

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0684552	(X3) Date Survey Completed 03/14/2019
Name of Provider or Supplier Laboratorio Avanzado Emmanuel	Street Address, City, State Calle Palmer #41, Ciales, 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
D2071	<p>SYPHILIS SEROLOGY CFR(s): 493.835(c)</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 review (2017-2018) and laboratory testing personnel interview on March 14, 2019 at 9:30 A.M., it was determined that the laboratory failed to report the proficiency testing results within the time frame established by the program. The findings include: 1. Puerto Rico Proficiency Testing Program records were review from year 2017 to 2018. 2. The records showed that the laboratory obtained a score of 0 % in the first testing event of syphilis Serology perform in May 2018 2015, due return the testing results out of the time frame specified by the Puerto Rico Proficiency Testing Program . 3. The ProficiencyTesting Program mailing date was May 7, 2018 and report deadline was May 25, 2018. 4. The laboratory testing personnel confirmed on March 14, 2019 at 9: 30 A.M, that the laboratory return the testing results out of the time frame specified by the Puerto Rico Proficiency Testing Program .</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> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing records review (2017-2018) and laboratory</p>

testing personnel interview on March 14, 2019 at 10:00 A.M., it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. The finding includes: 1. The laboratory failed to report the proficiency testing results within the time frame established by the program. Refer to D2071.