

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1031776	(X3) Date Survey Completed 05/25/2021
Name of Provider or Supplier Laboratorio Clinico Jireh	Street Address, City, State Carr #2 Km 18 Hm 6 Bo Mucarabones, Toa Alta, 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 Covid-19 report records review and general supervisor interview on May 25, 2021 at 8:43 AM, it was determined that the laboratory failed to report the Covid-19 results as required for 7 out of 13 days reviewed from March 04, 2021 to March 24, 2021. The findings include: 1. The laboratory utilized the Health Department instruction to send the Covid-19 results to the Bioportal. 2. The laboratory processed the Covid-19 rapid test by Healgen method. 3. On May 25, 2021 at 8:43 AM, the Covid-19 report records showed that the laboratory did not send the Covid-19 results in the required frequency (24 hrs) to the Bioportal in 7 out of 13 days reviewed from March 04, 2021 to March 24, 2021: Date Patients Date tested specimens reports tested sent 03/04/2021 10 03/10/2021 03/05/2021 7 03/10/2021 03/06/2021 6 03/10/2021 03/09/2021 7 03/11/2021 03/11/2021 14 03/13/2021 03/13/2021 4 03/15/2021 03/24/2021 13 03/26/2021 4. The general supervisor confirmed on May 25, 2021 at 8:43 AM that the laboratory did not send those Covid-19 results in the required frequency (24 hrs) to the Bioportal. She stated that the laboratory received high volume of covid-19 tests those days.</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)</p>

The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on Covid-19 IgG/IgM test quality control records review and interview with the laboratory supervisor on May 25, 2021 at 8:43 AM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 162 out of 162 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from March 1, 2021 to March 23, 2021 by the Healgen method. The findings include : 1. On May 25, 2021 at 8:43, the Covid-19 IgG /IgM test quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials when it tested 162 patient' s specimens the following days from March 1, 2021 to March 23, 2021 by the Healgen method: 01, 02, 03, 04, 05, 08, 09, 10, 11, 12, 13, 15, 16, 17, 18, 19 and 23. Instead the laboratory included the negative and the positive control materials when it placed in routine use a new box of reagents kit. 2. The general supervisor confirmed on May 25, 2021 at 8:43AM, that the laboratory did not include each day of testing the negative nor the positive control materials when patients specimens were tested for the Covid-19 IgG/IgM test. She stated that the laboratory includes the negative and the positive control materials when it placed in routine use a new box of reagents kit 3. The laboratory tested and reported 162 out of 162 patient's specimens for qualitative Covid-19 IgG/IgM test from March 1, 2021 to March 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 Covid-19 IgG/IgM test quality control records review and interview with the laboratory supervisor on May 25, 2021 at 8:43 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for Covid-19 IgG/IgM rapid tests from March 1, 2021 to March 23, 2021. Refer to D 5449 (The laboratory failed to include each day of testing a negative and a positive control materials when 162 out of 162 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from March 1, 2021 to March 23, 2021 by the Healgen method).