

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0722146	(X3) Date Survey Completed 12/15/2023
Name of Provider or Supplier Laboratorio Clinico Jariselle Ii	Street Address, City, State Carr 167 Km 11 0 Barrio Dajaos, Bayamon, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5014	<p>GENERAL IMMUNOLOGY 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 review of the Mycoplasma pneumoniae IgM quality control records on December 15, 2023 at 11:45 A.M., and laboratory supervisor interview, it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae IgM test. Refer to D5449.</p>
D5449	<p>CONTROL PROCEDURES 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 IgM test quality control and patient test worksheet records review on December 15, 2023 at 11:40 A.M., and laboratory supervisor interview, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae IgM patient testing, neither documented the internal control with each external control. The findings include: 1. The laboratory used the Immunocard reagent kit to perform</p>

	<p>patient Mycoplasma pneumoniae IgM test. 2. Review of Mycoplasma pneumoniae IgM quality control and patient test worksheet records on December 15, 2023 at 11:40 A.M., showed that the laboratory did not include an external positive and negative control material each day of patient testing, neither documented the internal control with each external control from January 1, 2022 to December 15, 2023, when the laboratory processed and reported a total of 1,248 patients. 3. The laboratory supervisor confirmed on December 15, 2023 at 11:45 A.M., that the laboratory failed to include a negative and positive control material each day of patient testing, and failed to document the internal control results with each external control.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae IgM quality control records review, and laboratory supervisor interview on December 15, 2023 at 11:45 A.M., it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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: Based on Mycoplasma pneumonia IgM quality control records and interview with the laboratory supervisor on December 15, 2023, at 11:45 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, neither documented the internal control of each external control. Refer to D5449.</p>