Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0946183	10/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Los Robles	Carr 401 Km 09 Bo Hatillo, Anasco, 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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on manufacturer instructions, syphilis serology quality control records review (years 2020-2021) and laboratory general supervisor interview on October 13, 2021 at 10:00 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for syphilis serology by ASI Rapid plasma reagin (RPR) method. The findings include: 1. The laboratory uses ASI Rapid plasma reagin (RPR) method when patient specimen were tested for syphilis serology since January 2021. 2. The manufacturer's instruction establishes that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. The laboratory only include two levels (reactive and non reactive). 3. From January 4, 2021 to October 12, 2021 (213 days - two hundred thirteen days), the syphilis serology quality control records showed that the laboratory did not include the three levels of control material when it processed and reported 941 out of 941 patients specimens for syphilis serology by ASI RPR method. 4. The laboratory general supervisor stated that the laboratory performed only two levels of controls those days (non reactive and reactive).
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument

	and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on manufacturer instructions, syphillis serology quality control records review (years 2020-2021)and laboratory general supervisor interview on October 13, 2021 at 10:00 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D5405.
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 manufacturer instructions, syphillis serology quality control records review (years 2020-2021) and laboratory general supervisor interview at 10:00 AM on October 13, 2021, it was found that the laboratory director did not ensure that syphillis serology quality controls procedures were established as per state by the manufacturer. Refer to D5405.
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 manufacturer instructions, syphillis serology quality control records review (years 2020-2021) and laboratory general supervisor interview at 10:00 AM on October 13, 2021, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D5405.