

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658073	(X3) Date Survey Completed 08/05/2021
Name of Provider or Supplier Laboratorio Clinico Corozal Inc	Street Address, City, State 16 Gandara St, Corozal, 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 Corozal Inc, 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 August 5, 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 Covid-19 report records review and general supervisor interview on August 5, 2021 at 11:25 AM, it was determined that the laboratory failed to report the Covid-19 results as required for 24 out of 47 days reviewed from April 1, 2021 to July 24, 2021. The findings include: 1. The laboratory utilized the Health Department instruction to send the Covid-19 results to the Bioportal. 2. The laboratory processed the Covid-19 test by the following methods: Rapid test Healgen, Covid-19 Antigen and Covid-19 molecular by ID Now. 3. On August 5, 2021 at 11:25 AM, the Covid-19 rapid report records showed that the laboratory did not send the Covid-19 results in the required frequency (24 hrs) to the Bioportal in 15 out of 36 days reviewed from April 1, 2021 to July 16, 2021: Date Patients Date tested specimens reports tested sent 04/01/2021 1 04/08/2021 04/06/2021 3 04/08/2021 04/12/2021 4 04/14/2021 04/15/2021 3 04/19/2021 04/16/2021 2 04/19/2021 04/20/2021 1 04/22/2021 05/04/2021 2 05/06/2021 05/10/2021 1 05/12/2021 05/13/2021 1 05/15/2021 05/22/2021 1 05/27/2021 05/29/2021 2 06/01/2021 06/05/2021 1 06/07/2021 07/03/2021 1 07/06/2021 07/10/2021 1 07/12/2021 07/16/2021 2 07/19/2021 4. On August 5, 2021 at 11:25 AM, the Covid-19 antigen report records showed that the laboratory did not send the Covid-19 results in the required frequency (24 hrs) to the Bioportal in 5 out of 5 days reviewed from July 16, 2021 to July 24, 2021: 07/16/2021 1 07/19/2021 07/17/2021 1 07/19/2021 07/21/2021 2 07/27/2021 07/23/2021 5 07/27/2021 07/24/2021 4 07/27</p>

/2021 5. On August 5, 2021 at 11:25 AM, the Covid-19 molecular (ID Now method) records showed that the laboratory did not send the Covid-19 results in the required frequency (24 hrs) to the Bioportal in 4 out of 6 days reviewed from July 16, 2021 to July 24, 2021: 07/16/2021 4 07/19/2021 07/21/2021 2 07/23/2021 07/23/2021 1 07/27/2021 07/24/2021 4 07/27/2021 6. The general supervisor confirmed on August 5, 2021 at 11:25 AM, that the laboratory did not send those Covid-19 results in the required frequency (24 hrs) to the Bioportal.