

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0715748	(X3) Date Survey Completed 09/22/2020
Name of Provider or Supplier Laboratorio Clinico Borges	Street Address, City, State Calle Arzuaga Num 168, Rio Piedras, 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
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to August 2020 and laboratory general supervisor interview on September 22, 2020 at 9:45 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed from February 2019 to August 2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent in Hematology Cell Identification, Differential White Blood Cell, Red Cell Count (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Cell Count (WBC) and Platelet Count tests in April 2020 (PRPTP first testing event) and 0 percent in Hematology Cell Identification and Differential White Blood Cell tests in July 2020 (PRPTP second testing event). No remedial actions were taken. 3. The general supervisor confirmed on September 22, 2020, that the laboratory did not take corrective actions on April 2020 and July 2020 testing events.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p>

The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

This STANDARD is not met as evidenced by:

Based on facility records review from January 1, 2019 to September 22, 2020 and laboratory general supervisor interview at 9:45 AM on September 22, 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 was due since February 11, 2020. 2. The laboratory general supervisor confirmed on September 22, 2020, that the Biomedical Generator Number was due since February 11, 2020.

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 January 1, 2019 to September 22, 2020 and laboratory general supervisor interview at 9:35 AM on September 22, 2020, 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 February 11, 2020. Refer to D3009.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2019 to August 2020 and laboratory general supervisor interview on September 22, 2020 at 10:22 AM, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2019 to August 2020. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent in Hematology Cell Identification, Differential White Blood Cell, Red Cell Count (RBC), Hematocrit (HCT), Hemoglobin (HGB), White Cell Count (WBC) and Platelet Count tests in April 2020 (PRPTP first testing event) and 0 percent in Hematology Cell Identification and Differential White Blood Cell tests in July 2020 (PRPTP second testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on September 22, 2020, that the laboratory did not take corrective actions on those testing events. Refer to D2128.