

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0666939	(X3) Date Survey Completed 03/24/2023
Name of Provider or Supplier Lab Clinico Santa Isabel	Street Address, City, State 38 Munoz Rivera, Santa Isabel, 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
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> <p>This STANDARD is not met as evidenced by: Based on facility records review (in years 2021-2023) and laboratory director interview at 10:00 AM on March 24, 2023, 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-RG-68-91-02-0441) was due since February 25, 2023. 2. The laboratory owner confirmed on March 24, 2023 at 10:00 A.M., that the Biomedical Generator Number was due since February 25, 2023 and the laboratory not renew the new Biomedical Generator Number. 3. The state law establishes that the Biomedical Generator Number must be renew 60 days before the expired date.</p>
D6084	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on facility records review (years 2021-2023) and laboratory director interview at 10:00 AM on March 24, 2023, it was determined that the laboratory director failed</p>

to be in compliance with the Puerto Rico State laboratory regulation. The finding includes: 1. The laboratory Biomedical Generator Number was due since February 25, 2023. Refer to D3009.