

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2032328	(X3) Date Survey Completed 12/11/2018
Name of Provider or Supplier Cdt-Policlinica Dr Melendez	Street Address, City, State Road 685 Km 1 Hm 9 Bo Tierras Nuevas, Manati, 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 2017 to 2018) and interview with the laboratory director and laboratory general supervisor on December 11, 2018 at 10:30 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 2017 to 2018) 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:</p>

Based on endocrinology quality control records review and interview with the laboratory director and laboratory general supervisor on December 11, 2018 at 10:15 AM , 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 aim step method.
2. Endocrinology quality control logs were reviewed from January 2017 to December 2018.
3. The records showed that the laboratory did not include a negative and a positive control material when performed hCG test from January 2017 to November 2018.
4. The laboratory performed and reported one hundred forty six patient samples in 2017 and one hundred thirty three patient samples in 2018.
5. The laboratory director and laboratory general supervisor confirmed on December 11, 2018 at 10:15 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 2017.

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 endocrinology quality control records review (2017-2018) and testing personnel interview on December 11, 2018 at 11:00 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system The finding includes: 1.The laboratory director failed to ensure that the laboratory include a negative and positive control material each day of testing when performed hCG test. Refer to D5449.

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 endocrinology quality control records review and interview with the laboratory director on December 11, 2018 at 10:15 A.M. , it was found that the laboratory director did not fulfill his responsibilities since year 2017. The findings include: 1. The laboratory director failed to ensure that the laboratory include a negative and positive control material each day of testing when performed hCG test. Refer to D5449.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate

results.

This STANDARD is not met as evidenced by:

Based on testing personnel records review and laboratory director interview on December 11 2018 at 9:00 A.M., it was found that the laboratory director did not make sure that the new testing personnel received the appropriate training before beginning to perform patient tests. The findings include: 1. The testing personnel # 1, 2 and 3 was hired and performed patient testing since March and August 2018. 2. The laboratory did not have any document related to testing personnel training. 3. The laboratory director confirmed on December 11, 2018 at 9:00 A.M., that the laboratory did not document the testing personnel training prior to perform patient tests.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records files and interview with the laboratory general supervisor and laboratory director on December 11, 2018 at 10:30 A.M. it was determined that the laboratory director did not specify the duties of the new testing personnel. The findings include: 1. Personnel records files were reviewed since January 2017. 2. The personnel records files showed that the laboratory did not include the written duties and responsibilities for the new testing personnel hired on March and August 2018. 3. The laboratory director confirmed on December 11, 2018 at 10:30 A.M., that the personnel records files of the new testing personnel did not include the written duties and responsibilities.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on personnel records review and laboratory director interview at 10:30 A.M. on December 11, 2018, it was determined that the technical supervisor failed to provide annually the competence evaluation to the general supervisor and testing personnel (MT# 4) that performed the high and moderate complexity tests. The findings include: 1. The technical supervisor failed to perform the annual competency evaluation to the general supervisor and testing personnel (MT # 4) that include at least the following

requirements since January 2017: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

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 endocrinology quality control records review(2017-2018) and interview with the laboratory general supervisor and laboratory director on December 11, 2018 at 10:15 A.M. , it was determined that the general supervisor failed to ensure that the laboratory include a negative and positive control material each day of testing when performed hCG test. The finding includes: 1. The laboratory failed to ensure that the laboratory include a negative and positive control material each day of testing when performed hCG test. Refer to D5449.

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 endocrinology quality control records review(2017-2018) and interview with the laboratory general supervisor and laboratory director on December 11, 2018 at 10:15 A.M. , it was determined that the testing personnel failed to ensure that the laboratory include a negative and positive control material each day of testing when performed hCG test. The finding includes: 1. The laboratory testing personnel failed to ensure that the laboratory include a negative and positive control material each day of testing when performed hCG test. Refer to D5449.