

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2082435	(X3) Date Survey Completed 09/13/2018
Name of Provider or Supplier Laboratorio Clinico La 116	Street Address, City, State Centro Comercial Plaza Guanica, Bo Cano., Guanica, 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 Immunostic manufacturer's instructions for qualitative rapid plasma reagin (RPR) test, RPR quality control record review and technical consultant interview on September 13, 2018 at 10:50 AM, it was determined that the laboratory failed to meet the subspecialty of Syphilis serology for qualitative RPR test. Refer to D 5405 (The laboratory did not follow the quality control procedures when 8 out of 8 patients specimens were tested for qualitative RPR from June 13, 2018 to July 24, 2018).</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 Immunostic manufacturer's instructions for qualitative rapid plasma reagin (RPR) test, RPR quality control record review and technical consultant interview on September 13, 2018 at 10:50 AM, it was determined that the laboratory failed to follow quality control procedures when 8 out of 8 patients specimens were tested for</p>

qualitative RPR from June 13, 2018 to July 24, 2018. The findings included: 1. The laboratory used the Immunostic RPR reagent kit (antigen lot 9495) from June 8, 2018 to August 11, 2018. 2. The Immunostic manufacturer's instructed the laboratory to include three control materials each day of testing (non reactive, weakly reactive and reactive). 3. The RPR quality control record showed that the laboratory did not include each day of testing the three control materials when 8 out of 8 patients specimens were tested for qualitative RPR from June 13, 2018 to July 24, 2018: Date request Date reported sample ID June 13, 2018 June 15, 2018 #30524 June 27, 2018 June 27, 2018 #30952 June 27, 2018 June 28, 2018 #30940 June 27, 2018 June 28, 2018 #30942 June 27, 2018 June 28, 2018 #30947 June 27, 2018 June 28, 2018 #30962 July 24, 2018 July 24, 2018 #31709 July 24, 2018 July 24, 2018 #31712 4. The technical consultant confirmed on September 13, 2018 at 10:55 AM, that the quality control record for the RPR test did not include the result of the three control materials those days. She stated, that the laboratory performed the quality control procedures but not documented the controls result.

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 Immunostic manufacturer's instructions for qualitative rapid plasma reagin (RPR) test, RPR quality control record, personnel file review, lack of technical consultant competence records and the technical consultant interview on September 13, 2017 at 11:15 AM, , it was determined that the laboratory director failed to fulfil her responsibilities and duties to comply with the analytic system and with the technical consultant competence. Refer to D6020 (The laboratory director failed to ensure that the laboratory performed the quality control procedures when 8 out of 8 patients specimens were tested for qualitative RPR from June 13, 2018 to July 24, 2018). Refer to D 6030 (The laboratory director failed to ensure that policies and procedures were established for monitoring the competence of the technical consultant since January 2017).

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 Immunostic manufacturer's instructions for qualitative rapid plasma reagin (RPR) test, RPR quality control record review and technical consultant interview on September 13, 2018 at 10:50 AM, it was determined that the laboratory director failed to ensure that the laboratory performed the quality control procedures when 8 out of 8

patients specimens were tested for qualitative RPR from June 13, 2018 to July 24, 2018. Refer to D 5012 (The laboratory failed to meet the subspecialty of Syphilis serology for qualitative RPR test).

D6030

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on personnel file review, lack of technical consultant competence records and the technical consultant interview on September 13, 2017 at 11:15 AM, it was determined that the laboratory director failed to ensure that policies and procedures were established for monitoring the competence of the technical consultant since January 2017. The findings include: 1. The technical consultant file showed that the laboratory director did not evaluate annually her performance as technical consultant since January, 2017. The laboratory director evaluated this personnel as general supervisor and testing personnel. 2. The technical supervisor confirmed that the laboratory director did not evaluate annually her performance as technical consultant since January 2017,

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on Immunostic manufacturer's instructions for qualitative rapid plasma reagin (RPR) test, RPR quality control record review and technical consultant interview on September 13, 2018 at 10:50 AM, it was determined that the technical consultant failed to ensure that the laboratory performed the quality control procedures when 8 out of 8 patients specimens were tested for qualitative RPR from June 13, 2018 to July 24, 2018. Refer to D5405.