

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0669486	(X3) Date Survey Completed 12/17/2019
Name of Provider or Supplier Laboratorio Clinico Lomar	Street Address, City, State Calle Palmer 16, Ciales, 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 virology quality control records review (2018-2019), manufacturer's instructions and laboratory director interview at 10:30 a.m. on December 17, 2019, it was determined that the laboratory failed to include and document a negative and a positive control material with each new lot when performed Influenza A& B test. The finding include : 1. The laboratory performed on 2018 and 2019 Influenza by Quick Vue and Osom method. 2. The manufacturer's establishes that the laboratory must include a positive and a negative control material with each new lot or new shipment. 3. The virology quality control records were review from 1/2018 to 12/2019. 4. The records showed that the laboratory did not include a negative and positive control material when begin to use the following Influenza A& B new lots: 4447L11 (1/25 /18) 4447M51 (1/29/18) 703661 (2/27/18) 4448K31 (1/2019) 448L11 (2/5/19) 4449H11 (11/20/19 5. The laboratory established document the quality control as done (QC=ok) , but failed to document the reaction of the positive and negative control for Influenza A& B . 6. The laboratory director confirmed on December 17, 2019 at 10:30 A.M., that the laboratory failed to document the reaction of the positive and negative control for Influenza A& B with each new lot or new shipment.</p>
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</p>

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:

Based on endocrinology quality control records, patient test records review from March 2018 to December 2019 and laboratory director interview at 10:10 a.m. on December 17, 2019, it was determined that the laboratory did not evaluate the new lots of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine. The findings include: 1. Endocrinology tests quality control records were review from March 2018 to December 2019. 2. The laboratory received the following reagent kit and no evaluation of their reactivity was performed: Test Lot Expiration Date hCG 73312 8/21/18 hCG 80332 12/22/18 hCG 82004 4/15 /19 3. Review of endocrinology patient's test log book showed that eighty-two (82) patients were tested and reported with these lots used form March 2018 to March 2019. 4. The laboratory director confirmed on December 17, 2019 at 10:15 A.M., that the laboratory failed to evaluate the new lots of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine.

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, patient test records review from March 2018 to December 2019 and laboratory director interview at 10:10 a.m. on December 17, 2019, it was determined that the laboratory director did not assure that the testing personnel evaluated the new lots of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine. 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 2018-2019) and laboratory director interview at 10:30 AM on December 17, 2019, it was determined that the general supervisor did not assure that quality control procedures for hCG test were followed by the testing personnel. Refer to D6177.

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 (years 2018-2019) and laboratory director interview at 10:30 AM on December 17, 2019, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The testing personnel failed to evaluate the new lots of hCG- Human Chorionic Gonadotropin test for positive and negative reactivity prior to placed it in routine. Refer to D5471.