Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1093514	10/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Bahia	Ave Ponce De Leon # 125 Bo Amelia, Guaynabo, 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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation of the laboratory physical area and interview with the laboratory general supervisor on October 28, 2021 at 12:15 P.M., it was determined that the laboratory work areas did not have sufficient space in order to ensure the specimen handling and testing. Refer to D 3001.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation and laboratory general interview on October 28, 2021 at 12:00 P. M., it was determined that the laboratory failed to ensure that an adequate space were

	available for handling, examination and testing of patient samples and minimized the contamination of patient specimens in the laboratory area. The findings include: 1. The size of the laboratory area is approximately 8 ' (length) and 7' (width). In this space the laboratory have a Cell Dyn 3200 system, Id Now system, Urinalysis system, centrifuge . 2. Over the Cell Dyn 3200 system the laboratory had the printer , monitor with the key board 3. In the area the laboratory also observed four solar battery in the floor. 4. The laboratory general supervisor confirmed on October 28, 2021 at 12:15 P. M. that the testing area were very crowded and letting few space to perform patient samples.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review (2021) and interview with the laboratory supervisor on October 28, 2021 at 11:30 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to D 5449- The laboratory did not include positive and negative control material.
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 (Mycoplasma pneumoniae test) quality control records review from January 2021 to October 28, 2021 and interview with the laboratory supervisor on October 28, 2021 at 11:30 AM, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. The findings include: a. The laboratory begin to perform Mycoplasma pneumoniae by Immuno Card system on January 2021. b. Review of Mycoplasma pneumoniae quality control at patient results record showed that the laboratory did not include any control material each day of testing the following days: date patient number 10/18/21 140662 10/20/21 1407292, 1407332 10 /26/21 1410082,1410132, 1410192 10/27/21 1410802 10/28/21 141095 c. The laboratory supervisor confirmed on October 28, 2021 at 11:30 AM, that the laboratory failed to include a negative and positive control material in these days of testing when performed Mycoplasma pneumonia test.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on General Immunology quality control records review (2021) , physical facilities observaction and laboratory general supervisor interview on October 28, 2021 at 12:15 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and physical facilities requirements. Refer to D 6083 and D 6093.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on physical plant observation and interview with the laboratory general supervisor on October 28, 2021 at 12:15 P.M. , it was determined that the laboratory director did ensure that the physical plant (crowded space) were appropriate for specimen testing and handling. Refer to D3001.
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 Mycoplasma pneumonia IgM quality control records and interview with the laboratory general supervisor on October 28,2021 at 11:30 AM, it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. Refer to D5449.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumonia IgM quality control records and interview with the laboratory general supervisor on October 28,2021 at 11:30 AM, it was determined that the laboratory general supervisor failed to ensure compliance with the requirement for analytic systems. Refer to D5449.