

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0719322	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Lab Diaz Garcia	Street Address, City, State Calle Juan Colon Padilla # 50, Arecibo, 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
D5020	<p>ENDOCRINOLOGY CFR(s): 493.1212</p> <p>If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on serum Human Chorionic Gonadotropin (hCG) test quality control records (years 2019 to 2020) and interview with the laboratory laboratory general supervisor on September 17, 2020 at 11:10 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for serum hCG qualitative tests. The finding includes: 1. The human chorionic gonadotropin (hCG) test quality control records (years 2019-2020) showed that the laboratory did not include each day of testing a negative and a positive control material when patients specimens were processed and reported for serum hCG qualitative test. Refer to D 5449.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on endocrinology quality control records review (year 2019-2020) and interview with the laboratory general supervisor on September 17, 2020 at 11:10 AM ,</p>

it was determined that the laboratory failed to include a negative and positive control material each day of testing when performed hCG test. The findings include : 1. The laboratory performed hCG (human chorionic gonadotropin) by one step method. 2. Endocrinology quality control logs were reviewed from January 2019 to September 17, 2020. 3. The records showed that the laboratory did not include a negative and a positive control material when performed hCG test from January 2020 to September 2020. 4. The laboratory performed and reported sixty one (61) patient samples in 2020. 5. The laboratory laboratory general supervisor confirmed on September 17, 2020 at 11:15 A.M., that the laboratory did not include a negative and a positive control material each day of testing when performed hCG test since January 2020.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

1. Based on syphilis serology quality control records review (year 2019-2020) and laboratory general supervisor interview on September 17, 2020 at 10:30 a.m., it was determined that the laboratory did not evaluate the new lots of Rapid plasma reagin (RPR) tests for positive and negative reactivity prior to placed it in routine use. The findings include: a. The laboratory quality control records were review since January 2019. b. The laboratory received the following reagent kits and no evaluation of their reactivity was performed: Test Lot Exp. Date First day of use RPR 81440 1/31/2020 7 /12/2019 85142 4/17/2020 4/17/2020 2. Based on endocrinology quality control records review (year 2019-2020) and laboratory general supervisor interview on September 17, 2020 at 10:30 a.m. , it was determined that the laboratory did not evaluate a new lot of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine use. The findings include: a. The laboratory quality control records were review from January 2019 to September 2020. b. The laboratory received the following reagent kit and no evaluation of their reactivity was performed: Test Lot Exp.Date First day of use hCG F812010 12/17 /2020 07/2019

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 quality control records review (year 2019-2020) and laboratory general

	<p>supervisor interview on September 17, 2020 at 11:30 A.M. , it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D 6093.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on endocrinology and syphilis serology quality control records review (from January 1, 2019 to September 2020) and laboratory director and testing personnel interview on September 17, 2020 at 11:30 A.M., it was determined that the laboratory director failed to follow quality control procedures for hCG test. The finding includes: 1. The laboratory did not include each day of testing a positive and negative control materials for hCG tests. Refer to D 5449. 2. The laboratory did not evaluate the new lots of Rapid plasma reagin (RPR) and hCG tests for positive and negative reactivity prior to placed it in routine use. Refer to D5471.</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 endocrinology quality control records review (years 2019-2020) and laboratory general supervisor interview at 11:30 AM on September 17, 2020, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D6177.</p>
<p>D6177</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on quality control records review (years 2019-2020) and laboratory general supervisor interview at 11:30 AM on September 17, 2020, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The testing personnel failed to include a negative and positive control material each day of testing when performed hCG test. Refer to D5449. 2. The testing personnel did not evaluate new RPR and hCG reagent lots for positive and negative reactivity prior to placed it in routine use. Refer to D5471.</p>