

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0865153	(X3) Date Survey Completed 02/07/2020
Name of Provider or Supplier Cdt Tmg Medical Group Csp	Street Address, City, State Calle Tomas Davila 1 Barceloneta, Barceloneta, 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	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>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 2019-2020) and laboratory director and general supervisor interview on February 7, 2020 at 11:10 A.M., 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 Instant view H. pylori Rapid Test method . The findings include: 1. The laboratory used the Instant view 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 Instant view H. pylori Rapid Test method showed as intended use: use with serum specimens of adults, 19 years and older. 3. From January 2019 to January 2020, the records showed that the laboratory tested and reported four patients samples specimens under 19 years of age: Date Patient's Id Patient's age 1/31/2019 111968 14 years 3/12/2019 114784 17 years 6/4/2019 35106 6 years 8/12/2019 8273 16 years 4. The laboratory director confirmed on February 7, 2020 at 11:30 A. M, that the laboratory used the Instant view H. pylori Rapid Test method and processed and reported four patients specimens of patients under 19 years of age.</p>
D5014	<p>GENERAL IMMUNOLOGY CFR(s): 493.1208</p> <p>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</p>

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 2019-2020) and laboratory director and general supervisor interview on February 7, 2020 at 11:10 A.M., 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 Instant view 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 2019-2020) review and laboratory director and general supervisor interview on February 7, 2020 at 11:10 A.M., 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 Instant view H. pylori test waived method to perform H. pylori patients samples tests. 2. The manufacturer's instructions showed under intended use " with serum specimens of adults, 19 years and older. 3. Review of patient's records from January 2019 to January 2020) showed that the laboratory processed and reported four patient's sample specimens which ages were under 19 years old. Date Patient's Id Patient age 1/31/2019 111968 14 years 3/12 /2019 114784 17 years 6/4/2019 35106 6 years 8/12/2019 8273 16 years 4. The laboratory did not established the performance specifications of the test before used with patients samples of 19 years and younger. 5. The laboratory director confirmed on February 7, 2020 at 11:30 A.M. that the laboratory used the H. pylori reagent kit for testing patient specimens under 19 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.

	<p>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 2019-2020) and laboratory director and general supervisor interview on February 7, 2020 at 11:30 A.M., 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 Instant view 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.</p>
<p>D6085</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)</p> <p>The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.</p> <p>This STANDARD is not met as evidenced by: Based on Instant view H. pylori Rapid Test method manufacturer's instructions, H. pylori testing records, H. pylori tests report records review and interview with the laboratory director on February 7, 2020 at 11:30 A.M., 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 19 years of age from January 2019 to January 2020. Refer to D 5423 (the laboratory failed to perform the evaluation of the performance specification for H. pylori by Instant view H. pylori Rapid Test method when modified this method).</p>
<p>D6144</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>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 2019-2020) and laboratory general supervisor interview on February 7, 2020 at 11:30 A.M., it was determined that the general supervisor (testing personnel) failed to perform the H. pylori patients test processing followed the manufacturer's instruction.</p>