

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2244974	(X3) Date Survey Completed 07/19/2024
Name of Provider or Supplier Rw Lab	Street Address, City, State Km 6, Hm 5, Carr 173, Bo Rabanal Sector San Jose, Cidra, 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 RW LAB on July 19, 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 19, 2024.
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation at the laboratory sample collection area, patient census report and laboratory general supervisor interview on July 19,2024 at 9:39 A.M., it was determined that the laboratory used sample collection tubes with exceeded expiration date. The findings include: 1. On July 19,2024, at 9:39 A.M., the laboratory sample collection area was observed: a. Twenty-nine Buffered Sodium Citrate pale blue top tubes, lot number 3194715, expiration date 2024-04-30 were found. 2. The patient census report reviewed, on July 19,2024, at 9:55 A.M., showed that ten coagulation patient's samples (Prothrombin time and Partial thromboplastin time) were collected and referred between May 1,2024 to July 18,2024. 3. The laboratory general supervisor confirmed during interview on July 19,2024, at 10:00 A.M., that the patient samples were collected with expired collection tubes.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p>

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 direct observation at the laboratory sample collection area and interview with the laboratory general supervisor and laboratory supervisor, on July 19,2024 at 12:00 P.M., it was determined that the laboratory director failed to ensure that the Buffered Sodium Citrate pale tube (coagulation samples) not exceed the expiration date. Refer to D5417.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on direct observation at the laboratory sample collection area and interview with the laboratory general supervisor (testing personnel), on July 19,2024 at 12:00 P. M., it was determined that the general supervisor did not assure that the Buffered Sodium Citrate pale tube (coagulation samples) not exceed the expiration date. Refer to D5417.