

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1094840	(X3) Date Survey Completed 05/07/2021
Name of Provider or Supplier Laboratorio Clinico Villa Ana	Street Address, City, State Carr 1, Km 27, Hm 8 Rio Canas,, Caguas, 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 test report records review and general supervisor interview on May 7 2021 at 1:40 PM, it was determined that the laboratory failed to report the Covid-19 IgG /IgM rapid tests results as required for 18 out of 22 days reviewed from March 1, 2021 to March 30, 2021. The findings include: 1. The laboratory utilized the Health Department written instruction to reports the Covid-19 IgG/IgM rapid tests results to the Bioportal. 2. The laboratory processed the Covid-19 IgG/IgM rapid tests by Healgen method. 3. The test report records showed that 18 out of 22 days from March 1, 2021 to March 30, 2021, the laboratory did not report the Covid-19 IgI/IgM patients results in the required frequency (24 hrs) to the Bioportal: Date Patients Date tested specimens reported 03/01/2021 8 03/04/2021 03/02/2021 5 03/04/2021 03/04/2021 5 03/09/2021 03/05/2021 6 03/09/2021 03/06/2021 5 03/09/2021 03/09/2021 1 03/15/2021 03/10/2021 7 03/15/2021 03/11/2021 5 03/15/2021 03/12/2021 7 03/15/2021 03/13/2021 3 03/15/2021 03/15/2021 5 03/18/2021 03/16/2021 6 03/18/2021 03/18/2021 6 03/24/2021 03/19/2021 3 03/24/2021 03/22/2021 2 03/24/2021 03/24/2021 4 04/12/2021 03/25/2021 5 04/12/2021 03/30/2021 3 04/12/2021 4. The laboratory general supervisor confirmed on May 7 2021 at 1:40 PM, that those results of Covid-19 IgG/IgM rapid tests were not reported in 24 hrs.</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--</p>

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.

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 7, 2021 at 1:40 PM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 71 out of 71 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from March 2, 2021 to March 30, 2021 by the Healgen method. The findings include : 1. On May 7, 2021 at 1:40 PM, 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 from March 2, 2021 to March 30, 2021. 2. The laboratory includes the negative and the positive control materials when it placed in routine use a new box of reagents kit: on 03/02/2021, 03/08/2021, 03/12/2021, 03/18/2021 and 03/30/2021. 3. The laboratory did not include the negative nor the positive control materials when 71 out of 71 patients specimens were processed the following days from March 2, 2021 to March 30, 2021: Day tested patients specimens 03/03/2021 6 03/04/2021 6 03/05/2021 5 03/06/2021 4 03/07/2021 1 03/10/2021 7 03/11/2021 4 03/15/2021 6 03/16/2021 6 03/17/2021 9 03/19/2021 3 03/20/2021 1 03/22/2021 1 03/23/2021 2 03/24/2021 4 03/25/2021 5 03/29/2021 1 4. The general supervisor confirmed on May 7, 2021 at 1:40 PM, 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 5. The laboratory tested and reported 71 out of 71 patients specimens for qualitative Covid-19 IgG/IgM test from March 2, 2021 to March 30, 2021 by the Healgen method.

D6042

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(4)

(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 Covid-19 IgG/IgM test quality control records review and interview with the laboratory supervisor on May 7, 2021 at 1:40 PM, it was determined that the technical consultant failed to ensure compliance with the requirements of the analytic systems for the Covid-19 IgG/IgM tests from March 2, 2021 to March 30, 2021. Refer to D 5449 (The laboratory did not include each day of testing a negative and a positive control materials when 71 out of 71 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from March 2, 2021 to March 30, 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 7, 2021 at 1:40 PM, it was determined that the laboratory director failed to ensure compliance with the requirements for the Covid-19 IgG/IgM tests from March 2, 2021 to March 30, 2021. Refer to D 5449 (The laboratory did not include each day of testing a negative and a positive control materials when 71 out of 71 patients specimens were tested and reported for qualitative Covid-19 IgG/IgM tests from March 2, 2021 to March 30, 2021 by the Healgen method.