Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658051	08/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Loiza Valley Inc	Z 977 Calle Bauhinia Loiza Valley, Canovanas, 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	Based on Covid-19 report and testing records review and laboratory director interview on August 23, 2021 at 10:52 AM, it was determined that the laboratory failed to report the Covid- 19 results as required for 7 out of 19 days reviewed from May 03, 2021 to May 27, 2021. The findings include: 1. The laboratory utilized the Health Department instruction to send the Covid-19 results to the Bioportal. 2. On August 23, 2021 at 10: 52 AM, the Covid-19 IgM and IgG qualitative tests report records showed that the laboratory did not send the Covid-19 results in the required frequency (24 hrs) to the Bioportal in 7 out of 19 days reviewed from May 03, 2021 to May 27, 2021: Date Patients Date tested specimens reports tested sent 05/03/2021 4 05/05/2021 05/06 /2021 1 05/10/2021 05/11/2021 1 05/13/2021 05/14/2021 2 05/17/2021 05/15/2021 9 05/17/2021 05/18/2021 4 05/21/2021 05/19/2021 1 05/21/2021 3. The laboratory director confirmed on August 23, 2021 at 10:52 AM, that the laboratory did not send the Covid-19 results in the required frequency (24 hrs) to the Bioportal.
D5449	Based on Mycoplasma IGM testing records (from October 31, 2020 to April 14, 2021) review and interview with the laboratory director on August 23, 2021 at 10:46 AM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 11 out of 11 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from November 4, 2020 to April 14, 2021 by the Immuno Card Mycoplasma method. The findings include : 1. On August 23, 2021 at 10:46 AM, the Mycoplasma IGM testing records showed that the laboratory did not include each day of testing the negative nor the positive control materials when the following patient's specimens were tested and reported from November 4, 2020 to April 14, 2021: Dated processed Patient's ID 11/04/2020 512707 11/06/2020 512883 11/09/2020 513088 11/10/2020 513129 11/13/2020 513357 11/14 /2020 513361 11/16/2020 513497 03/21/2021 521123 04/06/2021 521850 04/07/2021 521921 04/13/2021 522248 04/24/2021 522362 2. The laboratory includes the negative and the positive control materials when it placed in routine use the following lots numbers of the Immuno Card Mycoplasma reagents kit: lot 709030M112 in October 2020, lot 709030M113 and lot 709030M115 in March 2021. 3. The laboratory director confirmed on August 23, 2021 at 10:46 AM, that the laboratory

	did not include the negative and the positive control materials each day of testing, instead the laboratory includes a negative and a positive control materials when it places in routine use every new lot or new shipping of the Immuno Card Mycoplasma reagents Kit. 4. The laboratory tested and reported 11 out of 11 patients specimens for qualitative Mycoplasma IgM tests from November 4, 2020 to April 14, 2021 by the Immuno Card Mycoplasma method.
D6093	Based on Mycoplasma IGM testing records (from October 31, 2020 to April 14, 2021) review and interview with the laboratory director on August 23, 2021 at 10:46 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for Mycoplasma IGM qualitative tests. Refer to D 5449 (The laboratory did not include each day of testing a negative and a positive control materials when 11 out of 11 patients specimens were tested and reported for qualitative Mycoplasma IgM tests from November 4, 2020 to April 14, 2021 by the Immuno Card Mycoplasma method.