

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1020737	(X3) Date Survey Completed 07/08/2021
Name of Provider or Supplier Laboratorio Clinico Emanuel	Street Address, City, State Ave Trio Vegabajeno U 16, Vega Baja, 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 Emanuel 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 July 8, 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: A. Based on Bioportal records review and laboratory director interview on July 8, 2021 at 10:00 AM, it was determined that the laboratory failed to report the SARS-CoV 2 tests results as required for 14 out of 16 days reviewed from February 1, 2021 to February 28, 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 14 out of 28 days from February 1, 2021 to February 28, 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 02/01/2021 6 02/04/2021 02/02/2021 8 02/04/2021 02/08/2021 8 02/11/2021 02/09/2021 11 02/11/2021 02/22/2021 3 02/26/2021 02/04/2021 2 02/26/2021 02/05 /2021 9 02/26/2021 02/06/2021 4 02/26/2021 02/11/2021 13 02/26/2021 02/12/2021 2 02/26/2021 02/16/2021 6 02/26/2021 02/18/2021 2 02/26/2021 02/19/2021 14 02/26 /2021 02/20/2021 2 02/26/2021 3. The laboratory director confirmed on July 8, 2021 at 10:00 AM, that those results of SARS-CoV 2 tests were not reported in 24 hrs. The laboratory technical supervisor stated that he reported the test results to the Bioportal weekly. B. Based on Bioportal records review and laboratory director interview on July 8, 2021 at 10:00 AM, it was determined that the laboratory failed to report the SARS-CoV 2 tests results as required for 17 out of 17 days reviewed from June 1,</p>

2021 to July 7, 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 17 out of 17 days reviewed from June 1, 2021 to July 7, 2021, the laboratory did not report the SARS-Co-VIRAL RNA patients results in the required frequency (24 hrs) by the Bioportal. a. Date tested : 06/07/2021, 06/08 /2021, 06/09/2021, 06/10/2021, 06/11/2021, 06/12/2021, 06/14/2021, 06/15/2021, 06 /16/2021, 06/17/2021 and 06/19/2021. Patients tested: 34 Test reported: 06/22/2021 b. Date tested: 06/22/2021, 06/23/2021, 06/24/2021, 06/26/2021, 06/28/2021, 06/29 /2021 Patient tested : 20 Test reported : 07/07/2021 4. The laboratory director confirmed on July 8, 2021 at 10:00 AM, that those results of SARS-CoV 2 tests were not reported in 24 hrs.