Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658305	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico La Cumbre	264 Ave Emiliano Pol Urb La Cumbre, San Juan, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on Covid-19 report records review and laboratory director interview on September 21, 2021 at 11:20 AM, it was determined that the laboratory failed to report the Covid- 19 results as required for 6 out of 24 days reviewed from August 18, 20201 to September 18, 2021. The findings include: 1. The laboratory utilized the Health Department instruction to send the Covid-19 results to the Bioportal. 2. The laboratory processed the Covid-19 test by the two methods: Rapid test Healgen and Covid-19 Antigen. 3. On September 21, 2021 at 11:20 AM, the Covid-19 antigen report records showed that the laboratory did not send the Covid-19 results in the required frequency (24 hrs) to the Bioportal in 6 out of 24 days reviewed from August 18, 20201 to September 18, 2021: Date Patients Date tested specimens reports tested sent 08/20/2021 8 08/23/2021 08/21/2021 3 08/23/2021 09/03/2021 7 09/07/2021 09 /04/2021 11 09/07/2021 09/10/2021 5 09/13/2021 09/18/2021 5 09/20/2021 4. The laboratory director confirmed on September 21, 2021 at 11:20 AM, that the laboratory testing personnel did not send those Covid-19 results in the required frequency (24 hrs) to the Bioportal.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

	This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and laboratory director interview on September 21, 2021 at 11:50 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when eight out of eight patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from August 30, 2021 to September 14, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On September 21, 2021, the Mycoplasma testing records showed that the laboratory did not monitor nor recorded the room temperature when it processed the following patients specimens from August 30, 2021 to September 14, 2021: Testing Date Sample ID a. 08/30/2020 189925 b. 09/07/2021 190077 c. 09/10/2021 190168 d. 09/10/2021 190169 e. 09/10/2021 190170 f. 09/10 /2021 190172 g. 09/14/2021 190259 h. 09/16/2021 190314 3. The laboratory director confirmed on September 21, 2021 at 11:50 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported eight out of eight patient's specimen for mycoplasma test from August 30, 2021 to September 14, 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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and laboratory director interview on September 21, 2021 at 11:50 AM, it was determined that the laboratory director failed to comply with the analytic system requirements for the Mycoplasma test. Refer to D 5405 (The laboratory did not follow the manufacturer's instruction when eight out of eight patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from August 30, 2021 to September 14, 2021).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records and laboratory director interview on September 21, 2021 at 11:50 AM, it was determined that the testing personnel failed to follow quality control procedures for the Mycoplasma qualitative test from August 30, 2021 to September 14, 2021. Refer to D 5405 (The laboratory did not follow the manufacturer's instruction when eight out of eight patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from August 30, 2021 to September 14, 2021).