Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658032	05/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Jerico	Calle Brau #30, Cabo Rojo, 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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on manufactuer's instructions, general immunology quality control records review (years 2018-2019) and laboratory director interview at 1:00 PM on May 24, 2019, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of General immunology. The finding includes: 1. The laboratory did not include each day of testing a negative and a positives control materials when patients serum specimens were tested for qualitative H. pylori patient's samples tests by QuickVue H. pylori gII test method. Refer to D 5405.
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, general immunology quality control records review (years 2018-2019) and laboratory director interview at 1:00 PM on May 24, 2019, it was determined that the laboratory failed to include a negative and positive control material when performed H. pylori patient's samples tests by QuickVue H.

	pylori gII test method. The findings include: 1. The laboratory performed H. pylori patient's samples tests by QuickVue H. pylori gII test method. 2. This QuickVue H. pylori gII test method is classified by FDA as moderate complexity. 3. The manufacturer's establishes that two control material (negative and positive) must be included each day of testing for H. pylori patient's samples tests 4. Review of general immunology quality control records from January 2018 to May 2019, showed that the laboratory did not include a negative and positive control material each day of use. This laboratory established to perform the external quality control when each new lot or new shipping. 5. The laboratory director confirmed on May 24, 2019 that the laboratory did not include a negative and positive control material each day of use. This laboratory established to perform the external quality control when each new lot or new shipping. 4. The laboratory performed and reported seventy three (73) H. pylori patient's samples tests since 2018. (2018 = 42, 2019 = 31)
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review (years 2018-2019) and laboratory director interview at 1:00 PM on May 24, 2019, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. (When performed H. pylori patient's samples tests by QuickVue H. pylori gII test method). The finding includes: 1. The laboratory director did not comply with the requierement for analytical systems for qualitative H. pylori patient's samples tests by QuickVue H. pylori gII test method. Refer to D6093.
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's instructions, general immunology quality control records review (years 2018-2019) and laboratory director interview at 1:00 PM on May 24, 2019, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems when performed H. pylori patient's samples tests by QuickVue H. pylori gII test method. The findings include: 1. The laboratory director did not comply with the requierement for analytical systems for qualitative H. pylori patient's samples tests by QuickVue H. pylori gII test method. 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's instructions, general immunology quality control records review (years 2018-2019) and laboratory director interview at 1:00 PM on May 24, 2019, it was determined that the general supervisor failed to follow quality control procedures when performed H. pylori patient's samples tests by QuickVue H. pylori gII test method. The finding includes: 1. The laboratory did not comply with the requierement for analytical systems for qualitative H. pylori patient's samples tests by QuickVue H. pylori gII test method. Refer to D5405.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high 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, general immunology quality control records review (years 2018-2019) and laboratory director interview at 1:00 PM on May 24, 2019, it was determined that testing personnel failed to follow quality control procedures when performed H. pylori patient's samples tests by QuickVue H. pylori gII test method. The finding includes: 1. The laboratory did not comply with the requierement for analytical systems for qualitative H. pylori patient's samples tests by QuickVue H. pylori gII test method. Refer to D5405.