

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2007082	(X3) Date Survey Completed 08/31/2018
Name of Provider or Supplier Laboratorio Clinico Tu Salud	Street Address, City, State Road 417 Km 4 Hm 2 Barrio Mamey, Aguada, 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
D2123	<p>HEMATOLOGY 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 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 American Proficiency Institute (API) Proficiency Testing Program records reviewed (2017-2018) and laboratory general supervisor interview on August 31, 2018 at 9:30 A.M., it was determined that the laboratory failed to participate in the hematology third testing event performed in December 2017. The findings include: a. Proficiency testing records were reviewed from February 2017 to July 2018. b. The laboratory did not participate in the third testing event of hematology (complete blood count) performed in December 2017. c. The laboratory general supervisor confirmed on August 31, 2018 at 9:30 A.M., that the laboratory failed to participate in the third testing event of hematology in December 2017.</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure 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 American Proficiency Institute (API) Proficiency Testing Program records review (2017-2018) and laboratory general supervisor interview on August 31, 2018 at 9:30 A.M., it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2123.

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 American Proficiency Institute (API) Proficiency Testing Program records review (2017-2018) and laboratory general supervisor interview on August 31, 2018 at 9:30 A.M., it was determined that the laboratory general supervisor failed to ensure that the proficiency testing were tested as required under Subpart H requirements. Refer to D2123.