Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2006469	02/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Flamboyan	Carretera Pr- 172 Km 18, Hm 9, Cidra, 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
D0000	The laboratorio Clnico Flamboyan was found to be in substantial compliance with CLIA regulations (42 CFR Part 493, effective April 24, 2003). No deficiencies were cited as a result of a remote survey process performed on February 17, 2021.
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: 1. Based on test report records review and laboratory director interview on February 17, 2021 at 1:30 PM, it was determined that the laboratory failed to report the SARS-CoV 2 IgM and IgG rapid tests results as required for 4 out of 8 days reviewed from January 14, 2021 to February 8, 2021. The findings include: a. The laboratory utilized the Health Department written instruction to reports the SARS-CoV 2 IgM and IgG rapid tests results to the Bioportal. b. The laboratory processed the SARS-CoV 2 IgM and IgG rapid tests by Healgen method. c. The test report records showed that 4 out of 8 days from January 14, 2021 to February 8, 2021. the laboratory did not report the SARS-CoV 2 IgM and IgG rapid tests results in the required frequency (24 hrs) to the Bioportal: Date Patients Date reported specimens sent to the Bioportal 01/15/2021 9 01/20/2021 01/16/2021 4 01/20/2021 02/04/2021 2 02/08/2021 02/05/2021 8 02/08 /2021 d. The laboratory director confirmed on February 17, 2021 at 1:30 PM, those records. 2. Based on test report records review and laboratory director interview on February 17, 2021 at 1:30 PM, it was determined that the laboratory failed to report the SARS-CoV 2 antigen tests results as required for 4 out of 8 days reviewed from January 14, 2021 to February 8, 2021. The findings include: a. The laboratory processed the SARS-CoV 2 antigen tests by Care stat method. b. The test report records showed that 4 out of 8 days from January 14, 2021 to February 8, 2021. the laboratory did not report the SARS-CoV 2 antigen tests results in the required

	frequency (24 hrs) to the Bioportal: Date Patients Date reported specimens sent to the Bioportal 01/15/2021 11 01/20/2021 01/16/2021 7 01/20/2021 02/04/2021 6 02/08 /2021 02/05/2021 9 02/08/2021 c. The laboratory director confirmed on February 17, 2021 at 1:30 PM, those records.