

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658300	(X3) Date Survey Completed 07/26/2019
Name of Provider or Supplier Laboratorio Clinico Dr Cordova	Street Address, City, State 1055 Brumbaugh St, Rio Piedras, 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
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on endocrinology quality control records review (years 2017-2019) and laboratory director interview at 9:30 AM on July 26, 2019, it was determined that the laboratory did not evaluate the new reagents lots of hCG qualitative (human chorionic gonadotropin) test for positive and negative reactivity prior to placed it in routine use. The findings include: 1. The laboratory endocrinology quality control records were reviewed from August 2017 to July 26, 2019. 2. The laboratory uses Aim Step Combo hCG to perform hCG qualitative (human chorionic gonadotropin) patient's samples test. 3. The laboratory received the following reagent kit lots and no evaluation of their reactivity was performed: Lot Expiration Date 70522 6/30/19 71222 10/31/19 72862 12/31/19 80332 5/31/20 4. The laboratory processed and reported one hundred thirty one (131)) hCG qualitative (human chorionic gonadotropin) patient's samples from March 5, 2018 to July 26, 2019. 5. The laboratory director confirmed on July 26, 2019 at 9:30 AM that the laboratory received the hCG qualitative (human chorionic gonadotropin) reagent kit lots by Aim Step Combo hCG and no evaluation of their reactivity were performed.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</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.

This STANDARD is not met as evidenced by:
Based on endocrinology quality control records review (years 2017-2019) and laboratory director interview at 9:30 AM on July 26, 2019, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5471.

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 2017-2019) and laboratory director interview at 9:30 AM on July 26, 2019, it was determined that the general supervisor failed to assure that quality control procedures related to new reagent lots evaluation were performed. Refer to D5471.