

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0670593	(X3) Date Survey Completed 10/12/2022
Name of Provider or Supplier Laboratorio Clinico Renacer,Llc	Street Address, City, State Ave Carlos Javier Andaluz Il 32, 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
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 (years 2021 and 2022) and interview with the laboratory technical supervisor on October 12, 2022 at 11:20 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when seven out of seven patients specimens were tested and reported for Mycoplasma pneumoniae patient testing from September 9, 2022 to September 22, 2022. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2 . On October 12, 2022 at 11:20 AM, review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include each day of testing the external control materials when it performs the following patients specimens from September 9, 2022 to September 22, 2022: Date Patient ID 09/09/2022 # 16126 09/10/2022 # 16130 09/12/2022 # 16143 09/13/2022 # 16165 09/15/2022 # 16191 09/15/2022 # 16192 09/22/2022 # 16227 3. On October 12, 2022 at 11:25 AM, the laboratory technical supervisor confirmed that the laboratory failed to include each day of testing the external negative and positive control material from September 9, 2022 to September 22, 202 . She stated that the laboratory run the internal control with each patients testing and run the external controls when it received this new reagent kit. 4. The laboratory processed and reported seven patient samples for Mycoplasma pneumoniae qualitative test from September 9, 2022 to September 22, 2022,</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 (years 2021 and 2022) and interview with the laboratory technical supervisor on October 12, 2022 at 11:20 AM, it was determined that the it was determined that the laboratory director failed to ensure that quality control procedures for *Mycoplasma* tests are maintained in the laboratory. Refer to D 5449 (The laboratory did not include every day of testing did not include each day of testing an external positive and negative control material when seven out of seven patients specimens were tested and reported for *Mycoplasma pneumoniae* test from September 9, 2022 to September 22, 2022).