

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0676483	(X3) Date Survey Completed 09/20/2018
Name of Provider or Supplier Laboratorio Clinico Central De Toa Alta	Street Address, City, State Calle Antonio Lopez # 32, Toa Alta, 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 (2018) and laboratory director interview on September 20, 2018 at 11:00 A.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory failed to follow manufacturer's instructions when patients specimen were tested for syphilis serology from January 2018 to September 2018. Refer to D5405.</p>
D5405	<p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology quality control records (year 2018) , manufacturer's instructions review and laboratory director interview on September 20, 2018 at 11:00 A.M., it was determined that the laboratory failed to follow manufacturer's instructions when patients specimen were tested for syphilis serology from January 2018 to September 2018. The findings include: 1. The manufacturer's instruction</p>

establishes that three levels of control material (non reactive, reactive and weakly reactive) must be included each day of testing. 2. From January 2018 to September 2018, the syphilis serology quality control records showed that the laboratory did not include the three levels of control material 101 out of 141 days . 3. The laboratory did not include the three levels of control material the following days: a. January 2018 - 4 of 9 days b. February 2018 - 12 out of 18 days c. March 2018- 12 out of 16 days d. April 2018- 14 out of 20 days e. May 2018- 15 out of 21 days f. June 2018- 12 out of 14 days g. July 2018- 12 out of 16 days h. August 2018- 12 out of 16 days i. September 2018-8 out of 11 days 4. The laboratory processed and reported 225 syphilis serology patient samples those months. 5. The laboratory director stated on September 20, 2018 at 11:00 A.M., that the laboratory failed to document the three levels of control material each day of testing.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 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 syphilis serology quality control records review (2018) and laboratory director interview on September 20, 2018 at 11:00 A.M, it was determined that the laboratory director failed to fulfill his responsibilities with the laboratory analytical system for Syphilis Serology specialty. The finding includes: 1. The laboratory did not comply with the requirements in the Syphilis Serology specialty . Refer to D6020

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 (2018) and laboratory director interview on September 20, 2018 at 11:00 A.M, it was determined that the laboratory director failed to ensure compliance with the laboratory analytical system for Syphilis Serology specialty. The finding includes: 1. The laboratory director failed to ensure compliance with the analytic system of Syphilis Serology specialty . Refer to D 5405.