Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0673051	(X3) Date Survey Completed 05/14/2021
Name of Provider or Supplier Laboratorio Clinico Cossma Humacao	**Street Address, City, State** Boulevard Plaza Office Center, Oficina Num 3-A, Humacao, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on tests report records review and laboratory director visor interview on May 14, 2021 at 11:47 AM, it was determined that the laboratory failed to report the Covid- 19 results as required for 9 out of 27 days reviewed from April 1, 2021 to May 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 test by ID Now method and the Covid-19 rapid test by Healgen method. 3. The tests report records showed that the laboratory did not send the Covid-19 ID Now results in the required frequency (24 hrs) to the Bioportal in 9 out of 27 days reviewed from April 1, 2021 to May 14, 2021: Date Patients Date tested specimens reported tested 04/01/2021 4 04/05/2021 04/05/2021 6 04/07/2021 04 /07/2021 1 04/09/2021 04/09/2021 1 04/14/2021 04/12/2021 5 04/14/2021 04/22/2021 3 04/26/2021 04/23/2021 6 04/26/2021 04/28/2021 3 04/30/2021 05/12/2021 3 05/14 /2021 4. The laboratory director confirmed on May 14, 2021 at 11:47 AM, that the tests report records showed that the laboratory did not sent those results of Covid-19 in 24 hrs.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Covid-19 IgG/IgM test quality control records review and interview with the laboratory director on May 14, 2021 at 12:24 PM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 14 out of 14 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from January 14, 2021 to January 26, 2021 by the Healgen method. The findings include : 1. The Covid-19 IgG/IgM test quality control records showed that the laboratory did not include the negative nor the positive control materials when 14 out of 14 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from January 14, 2021 to January 26, 2021 by the Healgen method: Day tested patients specimens 01/14/2021 1 01/26/2021 13 2. The laboratory director confirmed on May 14, 2021 at 12:24 PM, that the Covid-19 IgG /IgM test quality control records showed that the laboratory did not include the negative nor the positive control materials those days. 3. The laboratory tested and reported 14 out of 14 patients specimens for qualitative Covid-19 IgG/IgM test from January 14, 2021 to January 26, 2021 by the Healgen method.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on Covid-19 IgG/IgM test quality control records review and interview with the laboratory director on May 14, 2021 at 12:24 PM, it was determined that the laboratory director failed to ensure compliance with the requirements for the Covid-19 IgG/IgM tests. Refer to D 5449 (The laboratory failed to include each day of testing a negative and a positive control materials when 14 out of 14 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from January 14, 2021 to January 26, 2021 by the Healgen method).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Covid-19 IgG/IgM test quality control records review and interview with the laboratory director on May 14, 2021 at 12:24 PM, it was determined that the it was determined that testing personnel failed to follow quality control procedures for the Covid-19 IgG/IgM tests. Refer to D 5449 (The laboratory failed to include each day

	of testing a negative and a positive control materials when 14 out of 14 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from January 14, 2021 to January 26, 2021 by the Healgen method).