

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D2059616	<b>(X3) Date Survey Completed</b> 08/23/2019
<b>Name of Provider or Supplier</b> Laboratorio Clinico Shaddai	<b>Street Address, City, State</b> Carr 2, Km 99 Bo Cocos, Quebradillas, 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>D2067</b>	<p><b>SYPHILIS SEROLOGY</b> CFR(s): 493.835(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed ( 2018-2019) laboratory director interview on August 23, 2019 at 10: 00 A.M., it was determined that the laboratory failed to participate in the syphilis serology second testing event performed in August 2018. The findings include: 1. Proficiency testing records were reviewed from February 2018 to July 2019. 2. The laboratory did not participate in the second testing event of syphilis serology performed in August 2018 established by the Proficiency Testing Program. 3. The laboratory director confirmed on August 23, 2019 at 10:00 A.M., that the laboratory failed to participate in the second testing event of syphilis serology specialty in August 2018.</p>
<b>D2123</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended</p>

during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on American Association of Bioanalysts (AAB) Testing Program records reviewed ( 2018-2019) laboratory director interview on August 23, 2019 at 10: 00 A. M., it was determined that the laboratory failed to participate in the hematology first testing event performed in February 2019. The findings include: 1. Proficiency testing records were reviewed from February 2018 to July 2019. 2. The laboratory did not participate in the first testing event of hematology performed in February 2019 established by the AAB Proficiency Testing Program. 3. The laboratory director confirmed on August 23, 2019 at 10:00 A.M., that the laboratory failed to participate in the first testing event of hematology specialty in February 2019.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on Puerto Rico proficiency testing records review ( 2018-2019) and laboratory director interview on August 23, 2019 at 10:00 A.M., it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D 2067 and D2123.