

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2048021	(X3) Date Survey Completed 05/25/2023
Name of Provider or Supplier Laboratorio Clinico Caimito	Street Address, City, State Carretera 842, Km 5, Hm4 Caimito Alto, San Juan, 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 syphilis serology quality control records, patients reports worksheets review (years 2022-2023) and laboratory director interview at 9:45 AM on May 25, 2023, it was determined that the laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test by TECO Method for positive and negative reactivity prior to placed it in routine use when reported and performed 98 out of 98 syphilis serology patients samples. The findings include: 1. The laboratory syphilis serology quality control records were review from January 2022 to May 2023. (reviewed on 5/25/2023 at 9:45 a.m.) 2. The patient reports worksheets (2022-2023) showed on May 25, 2023 at 9:50 a.m., that the laboratory received the following reagent kit for RPR Method and no evaluation of their reactivity was performed: Test Lot 1- RPR 94381 exp. date: 12/21/23 opened day : 5/3/2022 2.- RPR lot: 87405 exp. date: 4/30/2022 opened day : 1/10/2022 3. The laboratory used the lot -94381 from 1/10/2022 to 4/28 /2022 and reported and processed 36 RPR (Rapid plasma reagin) patient's samples. (reviewed on 5/25/23 at 10:10 a.m.) 4. The laboratory used the lot -87405 from 5/3 /2022 to 5/2023 and reported and processed 52 RPR (Rapid plasma reagin) patient's samples. (reviewed on 5/25/2023 at 10:10 a.m.) 5. The laboratory director confirmed on May 25, 2023 at 10:15 a.m. that the laboratory did not evaluate the new lot of</p>

Rapid Plasma reagin (RPR) test for positive and negative reactivity prior to placed it in routine use.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on syphilis serology quality control records review (2022-2023) and laboratory director interview on May 25, 2023 at 10:15 A.M., it was determined that laboratory director failed to ensure compliance with the requirements for syphilis serology analytic systems. Refer to D5471. (The laboratory did not evaluate the new lot of Rapid Plasma reagin (RPR) test by ASI RPR Method for positive and negative reactivity prior to placed it in routine use).