

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1095483	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Laboratorio Clinico Riaza	Street Address, City, State #502 Calle Riaza, Urb Matienzo Cintron, Bo Oriente, San Juan, 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
D2127	<p>HEMATOLOGY 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 (PRPTP) records reviewed from February 2017 to March 2019 and laboratory testing personnel interview on April 10, 2019 at 9:24 AM, it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the proficiency testing program. The findings include: 1. Proficiency testing records were reviewed from February 2017 to March 2019. 2. The deadline of the PRPTP first testing event report of hematology tests was March 21, 2019. 3. The laboratory did not report the PRPTP first testing event of hematology within the time frame established by the PRPTP. The laboratory obtained a score of 0% for the testing event. 4. The laboratory testing personnel confirmed on April 10, 2019 at 9:24 AM, that the laboratory did not report the hematology proficiency testing results of the PRPTP first testing event within the time frame established by the Proficiency Testing Program.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p>

This CONDITION is not met as evidenced by:
1. Based on records review and laboratory testing personnel interview on April 10, 2019 at 8:18 AM, it was determined that the laboratory director position is not filled since March 31, 2019. The findings include: a. The previous laboratory director resigned on March 31, 2019. b. The laboratory testing personnel confirmed on April 10, 2019, that the previous laboratory director resigned on March 31, 2019 and that the laboratory position position was not filled. 2. Based on proficiency records test results review on April 10, 2019, at 9:24 AM, it was determined that the laboratory failed to fulfill his responsibilities and duties to ensure compliance with the proficiency testing program. Refer to D 6090.

D6090

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2017 to March 2019 and laboratory testing personnel interview on April 10, 2019 at 9:24 AM, it was determined that the laboratory director failed to ensure that the proficiency testing test results were returned within the time frame established by the proficiency testing program. Refer to D 2127.