

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0677932	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Lab Clinico Caribe	Street Address, City, State Gautier Benitez #8, Cidra, 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
D5012	<p>SYPHILIS SEROLOGY CFR(s): 493.1207</p> <p>If the laboratory provides services in the subspecialty of Syphilis serology, 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 syphilis serology quality control records review and laboratory director interview on August 16, 2018 at 10:43 AM, it was determined that the laboratory failed to included meet the requirements for syphilis serology by Rapid Plasma Reagin (RPR) quantitative tests. Refer to D5451.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on urinalysis procedures manual, urinalysis quality control records review from January 7, 2018 to August 16, 2018 and laboratory director interview on August 16, 2018 at 10:55 AM, it was determined that the laboratory failed to follow manufacturer's instructions to perform the preventive maintenance of centrifuge and microscope. The findings include: 1. The laboratory did not perform the preventive maintenance of the centrifuge and microscope from January 7, 2018 to August 16, 2018. 2. The laboratory director confirmed on August 16, 2018, that those preventive maintenance did not perform from January 7, 2018 to August 16, 2018. 3. The 2017's</p>

	<p>annual volume records showed that the laboratory processed 7,788 patients specimens.</p>
<p>D5451</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (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 review from January 7, 2017 to August 16, 2018 and laboratory director interview on August 16, 2018 at 10:42 AM, it was determined that the laboratory failed to include at least once a day, a negative control material and a control material with tittered reactivity when patients were tested for syphilis serology by Rapid Plasma Reagin (RPR) quantitative tests. The finding includes: 1. The laboratory performed Rapid Plasma Reagin (RPR) by TECO RPR Reagents set. 2. Review of syphilis serology quality control fro January 7, 2017 to August 16, 2018, showed that the laboratory did not include at least once a day, a negative control material and a control material with tittered reactivity when the following patient specimen was processed and report on May 12, 2017 (ID # 424829, R 1:8 dils.). 3. The laboratory director confirmed on August August 16, 2018, that the laboratory did not include at least once day, a control material and a control material with tittered reactivity when patients specimens were tested for serology quantitative this day.</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on procedures manual, quality control records review from January 7, 2017 to August 16, 2018 and laboratory director interview on August 16, 2018, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: 1. failed to follow manufacturer's instructions to performed the preventive maintenance of centrifuge and microscope. Refer to D5429. 2. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (Rapid Plasma Reagin) by TECO. Refer to D5451.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on procedures manual, quality control records review and laboratory director interview on August 16, 2018 at 11:58 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The finding includes: 1. The laboratory director did not comply with the requirements for analytical systems and quality assessment requirements. Refer to D6220 and D6221.

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 procedures manual, quality control records review and laboratory director interview on August 16, 2018 at 11:56 AM, it was determined that the laboratory director failed to ensure compliance with requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. failed to perform the preventive maintenance of the centrifuges and microscope. Refer to D5429. b. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (rapid Plasma Reagin) by TECO. Refer to D5451.

D6021

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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review and laboratory director interview on August 16, 2018 at 11:58 AM, it was determined that the laboratory director failed to ensure compliance with Quality Assessment (QA) requirements. The finding includes: 1. The laboratory director did not evaluate the established Quality Assessment Program to monitor and document the following requirement for analytic systems: a. failed to follow manufacturer's instructions to performed the preventive maintenance of centrifuge and microscope. Refer to D5429. b. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (Rapid Plasma Reagin) by TECO. Refer to D5451.

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 procedures manual, quality control records review and laboratory director interview on August 16, 2018, it was determined that the testing personnel failed to follow the quality control requirements. The finding includes: 1. The laboratory testing personnel failed to following quality control procedures: a. failed to perform the preventive maintenance of the centrifuges and microscope. Refer to D5429. b. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (rapid Plasma Reagin) by TECO. Refer to D5451.