Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D2032328	**(X3) Date Survey Completed** 02/10/2021
Name of Provider or Supplier Cdt-Policlinica Dr Melendez	**Street Address, City, State** Road 685 Km 1 Hm 9 Bo Tierras Nuevas, Manati, 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 CDT Pliclinica Dr Melendez 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 an onsite survey performed on February 10, 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: Based on test report records review and testing personnel interview on February 10, 2021 at 10:50 AM, it was determined that the laboratory failed to report the SARS-CoV 2 IgM and IgG rapid tests results as required for 11 out of 13 days reviewed from January 4, 2021 to February 9, 2021. The findings include: 1. The laboratory utilized the Health Department written instruction to reports the SARS-CoV 2 IgM and IgG rapid tests results by the Bioportal. 2. The laboratory processed the SARS-CoV 2 IgM and IgG rapid tests by Healgen method. 3. The test report records showed that 11 out of 13 days from January 4, 2021 to February 9, 2021, the laboratory did not report the SARS-Co-VIRAL RNA patients results in the required frequency (24 hrs) by the Bioportal: Date Patients Date tested specimens reported 01/07/2021 6 01 /09/2021 01/08/2021 6 01/09/2021 01/011/2021 17 01/14/2021 01/12/2021 2 01/14 /2021 01/13/2021 8 01/14/2021 01/14/2021 13 01/15/2021 01/15/2021 6 01/21/2021 01/16/2021 4 01/21/2021 01/18/2021 12 01/21/2021 01/19/2021 10 01/21/2021 01/20 /2021 4 01/21/2021 01/21/2021 2 01/26/2021 01/22/2021 3 01/26/2021 01/25/2021 3 01/26/2021 01/26/2021 3 02/01/2021 01/27/2021 12 02/01/2021 01/28/2021 7 02/01 /2021 01/29/2021 7 02/01/2021 01/30/2021 2 02/01/2021 02/01/2021 10 02/04/2021 02/02/2021 5 02/04/2021 02/03/2021 2 02/04/2021 02/04/2021 7 02/08/2021 02/05

	/2021 10 02/08/2021 02/08/2021 8 02/09/2021 4. The laboratory director confirmed on February 10, 2021 at 10:50 AM, that those results of SARS-CoV 2 IgM and IgG rapid tests were not reported in 24 hrs.