Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0967204	07/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Del Barrio Corcovado	Carr 493 Km 3, Hm 1, Bo Corcovado, Hatillo, 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 Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at LABORATORIO CLINICO DEL BARRIO CORCOVADO on July 16, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on July 16, 2024.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on laboratory temperature records review (2023-2024) and laboratory director interview it was determined that the laboratory did not monitor nor document the temperature refrigerator since May 31, 2024. The findings include: 1. On July 16, 2024 at 10:20 AM, the laboratory refrigerator temperature records were review since January 2023. 2. The laboratory refrigerator temperature records showed that the laboratory failed to monitor and document the temperature refrigerator since May 31, 2024. The laboratory used the refrigerator to store the following reagents : hematology quality control vials, urinalysis control and RPR (rapid plasma reagin) reagent and control. 3.The laboratory performed and reported since June 1, 2024 the following tests: 170 CBC, 138 Urinalysis patient samples and 13 RPR patient samples. 4. The laboratory director confirmed on July 16, 2024 at 11:20 AM, that the laboratory failed to monitor and document the temperature refrigerator since May 31, 2024.
D5429	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 1. Based on manufacturer's written procedures, hematology preventive maintenance records review (2023-2024) and laboratory director interview on July 16, 2024 at 10: 28 A.M., it was determined that the laboratory failed to follow written instructions for the preventive maintenance of Cell Dyn 1600 systems. The findings include: a. The laboratory uses the Cell Dyn system to perform hematology (complete blood count) tests. b. The manufacturer's written procedures establishes that the laboratory must document and perform the daily, weekly and monthly preventive maintenance. c. Review of preventive maintenance records from January 2023 to July 16, 2024 , showed that the laboratory did not perform nor document the daily preventive maintenance (check reagent levels, check printer paper, check tubing in NC valves, put lyse pump tube under wheel, background check, run controls, daily shutdown and empty waste as needed) the weekly preventive maintenance (open and CS mode-auto clean, before weekend removed tubing from NC valves, aspiration probe exterior cleaning, closed sampler holder cleaning) and monthly preventive maintenance (check lyse pump tubing, clean lyse trail line and remove and clean fan filters) from June 5, 2024 to July 16, 2024 d. The laboratory processed and reported 171 CBC patient samples from June 5, 2024 to July 15, 2024. e. The laboratory director confirmed on July 16, 2024 at 10:30 A.M. that the laboratory failed to follow written instructions for the preventive maintenance of Cell Dyn 1600 systems. 2. Based on urinalysis preventive maintenance records review (2023-2024) and laboratory director interview on July 16, 2024 ay 10:35 A.M., it was determined that the laboratory failed to follow manufacturer's instructions for the preventive maintenance of Clinitek 100 instrument in 2023 and since February 26, 2024. The findings include: a. The manufacturer's written procedures establishes that the laboratory must document and perform the daily (general clean) and weekly (Clorox 5 % clean) preventive maintenance. b. The laboratory did not perform the preventive maintenance of the Clinitek 100 instrument in 2023 and since February 26, 2024. c. The laboratory director confirmed on July 16, 2024, that those preventive maintenance did not perform since February 26, 2024. d. The laboratory processed 1,434 urinalysis patients specimens in year 2023 and 471 urinalysis patients specimens since February 26, 2024.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

	This STANDARD is not met as evidenced by: 1. Based on laboratory preventive maintenance work sheets records review (2023-2024) and laboratory director interview on July 16, 2024 at 10:31 A.M., it was determined that the laboratory failed to monitor and document the laboratory rotator and microscope maintenance. The findings include: a. The laboratory preventive maintenance work sheets records (2023-2024) reviewed on July 16, 2024 at 10:31 A. M establishes that the laboratory must monitor and document , each day of use, the rotator and microscope maintenance. b. From January 2023 to December 2023 and from May 31/2024 to July 15, 2024 the laboratory did not monitor and document the daily microscope maintenance (cleaning) . c. Since December 2023 the laboratory failed to perform and document , each day of use , the RPR rotator preventive maintenance (external clean, revolution per minutes check and needle wash. d. The laboratory director confirmed on July 16, 2024 at 10:40 A.M., that the laboratory did not monitor and document the rotator and microscope maintenance in the indicated dates in 2023 and 2024.
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 laboratory preventive maintenance and temperature records review (2023-2024) and laboratory director interview on July 16, 2024 at 12:15 P.M, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5411, D5429 and D5435.