

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0670593	(X3) Date Survey Completed 02/24/2021
Name of Provider or Supplier Laboratorio Clinico Renacer,Llc	Street Address, City, State Ave Carlos Javier Andaluz Il 32, 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
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 qualitative Covid-19IgG/IgM rapid tests records review (years 2020 and 2021) and interview with the laboratory supervisor on February 24, 2021 at 9:50 AM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 844 out of 844 patient's specimens were tested and reported for qualitative Covid-19IgG/IgM rapid tests from November 1, 2020 to February 23, 2021 by the Healgen method. The findings include : 1. The Covid-19IgG /IgM testing records showed that the the laboratory did not include each day of testing a negative and a positive control materials when patient's specimens were tested for qualitative Covid-19IgG/IgM tests from November 1, 2020 to February 23, 2021. 2. The laboratory evaluate and documented the procedural control each day of testing from November 1, 2020 to February 23, 2021. 3. The general supervisor confirmed on February 24, 2021 at 9:50 AM (by telephone call), that the laboratory did not include the negative nor the positive control materials each day of qualitative Covid-19IgG /IgM testing. 4. The laboratory tested and reported 844 out of 844 patient's specimens for qualitative Covid-19IgG/IgM rapid tests from November 1, 2020 to February 23, 2021.</p>
D6042	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)</p>

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on qualitative Covid-19IgG/IgM rapid tests records review (years 2020 and 2021) and interview with the laboratory supervisor on February 24, 2021 at 9:50 AM, it was determined that technical consultant failed to ensure compliance with the requirements for analytic systems for the Covid-19IgG/IgM rapid tests from November 1, 2020 to February 23, 2021 Refer to D 5449 (The laboratory failed to include each day of testing a negative and a positive control materials when 844 out of 844 patient's specimens were tested and reported for qualitative Covid-19IgG/IgM rapid tests from November 1, 2020 to February 23, 2021 by the Healgen method).

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 qualitative Covid-19IgG/IgM rapid tests records review (years 2020 and 2021) and interview with the laboratory supervisor on February 24, 2021 at 9:50 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the Covid-19IgG/IgM rapid test from November 1, 2021 to February 23, 2021. Refer to D 5449 (The laboratory failed to include each day of testing a negative and a positive control materials when 844 out of 844 patient's specimens were tested and reported for qualitative Covid-19IgG/IgM rapid tests from November 1, 2020 to February 23, 2021 by the Healgen method).