

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2092321	(X3) Date Survey Completed 02/07/2023
Name of Provider or Supplier Lab Cl Centro De Diagnostico Y Tratamiento	Street Address, City, State Calle Manuel Pimentel Y Castro Num 200, Rio Grande, 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
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 (years 2021-2023), patient's reports worksheets review and laboratory general supervisor interview on February 7, 2023 at 10:45 AM, it was determined that the laboratory failed to include a negative and positive control material each day of testing when reported and performed hCG test 13 out of 368 patient's samples in 7 out of 217 days. The findings include : 1. The laboratory performed hCG (human chorionic gonadotropin) by Alere one step method. Review on February 7, 2023 at 10:45 AM. 2. Endocrinology quality control logs and patient's reports worksheets were reviewed from November 1, 2022 to February 6, 2023. Review on February 7, 2023 at 10:50 AM. 3. The endocrinology quality control logs and patient's reports worksheets records showed that the laboratory did not include a negative and positive control material each day of testing from April 24, 2022 to October 27, 2022, when performed and reported 13 patient's samples in the following days: (reviewed on February 7, 2023 at 10:53 AM) Date hCG patient's samples 4/24/2022 1 6/11/2023 3 7/21/2022 2 10/20/2022 1 10/21/2022 4 10/25/2022 1 10/27/2022 1 4. The laboratory general supervisor confirmed on February 7, 2023 at 10:55 a.m. , that the laboratory failed to include a negative and positive control material each day of testing when performed hCG test.</p>
D6072	TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate 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 (years 2021-2023), patient's reports worksheets review and laboratory general supervisor interview on February 7, 2023 at 10:45 AM, it was determined that testing personnel failed to follow quality control procedures. 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 (years 2021-2023), patient's reports worksheets review and laboratory general supervisor interview on February 7, 2023 at 10:45 AM, it was determined that the laboratory director failed to maintain the quality control procedures for hCG test 13 out of 368 patient's samples in 7 out of 217 days by Alere One Step Method. The finding include: 1. The laboratory failed to include a negative and positive control material each day of testing when reported and performed hCG test 13 out of 368 patient's samples in 7 out of 217 days. Refer to D5449.

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 (years 2021-2023), patient's reports worksheets review and laboratory general supervisor interview on February 7, 2023 at 10:45 AM, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D5449.