

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1097944	(X3) Date Survey Completed 02/17/2022
Name of Provider or Supplier Laboratorio Clinico Beatriz Inc	Street Address, City, State Car Pr-787 Km 4 Hm 7 Barrio Bayamon, Cidra, 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 (Mycoplasma pneumoniae test) testing records review and interview with the laboratory supervisor on February 17, 2022 at 10:09 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 27 out of 27 patients specimens were tested and reported for of Mycoplasma pneumoniae patient testing from October 1, 2021 to October 27, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. The record was reviewed from April 27, 2021 to December 30, 2021. 2. On February 17, 2022 at 10:00 AM, review of Mycoplasma pneumoniae testing record showed that the laboratory performs patient testing from October 1, 2021 to October 27, 2021. The laboratory did not include each day of testing the external control materials. 3. The laboratory supervisor confirmed on February 17, 2022 at 10:09 AM, that the laboratory failed to include each day of patient testing the external negative and positive control material . He stated that the laboratory run the external controls when it received a new reagent kit. 4. The laboratory processed and reported 27 patients specimens for Mycoplasma pneumoniae from October 1, 2021 to October 27, 2021.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</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.

This STANDARD is not met as evidenced by:

Based on Mycoplasma pneumonia IgM quality control records and interview with the laboratory supervisor on February 17, 2022 at 10:09 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. Refer to D5449.