

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0705731	(X3) Date Survey Completed 04/06/2021
Name of Provider or Supplier Laboratorio Clinico Santana	Street Address, City, State Calle 25 De Julio #45, Guanica, 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 2019-2021) and laboratory director interview at 10:00 AM on April 6, 2021, 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-RP-29-92-02-0088) was due since December 18,2019. 2. The laboratory owner confirmed on April 6, 2021 at 10:00 A.M., that the Biomedical Generator Number was due since April 29, 2021 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>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on general immunology quality control records review (from August 24, 2020 to April 5, 2021) and laboratory director interview on April 6, 2021 at 10:30 AM, it</p>

was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 40 out of 125 days when patients specimens were tested and reported for qualitative Covid 19 IgG / IgM tests from August 24, 2020 to April 5, 2021 by the Healgen method. The findings include : 1. The laboratory uses Healgen method to perform Covid 19 IgG/IgM patient's samples tests. 2. On April 6, 2020 at 10:30 AM, the general immunology quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials from August 24, 2020 to April 5, 2021. 3. The laboratory does not include the negative and a positive control materials in the following days: Date # patient's samples 9/10/2020 2 9/22/2020 11 9/29/2020 8 12/28/2020 9 1/4/2021 9 1/5/2021 8 1/8/2021 11 1/11/2021 15 1/19/2021 5 1/28/2021 10 1/29/2021 6 2/2/2021 4 2/4/2021 12 2/5/2021 7 2/8/2021 1 2/10/2021 4 2/12/2021 16 2/17/2021 7 2/18/2021 7 2/19/2021 10 2/22/2021 12 2/24/2021 7 2/25/2021 14 2/26/2021 12 3/1/2021 18 3/3/2021 9 3/4/2021 7 3/5/2021 9 3/8/2021 8 3/9/2021 4 3/10/2021 4 3/12/2021 4 3/15/2021 5 3/16/2021 4 3/18/2021 14 3/19/2021 7 3/24/2021 4 3/25/2021 2 3/26/2021 8 3/29/2021 2 4. The laboratory director on April 6, 2021 at 10:30 AM confirmed that the laboratory did not include the negative and the positive control materials each day of qualitative Covid 19 IgG/IgM patient's samples testing, instead the laboratory includes a negative and a positive control materials before September 10, 2020 all days and when it places in routine use every new lot or new shipping of the Covid 19 IgG/IgM reagent kits. 4. The laboratory processed and reported three hundred sixteen (316) patient's specimens for qualitative Covid 19 IgG/IgM tests from August 24, 2020 to April 5, 2021 by the Healgen method.

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 (in years 2019-2021) and laboratory director interview at 10:00 AM on April 6, 2021, 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 April 29, 2021. Refer to D3009. (The laboratory failed to be in compliance with the Puerto Rico State laboratory regulation).

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 general immunology quality control records review (from August 24, 2020 to April 5, 2021) and laboratory director interview on April 6, 2021 at 10:30 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the Covid 19 IgG/IgM rapid test from August 24, 2020 to April 5,

2021 by the Healgen method. Refer D5449. (The laboratory did not include each day of testing the negative nor the positive control materials from August 24, 2020 to April 5, 2021)