Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2121312	04/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Centro Comprensivo De Cancer	Carr Pr-18, Esq Carr Pr-21, San Juan, 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 Centro Comprensivo de Cancer on April 21, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on April 21, 2026.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 Cryostat HM525NX room temperature and relative humidity records (years 2025-2026), direct observation for room temperature and relative humidity ranges established by the manufacturer in frozen section area and interview with the laboratory director on April 21, 2026 at 11:00 A.M, the laboratory failed to follow the manufacturer instructions for relative humidity ranges on Cryostate from July 1, 2025 to April 21, 2026. The findings include: 1. The laboratory use a Cryostat HM525NX to perform frozen sections on patient's samples. 2. The Laboratory Procedure Manual and Manufacturer's Instructions establishes that the laboratory monitoring the room temperature and relative humidity each day of use. The room temperature must be between 18 to 35 and the relative humidity must be between 20% to 60%. 3. From July 1, 2025 to April 21, 2026, the records showed that the relative humidity was out

	of acceptable range in two hundred seven (207) days out of two hundred thirteen (213) days and the laboratory performed seventy two (72) frozen sections. Fifty three (53) frozen sections in 2025 and nineteen (19) frozen sections in 2026. The relative humidity was above 60%. 4. On April 21, 2026 at 11:00 A.M., the laboratory director confirmed that the relative humidity was out of the range (above 60 %) establishes by the manufacturer's.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on the Clostridium Difficile quality control records reviewed, manufacturer instructions and laboratory supervisor interview on April 21, 2026 at 1:52 P.M., the laboratory did not perform the external negative control material each day of patient testing. The laboratory processed and reported 87 patients sample from January 5, 2025 to December 26, 2025. The findings include: 1. The laboratory use C. Diff Quick Check Complete to perform the Clostridium difficile test. The manufacturer established that the test is classified as Moderate test. 2. Review of the Clostridium Difficile quality control records on April 21, 2026 at 1:42 P.M., showed that the laboratory did not perform the external negative control material each day of patient testing. 3. The laboratory supervisor confirmed on April 21, 2026 at 1:52 P.M., that the laboratory failed to perform the negative external control material each day of patient testing. The laboratory processed and reported 87 patients sample from January 5, 2025 to December 26, 2025.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment 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: 1. Based on Cryostat HM525NX room temperature and relative humidity records (years 2025-2026), direct observation for room temperature and relative humidity ranges established by the manufacturer in frozen section area and interview with the laboratory director on April 21, 2026 at 11:00 AM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions requirements. Refer to D5413. 2. Based on Colstidium difficile quality control records, manufacturer instructions and interview with the laboratory supervisor on April 21, 2026 at 1:52 P.M., the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the manufacturer's instructions requirements. Refer to D5449.