Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658043	05/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Villa Ana Caguas	Borgona 3 B5 3ra Sec Villa Del Rey, Caguas, 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
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; This STANDARD is not met as evidenced by: Based on the Rapid Reagin Plasma (RPR) quality control records, patient's worksheet records and interview with the technical consultant on May 9, 2025 at 10:00 A.M.; it was determined that the laboratory fail to include control material with graded reactivity when processed and reported patient samples for RPR dilutions on November 22, 2024. The laboratory processed and reported two (2) patient's samples without the serial dilution quality control. The finding are: 1. The patient worksheet records were reviewed on May 9, 2025 at 9:53 A.M. and showed that the laboratory performed a serial dilution in every reactive patient's of RPR. 2. The RPR quality control records were reviewed on May 9, 2025 at 9:57 A.M. and showing that the laboratory did not include a control material with graded reactivity on November 22, 2024 when two (2) patient's were processed and reported with the following graded reactivity: ID:3780092 1:2 ID:3780172 1:16 3. The laboratory technical consultant confirmed on May 9, 2025 at 10:00 A.M. that the laboratory fail to include a control material with graded reactivity when processed and reported patient's samples for RPR graded reactivity on November 22, 2024. The laboratory processed and reported two (2) patient's samples without the graded reactivity control material.
D6068	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425 The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

	This STANDARD is not met as evidenced by: Based on the Rapid Reagin Plasma (RPR) quality control records, patient worksheet records and interview with the technical consultant on May 9, 2025 at 10:00 A.M.; it was determined that the laboratory testing personnel fail to include a control material with graded reactivity when processed and reported patient's samples for RPR graded reactivity on November 22, 2024. The laboratory processed and reported two (2) patient samples without the graded reactivity control material. Refer to D5451.