

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0684520	(X3) Date Survey Completed 02/12/2021
Name of Provider or Supplier Laboratorio Clinico Caribe	Street Address, City, State Edificio Medical Ophthalmic Plaza, 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 Caribe de Bayamon 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 12, 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 testing personnel interview on February 12, 2021 at 11:35 AM, it was determined that the laboratory failed to report the SARS-CoV 2 IgM and IgG rapid tests results as required for 12 out of 18 days reviewed from January 4, 2021 to February 10, 2021. The findings include: 1. The laboratory reported the SARS-CoV-2 rapid tests from the Laboratory information system (TEKPRO) to the Bioportal. 2. The laboratory processed the SARS-CoV-2 rapid tests tests by Healgen method. 3. The test report records showed that 12 out of 18 days reviewed from January 4, 2021 to February 10, 2021 the laboratory did not report the SARS-CoV-2 rapid tests results in the required frequency (24 hrs) to the Bioportal: Date Patients Date tested specimens reported 01/04/2021 6 01/07/2021 01/13/2021 6 01/16/2021 01/14/2021 1 01/16/2021 01/18/2021 3 01/20/2021 01/20/2021 6 01/22/2021 01/23/2021 3 01/28/2021 01/25/2021 3 01/28/2021 01/26/2021 2 01/28/2021 01/30/2021 2 02/03/2021 02/06/2021 3 02/08/2021 02/05/2021 3 02/08/2021 02/09/2021 2 02/10/2021 4. The testing personnel confirmed on February 12, 2021 at 11:35 AM, that those results of SARS-CoV 2 IgM and IgG rapid tests were not reported in 24 hrs.</p>