

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1090189	(X3) Date Survey Completed 02/09/2021
Name of Provider or Supplier Laboratorio Clinico Victoria Inc	Street Address, City, State Carr Pr-861 Km 3 Hm 3 Sector Alegria, Bayamon, 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 Clinico Victoria 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 9, 2021.
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on test report records review and laboratory director interview on February 9, 2021 at 9:05 AM, it was determined that the laboratory failed to report the negative results of the SARS-CoV -2 IgM and IgG tests as required for 2 out of 5 days reviewed from June 15, 2020 to February 2, 2021. The findings include: 1. The laboratory utilized the Health Department written instruction to reports the SARS-CoV -2 IgM and IgG tests by the Bioportal. 2. The laboratory processed the SARS-CoV -2 IgM and IgG tests by Healgen method. 3. The test report records showed that 2 out of 5 days from June 15, 2020 to February 2, 2021, the laboratory did not report the negative results of the SARS-CoV -2 IgM and IgG tests in the required frequency (24hrs): Date Patients Date processed specimens reported 10/08/2020 8 10/14/2020 12 /10/2020 8 12/23/2020 4. The laboratory director confirmed on February 9, 2021 at 9: 05 AM all the records submitted. She stated that the laboratory have to enter manually all the Covid results due to the Bioportal has not configured the Laboratorio Clinico Victoria information system to report the Covid results.</p>