

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0695251	<b>(X3) Date Survey Completed</b> 03/06/2018
<b>Name of Provider or Supplier</b> Laboratorio Clinico Ramirez	<b>Street Address, City, State</b> 20 Sur Calle 65 Infanteria Suite 2, Lajas, 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>D2127</b>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(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: Based on Puerto Rico Proficiency Testing Program records reviewed ( 2016-2017) and laboratory general supervisor interview on March 6, 2018 at 10:00 A.M., it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2016 to July 2017. 2. The return deadline of the second testing event report of hematology tests was July 29, 2016. 3. The laboratory did not report the second testing event of hematology within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event. 4. The laboratory general supervisor director confirmed on March 6, 2018 at 10:00 A.M. that the laboratory did not report the hematology proficiency testing results of the second testing event within the time frame established by the Proficiency Testing Program.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p>

This STANDARD is not met as evidenced by:  
Based on Puerto Rico Proficiency testing records review and laboratory general supervisor interview on March 6, 2018 at 10:00 AM, it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2127.

**D6144**

**GENERAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:  
Based on Puerto Rico Proficiency testing records review and laboratory general supervisor interview on March 6, 2018 at 10:00 AM, it was determined that the laboratory general supervisor failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2127.