

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1089092	(X3) Date Survey Completed 02/26/2021
Name of Provider or Supplier Laboratorio Clinico Playa Puerto Real	Street Address, City, State Carr Pr-308 Km 4 Hm 8 Parcelas Elizabeth, Cabo Rojo, 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 Playa Puerto Real 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 26, 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 Bioportal records review and laboratory Bioportal records review by remote survey on February 26, 2021 at 4:30 P.M, it was determined that the laboratory failed to report the SARS-CoV 2 tests results as required for 5 out of 9 days reviewed from January 16, 2021 to February 22, 2021 The findings include: 1. The laboratory utilized the Health Department written instruction to reports the SARS-CoV 2 (respiratory panel-PCR, rapid test, total antibodies and Covid Antigen) tests results by the Bioportal. 2. The test report records showed that 5 out of 9 days from January 16, 2021 to Febraury 22, 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 01/16/2021 2 01/19/2021 01/28/2021 1 02/02/2021 01/30 /2021 1 02/02/2021 02/01/2021 3 02/02/2021 02/18/2021 2 02/22/2021 02/19/2021 2 02/22/2021</p>