 09/27/2021 8 10/04/2021 09/28/2021 5 10/04/2021 09/29/2021 6 10/04/2021 09/30/2021 3 10/04/2021 10/01/2021 2 10/04/2021 10/02/2021 7 10/04/2021 10/04/2021 5 10/11/2021 10/05/2021 4 10/11/2021 10/06/2021 2 10/11/2021 10/07/2021 1 10/11/2021 10/08/2021 1 10/11/2021 10/09/2021 2 10/11/2021 10/11/2021 7 10/18/2021 10/12/2021 4 10/18/2021 10/13/2021 7 10/18/2021 10/14/2021 2 10/18/2021 10/15/2021 1 10/18/2021 10/16/2021 5 10/18/2021 10/18/2021 4 10/26/2021 10/19/2021 6 10/26/2021 10/20/2021 7 10/26/2021 10/21/2021 2 10/26/2021 10/22/2021 9 10/26/2021 10/23/2021 7 10/26/2021 10/26/2021 4 11/09/2021 10/27/2021 4 11/09/2021 10/28/2021 9 11/09/2021 10/29/2021 5 11/09/2021 10/30/2021 6 11/09/2021 11/02/2021 10 11/09/2021 11/03/2021 10 11/09/2021 11/04/2021 4 11/09/2021 11/05/2021 2 11/09/2021 11/06/2021 5 11/09/2021 Total of report greater than 24 hours: 263 reports. 4. The laboratory general supervisor confirmed on February 19, 2021 at 10:10 AM, that the before mentioned tests were not reported within the 24 hours of the final test report.

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

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 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 December 7, 2020 to November 8, 2021 and laboratory director interview on November 10, 2021 at 10:28 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 233 out of 233 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from December 7, 2020 to November 8, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. On November 10, 2021 at 10:28 AM, the Mycoplasma testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from December 7, 2020 to November 8, 2021. 3. The laboratory director confirmed on November 10, 2021 at 10:28 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 233 out of 233 patients specimens for mycoplasma test by Immuno Card Meridian method from December 7, 2020 to November 8, 2021.

**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 and laboratory director interview on November 10, 2021 at 10:28 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the manufacturer's instruction for monitor and documented the room temperature 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 director interview on November 10, 2021 at 10:28 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 December 7, 2021 to November 8, 2021. Refer to D5403.