

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0926407	(X3) Date Survey Completed 10/16/2020
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
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 Puerto Rico Proficiency Testing Program records review (2019-2020) and laboratory general supervisor interview on October 16, 2020 at 9:10 A.M., it was determined that the laboratory failed to participate in the Hematology third testing event performed in November 2019. The findings include: 1. Puerto Rico Proficiency Testing Program records were review from year 2019 to 2020. 2. The records showed that the laboratory did not participate in the third testing event of hematology (November 2019) established by the Proficiency Testing Program. 3. The laboratory general supervisor confirmed on October 16, 2020 at 9:10 A.M., that the laboratory failed to participate in the third testing event of hematology specialty in November 2019.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p>

This STANDARD is not met as evidenced by:
Based on facility records review (2019-2020) and laboratory general supervisor interview at 9:45 AM on October 16, 2020, it was determined that the laboratory failed to be in compliance with the Puerto Rico State laboratory regulation. The findings include: 1. The laboratory Biomedical Generator Number (DBR-RA-47-14-02-0089) was due since December 18,2019. 2. The laboratory owner confirmed on October 16, 2020 at 10:30 A.M.01/13/2016, that the Biomedical Generator Number was due since December 18, 2019 and the laboratory renew the new Biomedical Generator Number on September 2020. 3. The state law establishes that the Biomedical Generator Number must be renew 60 days before the expired date.

D6084

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

This STANDARD is not met as evidenced by:
Based on facility records review (from 2019-2020) and laboratory general supervisor interview on October 16, 2020 at 10:30 A.M., it was determined that the laboratory director failed to be in compliance with the Puerto Rico State laboratory regulation. The finding includes: 1. The laboratory Biomedical Generator Number was due since December 18, 2019 and renew on September 2020. Refer to D3009.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency testing records review (2019-2020) and laboratory general supervisor interview on October 16, 2020 at 9:10A.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 participate in the Hematology third testing event performed in November 2019. Refer to D2023.