

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0697955	(X3) Date Survey Completed 10/19/2021
Name of Provider or Supplier Laboratorio Clinico Chegar	Street Address, City, State Garcia De La Noceda B27 Villas De Rio Grande, Rio Grande, 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) quality control records review from January 16, 2021 to October 7, 2021 and interview with the laboratory supervisor on October 19, 2021 at 10:30 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 332 out of 332 patients specimens were tested and reported for Mycoplasma pneumoniae test from January 16, 2021 to October 7, 2021 . The findings include: a. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. b. On October 19, 2021 at 10:30 AM, review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory performs patient testing January 16, 2021 to October 7, 2021. The laboratory did not include each day of testing the external control materials. c. The laboratory supervisor confirmed on October 19, 2021 at 10:30 AM, that the laboratory failed to include each day of testing the external negative and positive control material . She stated that the laboratory run the external control when it received a new kit reagent or shipping. d. The laboratory processed and reported 332 patient samples for Mycoplasma pneumoniae test from January 16, 2021 to October 7, 2021.</p>
D6093	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

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 General Immunology (*Mycoplasma pneumoniae* test) quality control records review from January 16, 2021 to October 7, 2021 and interview with the laboratory supervisor on October 19, 2021 at 10:30 AM, it was determined that the laboratory director failed to establish the quality control procedures for the *Mycoplasma pneumoniae* test. Refer to D 5449 (The laboratory did not include each day of testing an external positive and negative control material when 332 out of 332 patients specimens were tested and reported for *Mycoplasma pneumoniae* test from January 16, 2021 to October 7, 2021).