

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2030981	(X3) Date Survey Completed 10/28/2020
Name of Provider or Supplier Laboratorio Clinico Santa Olaya	Street Address, City, State Barrio Santa Olaya Carretera 829 Km 6 Hm 2, Bayamon, 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 (from January 1, 2019 to October 28, 2020) and laboratory director and general supervisor interview on October 28, 2020 at 9:45 AM, 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 OC-11-11-02-0288 RN 20) was due since July 17, 2020. 2. The laboratory director and general supervisor confirmed on October 28 2020, that the Biomedical Generator Number was due since July 17, 2020. 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 (from January 1, 2019 to October 28, 2020) and laboratory director and general supervisor interview at 9:45 AM on October 28, 2020, it was determined that the laboratory director failed to be in compliance with the</p>

Puerto Rico State laboratory regulation. The finding includes: 1. The laboratory Biomedical Generator Number (DBR OC-11-11-02-0288 RN 20) was due since July 17, 2020. Refer to D3009.