

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1084371	<b>(X3) Date Survey Completed</b>  04/23/2019
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Costa Isabela	<b>Street Address, City, State</b>  Carr Pr-459 Km 14 Hm 6 Bo Bejucos, Isabela, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2071</b>	<p><b>SYPHILIS SEROLOGY</b> CFR(s): 493.835(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review ( 2017-2018) and laboratory director interview on April 23, 2019 at 10:00 A.M., it was determined that the laboratory failed to report the syphilis serology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2017 to February 2019. 2. The deadline of the first testing event report of syphilis serology tests was May 25, 2018. 3. The laboratory did not report the first testing event of syphilis serology within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event 4. The laboratory director confirmed on April 23, 2019 at 10:00 A.M. that the laboratory did not report the syphilis serology proficiency testing results of the first testing event within the time frame established by the Proficiency Testing Program.</p>
<b>D2081</b>	<p><b>GENERAL IMMUNOLOGY</b> CFR(s): 493.837(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on Puerto Rico Proficiency Testing Program records review ( 2017-2018) and laboratory director interview on April 23, 2019 at 10:00 A.M., it was determined that the laboratory failed to report the general immunology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2017 to February 2019. 2. The deadline of the first testing event report of general immunology tests ( Rheumatoid factor and C-reactive protein ) was May 25, 2018. 3. The laboratory did not report the first testing event of general immunology within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event. 4. The laboratory director confirmed on April 23, 2019 at 10:00 A.M. that the laboratory did not report the general immunology proficiency testing results of the first testing event within the time frame established by the Proficiency Testing Program.

**D6017**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(ii)

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)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on observation , Puerto Rico Proficiency Testing Program records review (year 2017-2018) and laboratory director interview on April 23, 2019 at 10:00 A.M., it was determined that the laboratory failed to ensure that report proficiency testing test results are returned within the time frame established by the proficiency testing program. The findings include: 1. Proficiency testing records were reviewed from February 2017 to February 2019. 2. The deadline of the Puerto Rico Proficiency Testing Program (May 2018 - first testing event) report of syphilis serology and general immunology tests was May 25, 2018. 3. The laboratory did not report the first testing event of syphilis serology and general immunology tests within the time frame established by the Puerto Rico Proficiency Testing Program. 4. The laboratory director stated on April 23, 2019 at 10:00 A.M. that the laboratory did not report the syphilis serology and general immunology proficiency testing results of the first testing event within the time frame established by the Puerto Rico Proficiency Testing Program.