Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658210	10/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Lebron	Ave Emerito Estrada Rivera, Edificio San Sebastian, San Sebastian, 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	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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. This STANDARD is not met as evidenced by: 1. Based on General Immunology (COVID-19 IgM/IgG) quality control records review, manufacturer instructions for use (IFU) and interview the laboratory supervisor on October 20, 2021 at 11:05 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 491 out of 491 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests form January 5, 2021 to October 18, 2021 . The findings include: a. The laboratory use the Healgen COVID-19 IgG/IgM Rapid Test Cassette to perform rapid immunology IgM/IgG patient test. b. The quality control section of the IFU stated that: additional controls may be required according to guidelines or local, state and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations. c. On October 20, 2021 at 11:05 AM, Review of COVID-19 IgM/IgG quality control at patient results records showed that the laboratory performs patient testing form January 5, 2021 to October 18, 2021 , 0, 2021. The laboratory did not include every day of testing the positive and the negative external control materials. Instead the laboratory run the external controls when it opened a reagent kit box. d. The general supervisor confirmed on October 20, 2021 at 11:05 AM, that the laboratory did not include a negative and positive external control materials each day of testing. e. The laboratory processed and reported 491 COVID-19 IgG/IgM Rapid tests form January 5, 2021 to October 18, 2021. 2. Based on General Immunology

	(Mycoplasma pneumoniae test) quality control records review from January 23, 2021 to October 13, 2021 and interview with the laboratory supervisor on October 20, 2021 at 10:00 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 71 out of 71 patients specimens were tested and reported for of Mycoplasma pneumoniae test from January 23, 2021 to October 13, 2021 . The findings include: a. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. b. On October 20, 2021 at 10:00 AM, review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory performs patient testing January 23, 2021 to October 13, 2021. The laboratory did not include each day of testing the external control materials. c. The laboratory supervisor confirmed on October 20, 2021 at 10:00 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 reagent kit. d. The laboratory processed and reported 71 patient samples for Mycoplasma pneumoniae from January 23, 2021 to October 13, 2021.
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 (COVID-19 IgM/IgG) quality control records review, manufacturer instructions for use (IFU), Mycoplasma pneumoniae test quality control records and interview the laboratory supervisor on October 20, 2021 at 11:05 AM, it was determined that the laboratory director failed to establish the quality control procedures for the COVID-19 IgM/IgG test and the Mycoplasma pneumoniae test. Refer to D 5449 (1). The laboratory did not include each day of testing an external positive and negative control material when 491 out of 491 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests form January 5, 2021 to October 18, 2021 . Refer to D 5449 (2). The laboratory did not include each day of testing an external positive and negative control material when 71 out of 71 patients specimens were tested and reported for of Mycoplasma pneumoniae patient testing from January 23, 2021 to October 13, 2021 . .