Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2179037	09/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Cossma San Lorenzo	Calle Munoz Rivera # 181, Lote 186, San Lorenzo, 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 Covid-19 report records review and general supervisor interview on September 3, 2021 at 12:45 PM, it was determined that the laboratory failed to report the Covid- 19 results as required for 10 out of 28 days reviewed from April 15, 2021 to September 3, 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 and Covid-19 molecular by ID Now. 3. On September 3, 2021 at 12:45 PM, 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 5 out of 7 days reviewed from April 15, 2021 to September 3, 2021: Date Patients Date tested specimens reports tested sent 04/15/2021 1 04/28/2021 04/23/2021 1 04/28/2021 04/20/2021 1 04/22/2021 05 /12/2021 1 05/19/2021 05/17/2021 1 05/19/2021 06/25/2021 1 09/03/2021 4. On September 3, 2021 at 12:45 PM, 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 5 out of 21 days reviewed from July 2, 2021 to September 1, 2021: 07/02/2021 11 08/02/2021 07/09/2021 5 08/02/2021 07/22/2021 4 08/02 /2021 08/19/2021 2 08/23/2021 08/20/2021 25 08/25/2021 5. The general supervisor confirmed on September 3, 2021 at 12:45 PM, that the laboratory did not send those Covid-19 results in the required frequency (24 hrs) to the Bioportal.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of validation records and laboratory general supervisor interview on September 3, 2021 at 12:15 PM, it was determined that the laboratory failed to perform the validation of the urine microscopic exam before reporting 200 out of 200 patients urinalysis specimens from October 1, 2020 to September 3, 2021. The findings include: 1. The laboratory did not perform the validation of the urine microscopic exam. 2. The laboratory general supervisor confirmed on September 3, 2021 at 12:15 PM, that the laboratory did not perform the validation of the urine microscopic exam before reporting urinalysis patients specimens. 3. The laboratory performed and reported 200 out of 200 patients urinalysis specimens from October 1, 2020 to September 3, 2021.
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 lack of validation records and laboratory general supervisor interview on September 3, 2021 at 12:15 PM, it was determined that the laboratory director failed to ensure compliance with the requirements of urinalysis tests. Refer to D 5421 (The laboratory did not perform the validation of the urine microscopic exam before reporting 200 out of 200 patients urinalysis specimens from October 1, 2020 to September 3, 2021).