

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0972372	<b>(X3) Date Survey Completed</b> 04/15/2021
<b>Name of Provider or Supplier</b> Laboratorio Clinico Royal Gardens	<b>Street Address, City, State</b> Esther St E4 Royal Garden, Bayamon, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratorio Clinico Royal Gardens 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 April 15, 2021.
<b>D3009</b>	<p><b>FACILITIES</b> 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 April 15, 2021 at 2:00 PM, it was determined that the laboratory failed to report the Covid results ( Covid 19 antigen and Covid rapid IgM and IgG tests) as required for 4 out of 10 days reviewed from March 15, 2021 to April 14, 2021. The findings include: 1. The laboratory utilized the Health Department written instruction to reports the Covid 19 results to the Bioportal. 2. The laboratory processed the Covid 19 IgM and IgG rapid tests by Healgen method and the Covid 19 antigen by Care Star method. 3. The test report records showed that 4 out of 10 days from March 15, 2021 to April 14, 2021 , the laboratory did not report the Covid 19 patients results in the required frequency (24 hrs) to the Bioportal: Date Patients Date tested specimens reported 03 /16/2021 12 03/18/2021 03/19/2021 9 03/22/2021 03/20/2021 6 03/22/2021 04/10 /2021 45 04/12/2021 4. The laboratory director confirmed on April 15, 2021 at 2:00 PM, that those covid results were not reported in 24 hrs. She stated that those tests were done around the weekend and said that the laboratory improved the reporting frequency of the Covid 19 tests.</p>