

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1085985	(X3) Date Survey Completed 10/13/2022
Name of Provider or Supplier Laboratorio Clinico Jariselle	Street Address, City, State Carr Pr-829 Km 1 Hm 8 Bo Pinas, Toa Alta, 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
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 General Immunology (COVID-19 Ab IgG/IgM) quality control records review from May 13, 2022 to August 19, 2022 and interview the laboratory supervisor; it was determined that the laboratory did not include an external positive and negative control material of COVID-19 Ab IgG/IgM when the laboratory performed and reported 7 patient's samples The findings include: 1. On October 13, 2022 at 12:45 pm the COVID-19 Ab IgG/IgM quality control record was reviewed. 2. The quality control showed that the laboratory performed patient testing on; May 13, 2022 to August 19, 2022, and the laboratory did not include any external control material each day of patient testing. 3. The laboratory supervisor confirmed on October 13, 2022 at 1:10 PM, that the laboratory failed to include a external negative and positive control material each day of patient testing. The laboratory run the external control only with a new open box or new lot.</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>

This STANDARD is not met as evidenced by:
Based on general immunology quality control (from May 13, 2022 to August 19, 2022) records review and laboratory supervisor interview on October 13, 2022 at 1:50 PM, it was determined that the laboratory director did not fulfill her responsibilities to ensure the compliance with the quality control. Refer to D 5449.