

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0667081	<b>(X3) Date Survey Completed</b>  12/12/2018
<b>Name of Provider or Supplier</b>  Laboratorio Medico	<b>Street Address, City, State</b>  31 Mayor, Ponce, 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>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on lack of Puerto Rico Proficiency Testing records in years 2017-2018 and laboratory director interview at 11:00 AM on December 12, 2018, it was determined that the laboratory failed to maintain Proficiency Testing events records. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed from January 2017 to December 2018. 2. Review of proficiency testing records showed that the laboratory did not maintain the proficiency testing events records from January to December, except the second event for routine chemistry (June 2018). 3. The laboratory director confirmed on December 12, 2018 that the laboratory did not maintain these proficiency testing event records.</p>
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure</p>

that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.

This CONDITION is not met as evidenced by:  
Based on lack of Puerto Rico Proficiency Testing records in years 2017-2018 and laboratory director interview at 11:00 AM on December 12, 2018, it was determined that the laboratory failed to keep Proficiency Testing records for at least 2 years. Refer to D3037 (the laboratory failed to retain proficiency testing records for at least 2 years).

**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 lack of Puerto Rico Proficiency Testing records in years 2017-2018 and laboratory director interview at 11:00 AM on December 12, 2018, it was determined that the laboratory failed to retain proficiency testing records for at least 2 years. The findings include: 1. Puerto Rico Proficiency Testing records were reviewed from January 2017 to December 2018. 2. The laboratory did not have available the proficiency testing records documentation from January 2017 to December 2018, only the laboratory had the second event of routine chemistry (June 2018). 3. The laboratory director confirmed on December 12, 2018 at 11:00 AM that the laboratory did not have available the Proficiency Testing records since January 2017 to December 2018, except the second event of routine chemistry (June 2018).

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:  
Based on lack of Puerto Rico Proficiency Testing records in years 2017-2018 and laboratory director interview at 11:00 AM on December 12, 2018, it was determined that the laboratory failed to keep Proficiency Testing records for at least 2 years. Refer to D3000 (the laboratory failed to retain proficiency testing records for at least 2 years).