

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0926407	(X3) Date Survey Completed 05/16/2018
Name of Provider or Supplier Laboratorio Clinico Acropolis	Street Address, City, State Villa Beatriz D-6, Manati, 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 records review (2016 to 2018) and laboratory general supervisor interview on May 16, 2018 at 11:000 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. Proficiency testing records were reviewed from February 2016 to February 2018. 2. The deadline of the second testing event report of hematology tests was July 29, 2016. 3. The laboratory did not report the second testing event of hematology (cell identification and sedimentation rate test) within the time frame established by the Proficiency Testing Program. 4. The laboratory general supervisor confirmed on May 16, 2018 at 11:30 A. M. , that the laboratory did not report the hematology testing results of the second testing event within the time frame established by the Proficiency Testing Program.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

	<p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (2016 to 2018) and laboratory general supervisor interview on May 18, 2018 at 10:30 A.M., it was determined that the laboratory failed to verify the accuracy of the hematology cell identification and sedimentation rate test that received a zero score for nonparticipation. The findings include: 1. Proficiency testing records were reviewed from February 2016 to February 2018. 2. The deadline of the second testing event report of hematology tests was July 29, 2016. 3. The proficiency testing records showed that the laboratory did not verify the accuracy of the hematology cell identification and sedimentation rate tests that received a zero score for nonparticipation in July 2016. 4. The general supervisor stated on May 16, 2018 at 11:00 A.M. that the laboratory did not have a mechanism to verify the accuracy of the hematology cell identification and sedimentation rate tests that received a zero score for nonparticipation on July 2016.</p>
<p>D5293</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review and laboratory general supervisor interview on May 16, 2018 at 11:15 AM, it was determined that the laboratory failed to have a mechanism to evaluate issues related to Proficiency testing performance. The findings include: 1. The quality assessment records were reviewed since January 2016. 2. The records showed that the laboratory did not have a mechanism used to evaluate and verify problems related to Proficiency Testing performance. 3. The laboratory did not verify the accuracy of the hematology cell identification and sedimentation rate tests that received a zero score for nonparticipation on July 2016. 4. The general supervisor stated on May 16, 2018 at 11:00 A.M. that the laboratory did not have a mechanism to verify the accuracy of the hematology cell identification and sedimentation rate tests that received a zero score for nonparticipation on July 2016.</p>
<p>D6089</p>	<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 Program testing records review (2016 to 2018) and laboratory general supervisor interview on May 16, 2018 at 11:00 AM, it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2127.</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES</p>

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review and laboratory general supervisor interview on May 16, 2018 at 11:30 A.M, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The finding includes: 1. The laboratory director failed to assess the general laboratory systems for the Proficiency testing performance. Refer to D5293.