Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1088269	09/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Centro De Servicios De Salud Juan Santiago De	Ramal 1116 Km 2, Guanica, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, syphillis serology quality control records review in years 2017-2018 and laboratory general supervisor interview at 10:30 AM on September 13, 2018, it was determined that the laboratory failed to perform syphillys serology test as required by manufacturer's instructions by Detertor RPR method. The findings include: 1. The laboratory performed RPR (Rapid plasma reagin) by Detector RPR Method. 2. The manufacturer's establishes that the RPR (Rapid plasma reagin) test must be performed at room temperature between 23 C to 29 C for Lot 607207, Exp. 2/28/2019. 3. Review of syphillis serology records from January 2017 to September 12, 2018, the records showed that the laboratory processed and reported one hundred thirty two (132) RPR (Rapid plasma reagin) patient's tests in 2018 that was performed at temperatures out of range in the following nineteen (19) days: Date Temp.C # samples 1/10/2018 29.7 1 1/11/2018 29.9 3 1/13/2018 29.4 9 1/25/2018 20.0 4 1/27/2018 29.3 2 2/3/2018 29.9 2 2/7/2018 29.8 13 2/8/2018 29.5 6 2/14/2018 29.5 5 2/15/2018 29.3 10 2/17/2018 29.8 3 3/14/2018 29.2 11 3/15/2018 29.1 10 4/5 /2018 29.9 4 4/12/2018 29.3 1 4/13/2018 29.7 6 4/18/2018 29.2 6 6/3/2018 20.4 12 6/7 /2018 29.7 6 4. The laboratory proccessed and reported one hundred thirty two (132) RPR (Rapid plasma reagin) patient's samples those days. 5. The laboratory general supervisor confirmed that the laboratory performed RPR (Rapid plasma reagin) tests out of the range established by the manufacturer's those days.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Manufacturer's instructions, syphillis serology quality control records review in years 2017-2018 and laboratory general supervisor interview at 11:30 AM on September 13, 2018, it was determined that laboratory general director failed to ensure compliance with the requirements for analytic systems. Refer to D5411.
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's instructions, syphillis serology quality control records review in years 2017 -2018 and laboratory general supervisor interview at 10:30 AM on September 13, 2018, it was determined that the testing personnel failed to follow quality control procedures. Refer to D5411.
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's instructions, syphillis serology quality control records review in years 2017-2018 and laboratory general supervisor interview at 10:30 AM on September 13, 2018, it was determined that the general supervisor failed to follow quality control procedures. Refer to D5413.