Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0673282	03/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Barbosa	Ave Barbosa #315, Hato Rey, 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on COVID19 worklist, quality control records review from January 4, 2021 to March 5, 2021, manufacturer's instructions for COVID19 IgG / IgM (FaStep rapid test), COVID19 antigen (CareStart) and laboratory testing personnel interview on March 10, 2021 at 10:23 AM, it was determined that the laboratory failed to follow manufacturer's instructions for monitor and document the laboratory's room temperature and relative humidity. The findings include: 1. The laboratory used the FaStep Rapid Test Device for antibody (IgG / IgM) test kit and CareStart COVID19 for antigen test kit. 2. The manufacturer's instructions of the COVID19 antibody (FaStep Rapid Test Device) and COVID19 antigen (CareStart COVID19 antigen), stated that the laboratory monitor and document each day of use of COVID19 antibody and COVID19 antigen the room temperature and relative humidity. 3. Review of the COVID19 (antibody and antigen) quality control records, showed that the laboratory did not monitor and document the room temperature and relative humidity from January 4, 2021 to March 5, 2021. 4. The laboratory processed and reported 239 patient's tests by COVID19 antibody (FaStep Rapid testDevice) and 53 patient's tests by COVID19 antigen (CareStart) from January 4, 2021 to March 5,

	2021. 5. The testing personnel confirmed on March 10, 2021 at 10:23 AM, that the laboratory did not monitor and document the room temperatures and relative humidity those days.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on COVID19 quality control records review from January 4, 2021 to March 5, 2021, manufacturer's instructions review and laboratory testing personnel interview on March 10, 2021 at 10:23 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to follow manufacturer's instructions for monitor and document the laboratory's room temperature and relative humidity each day of use. Refer to D5413.