Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0717798	06/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Clausells	Victoria 333 St, Ponce, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of Helicobacter pylori (H. pylori) test manufacturer's instructions, Helicobacter pylori testing records review (years 2018-2019) and laboratory general supervisor interview on June 11, 2019 at 1:00 PM, it was determined that the laboratory failed to follow the H. pylori test manufacturer's instructions when patients samples were tested for H. pylori by Cardinal Health H. pylori Rapid Test method . The findings include: 1. The laboratory used the Cardinal Health H. pylori Rapid Test method to perform H. pylori patient's samples tests. The test was classified as waived. 2 . The manufacturer's instructions (insert) for Cardinal Health H. pylori Rapid Test method showed as intended use: to aid in the diagnosis of H. Pylori in adults 18 years of age and older. 3. From January 2018 to June 2019, the records showed that the laboratory tested and reported eight patients samples specimens under 18 years of age: Date Patient's Id Patient's age 1/24/18 201709-ABV 5 years 4/10/18 211672-GCR 11 years 6/13/18 217786-YCM 10 years 7/12/18 220297-YPT 16 years 8/31/18 225263-AGE 8 years 9/6/18 225822-YMR 3 years 11/2/18 231167-KTR 17 years 2/20/19 242295-VRG 9 years 4. The laboratory general supervisor confirmed on June 11, 2019 at 1:00 PM, that the laboratory used the Cardinal Health H. pylori Rapid Test method and processed and reported eight patients specimens of patients under 18 years of age.
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 review of Helicobacter pylori (H. pylori) test manufacturer's instructions, Helicobacter pylori testing records review (years 2018-2019) and laboratory general supervisor interview on June 11, 2019 at 1:00 PM, it was determined that the laboratory failed to meet the requirements in the subspecialty of general immunology for H. pylori test. Refer to D5423 (the laboratory failed to perform the evaluation of the performance specification for H. pylori by Cardinal Health H. pylori Rapid Test method when modified this method).
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of Helicobacter pylori (H. pylori) test manufacturer's instructions, Helicobacter pylori patient's testing records (years 2018-2019) review and laboratory general supervisor interview on June 11, 2019 at 1:00 PM, it was determined that the laboratory modified the H. pylori Federal Drug Administration (FDA) test, however they did not established the performance specifications prior to use it. The findings include: 1. The laboratory used the Cardinal Health H. pylori test waived method to perform H. pylori patients samples tests. 2. The manufacturer's instructions showed under intended use " to aid in the diagnosis of H. pylori in adults 18 years of age and older. 3. Review of patient's records on June 11, 2019 at 1:00 PM (from January 2018 to June 2019) showed that the laboratory processed and reported eight patient's sample specimens which ages were under 18 years old. Date Patient's Id Patient age 1 /24/2018 201709-ABV 5 years 4/10/2018 211672-GCR 11 years 6/13/2018 217786-YCM 10 years 7/12/2018 220297-YPT 16 years 8/31/2018 225263-AGE 8 years 9/6 /2018 225822-YMR 3 years 11/2/2018 231167-KTR 17 years 2/20/2019 242295-VRG 9 years 4. The laboratory did not established the performance specifications of the test before used with patients samples of 18 years and younger. 5. The laboratory general supervisor confirmed on June 11, 2019 at 1:00 PM that the laboratory used the H. pylori reagent kit for testing patient specimens under 18 years old and did not established the performance specifications of the modified test.
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 review of Helicobacter pylori (H. pylori) test manufacturer's instructions, Helicobacter pylori testing records review (years 2018-2019) and laboratory general supervisor interview on June 11, 2019 at 1:00 PM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for the subspecialty of General immunology for H. pylori test by Cardinal Health H. pylori Rapid Test method . The finding includes: 1.The laboratory director did not comply with the requirements in the subspecialty of General immunology for H. pylori test. Refer to D 6085.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on Cardinal Health H. pylori Rapid Test method manufacturer's instructions, H. pylori testing records, H. pylori tests report records review and interview with the technical consultant on June 11, 2019 at 1:00 PM, it was found that the laboratory director failed to ensure that the H. pylori test methodology used and selected by the laboratory, have the capability of providing the quality of results required for patient with under 18 years of age from January 2018 to June 2019. Refer to D 5421 (the laboratory failed to perform the evaluation of the performance specification for H. pylori by Cardinal Health H. pylori Rapid Test method when modified this method).
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 review of Helicobacter pylori (H. pylori) test manufacturer's instructions, Helicobacter pylori testing records review (years 2018-2019) and laboratory general supervisor interview on June 11, 2019 at 1:00 PM, it was determined that the general supervisor failed to assure that the testing personnel in charge of the H. pylori patients test processing followed the manufacturer's instruction. Refer to 6177.
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 review of Helicobacter pylori (H. pylori) test manufacturer's instructions, Helicobacter pylori testing records review (years 2018-2019) and laboratory general supervisor interview on June 11, 2019 at 1:00 PM, it was determined that the testing personnel failed to follow manufacturer's instruction for specimens processing. The findings includes: 1. The laboratory used the Cardinal Health H. pylori Rapid Test method to perform H. Pylori test. 2. The manufacturer's instructions established that the test must be used with patients of 18 years of age and older. 3. The testing records showed that the testing personnel performed the test in patients younger than 18 years years old. Date Patient's Id Patient age 1/24/2018 201709-ABV 5 years 4/10/2018 211672-GCR 11 years 6/13/2018 217786-YCM 10 years 7/12/2018 220297-YPT 16 years 8/31/2018 225263-AGE 8 years 9/6/2018 225822-YMR 3 years 11/2/2018 231167-KTR 17 years 2/20/2019 242295-VRG 9 years 4. The general supervisor confirmed that the tests were performed in patients younger than 18 years years old.