Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1072692	(X3) Date Survey Completed 06/15/2018
Name of Provider or Supplier Laboratorio Clinico Bio Tech Ii	**Street Address, City, State** Carr Pr 3 Km 28 Hm 6 Calle 1 Bloque A-15, Rio Grande, 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's instructions, rapid plasma regain (RPR) test quality control records and laboratory director interview on June 15, 2018 at 11:00 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 56 out of 56 patients specimens were tested and reported for RPR by Immnuno Detector RPR method from January 11, 2018 to June 14, 2018. The findings include: 1. The Immnuno Detector RPR manufacturer instructed the laboratory to perform the RPR tests at room temperature range from 23 to 29 C. 2. On June 15, 2018 at 11:00 AM, the RPR test quality control records showed that the laboratory tested and reported 56 out of 56 patients for RPR tests at temperatures below the manufacturer required from January 11, 2018 to June 14, 2018: Date temperature (C) January 11, 2018 22 January 16, 2018 22 January 22, 2018 21 January 24, 2018 22 January 30, 2018 22 February, 1, 2018 21 February, 5, 2018 22 February, 7, 2018 22 February, 8 2018 22 February, 12, 2018 22 February, 14, 2018 21 February, 15, 2018 22 February, 26, 2018 22 March 3, 2018 21 March 10, 2018 22 March 14, 2018 21 March 17, 2018 22 March 19, 2018 21 March 22, 2018 22 April 2, 2018 21 April 3, 2018 22 April 13, 2018 22 April 25, 2018 22 April 26, 2018 22 May 1, 2018 22 May 7, 2018 22 May 15, 2018 22 May 23, 2018 22 May 24, 2018 22 May 28, 2018 22 May 29, 2018 22 June 4, 2018 22 June 6, 2018 22 June 13, 2018 22 June 14, 2018 22 3. The laboratory director

	confirmed on June 15, 2018 at 11:10 AM, that the laboratory tested and reported 56 out of 56 patients for RPR tests at temperatures below the manufacturer required from January 11, 2018 to June 14, 2018.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, rapid plasma regain (RPR) test quality control records and laboratory director interview on June 15, 2018 at 11:00 AM, it was determined that the laboratory director failed to ensure that the laboratory follow manufacturer's instructions when 56 out of 56 patients specimens were tested and reported for RPR by Immnuno Dtector RPR method from January 11, 2018 to June 14, 2018. Refer to D5405 (The laboratory tested and reported 56 out of 56 patients for RPR tests at temperatures below the manufacturer required from January 11, 2018 to June 14, 2018).
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, rapid plasma regain (RPR) test quality control records and laboratory director interview on June 15, 2018 at 11:00 AM, it was determined that the testing personnel failed to follow manufacturer's instructions when 56 out of 56 patients specimens were tested and reported for RPR by Immnuno Dtector RPR method from January 11, 2018 to June 14, 2018. Refer to D 5405 (The laboratory tested and reported 56 out of 56 patients for RPR tests at temperatures below the manufacturer required from January 11, 2018 to June 14, 2018).