

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1057413	<b>(X3) Date Survey Completed</b>  09/26/2018
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Rolon Green	<b>Street Address, City, State</b>  Carr Pr-635 Km 0 Hm 1 Bo Dominguito, Arecibo, 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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing records review ( 2017-2018) and laboratory general supervisor interview on September 26, 2018 at 10:00 A.M., it was determined that the laboratory failed to sign the attestation statements. The finding include: 1. Puerto Rico Proficiency testing records were review from February 2017 to July 2018. 2. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2017. 3. The laboratory general supervisor confirmed on September 26, 2018, that the laboratory director and testing personnel failed to sign the attestation statements since 2017.</p>
<b>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during</p>

the PT event.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency testing records review ( 2017-2018) and laboratory general supervisor interview on September 26, 2018 at 10:00 A.M., it was determined that the laboratory failed to maintain a copy of the Proficiency testing results since February 2018. The findings include: 1. The laboratory performed and reported Puerto Rico Proficiency testing samples from February 2018 to July 2018. 2. On September 26, 2018 the laboratory failed to maintain a copy of the Proficiency testing results from February 2018 to July 2018. 3. The laboratory general supervisor printed the Proficiency testing results during the survey performed on September 26, 2018. 4. The laboratory general supervisor confirmed on September 26, 2018 at 11:30 A.M., that the laboratory failed to maintain a copy of the Proficiency testing results from February 2018 to July 2018.

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency testing records review ( 2017-2018) and laboratory general supervisor interview on September 26, 2018 at 10:00 A.M., it was determined that the laboratory failed to maintain a copy of the Proficiency testing results since February 2018. The findings include: 1. The laboratory performed and reported Puerto Rico Proficiency testing samples from February 2018 to July 2018. 2. On September 26, 2018 the laboratory did not have available the Proficiency testing results from February 2018 to July 2018. 3. The laboratory general supervisor confirmed on September 26, 2018 at 11:30 A.M., that the laboratory failed to maintain a copy of the Proficiency testing results from February 2018 to July 2018.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

1. Based on Puerto Rico Proficiency testing records review ( 2017-2018) and laboratory general supervisor on September 26, 2018 at 11:30 A.M, it was determined that the laboratory director failed to sign the attestation statements. The findings include: a. Puerto Rico Proficiency testing records were review from February 2017 to July 2018. b. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2017. c. The laboratory general supervisor confirmed on September 26, 2018 at 11:30 A.M., that the laboratory director failed to sign the attestation statements since February 2017. 2. Based on Puerto Rico Proficiency testing records review ( 2017-2018) and laboratory general supervisor interview on September 26, 2018 at 10:00 A.M., it was determined that the laboratory failed to ensure to maintain a copy of the Proficiency testing results

since February 2018. The findings include: a. The laboratory performed and reported Puerto Rico Proficiency testing samples from February 2018 to July 2018. b. The laboratory director failed to ensure that the laboratory maintain a copy of the Proficiency testing results from February 2018 to July 2018. c. The laboratory general supervisor confirmed on September 26, 2018 at 11:30 A.M., that the laboratory director failed to ensure that the laboratory maintain a copy of the Proficiency testing results since February 2018.