Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0000464	05/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Ryder Memorial Hospital	355 Ave Font Martelo, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clnico Ryder Memorial Hospital, Inc. on May 22, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on May 22, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 Condition: General Immunology 42 CFR 493.1441 Condition: Laboratory Director 42 CFR 493.1459 Condition: Laboratory performing high complexity testing; general supervisor. In addition, the laboratory was found out of compliance with the following standard level deficiencies found during the recertification CLIA survey on May 22, 2025.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Human Immunodeficiency Virus (HIV) quality control records review (years 2024-2025), the patient's test worksheets records, the manufacturer's insert test review, and laboratory director interview on May 22, 2025, at 10:15 AM, it was determined that the laboratory failed to include external negative and positive control materials on each day HIV patient's samples. Refer to D5449.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on review of written personnel competency policies, personnel records review (years 2024-2025) and laboratory director interview on May 22, 2025 at 1:15 PM, it was determined that the laboratory failed to follow the established schedule for competency evaluation for the technical supervisor (TS), technical consultant (TC), and respiratory therapist (RT). The finding includes: 1. On May 22, 2025 at 1:15 PM, the laboratory written policies for personnel competency procedures showed that the competency procedures must be performed annually. 2. The personnel records review, on May 22, 2025, at 1:20 PM, showed that there was no competency evaluation of TS#2 and TS#3 (years 2024-2025). The last competency evaluations for TC#1 and TC#3 were performed in June 2023, and for the RT#1 and RT#2 were performed in March 2024 (CMS-209 form). 3. During the interview on May 22, 2025 at 1:30 PM, the laboratory director confirmed that the technical supervisor, technical consultant, and respiratory therapist (testing personnel) competency evaluations were not performed during the year 2024.
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 review of Human Immunodeficiency Virus (HIV) quality control records review (years 2024-2025), the patient's test worksheets records, the manufacturer's insert test review, and laboratory director interview on May 22, 2025, at 10:00 AM, it was determined that the laboratory failed to include external negative and positive control materials, each day HIV patient's samples. The laboratory performed and reported 20 out of 23 HIV-1/2 Ag/Ab patient's samples without external quality control (QC) from February 26, 2024, and April 22, 2025. The findings include: 1. The laboratory used the Determine HIV-1/2 Ag/Ab Combo to detect HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2 in serum. Review of manufacturer's insert test, showed that the HIV testing for serum samples is classified as a moderate complexity test.(Reviewed on May 22, 2025, at 10:00 AM.) 2. The HIV-1/2 Ag/Ab Combo quality control and patient's test worksheets records showed that the laboratory did not include external negative and positive control materials each day of patient's samples. The laboratory performed and reported 20 out of 23 HIV-1/2 Ag/Ab patient's samples without external QC from February 26, 2024, to April 22, 2025. (Reviewed on May 22, 2025, at 10:05 AM.) 3. The laboratory director confirmed on May 22, 2025, at 10:15 AM., that the laboratory failed to include external negative and positive control materials each day of testing for HIV-1/2 Ag /Ab Combo.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on Human Immunodeficiency Virus (HIV) quality control records review (years 2024-2025), the patient's test worksheets records, the manufacturer's insert test review, and laboratory director interview on May 22, 2025, at 2:00 P. M, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory general immunology requirements. Refer to D6093.
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: Based on the review of Human Immunodeficiency Virus (HIV) quality control records review (years 2024-2025), patient's test worksheets records, the manufacturer's insert test review, and laboratory director interview on May 22, 2025, at 10:15 AM, it was determined that the laboratory director did not ensure that the testing personnel included external negative and positive control materials each testing day for the HIV patient's sample . Refer to D5449.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on Centers for Medicare & Medicaid Services (CMS) 209 Laboratory Personnel Report and laboratory director interview on May 22, 2025, at 1:00 PM, it was determined that the laboratory failed to fill the general supervisor position from May 2023 until present.