Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0977871	(X3) Date Survey Completed 04/16/2021
Name of Provider or Supplier Lab Clinico Obymar	**Street Address, City, State** Carr 420 Km 04 Barrio Voladoras, Moca, 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
D2122	HEMATOLOGY CFR(s): 493.851(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (2019-2020) and laboratory general supervisor interview on April 16, 2021 at 9:00 A.M., it was determined that the laboratory failed to attain a satisfactory results in hematology event. The findings include: 1. P.R. Proficiency Testing Program records and results were reviewed from February 2019 to February 2021. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 36.1 % in the second hematology testing event performed in July 2020.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on Bioportal records review (December 2020 to February 2021) and laboratory general supervisor interview on April 16, 2021 at 10:30 AM, it was determined that the laboratory failed to report the SARS-CoV 2 tests results as required . The findings include: 1. The laboratory utilized the Health Department written instruction to reports the SARS-CoV 2 (rapid test,total antibodies and Covid Antigen) tests results by the Bioportal. 2. The test report records showed that from December 21, 2020 to January 26, 2021, the laboratory did not report the SARS-Co-

	Antigen patients results in the required frequency (24 hrs) by the Bioportal. Patient date report : 12/21/20, 12/22/20, 12/28/20, 12/29/20, 12/30/20, 1/4/21, 1/5/21, 1/7,21, 1/8/21, 1/11/21, 1/12,21, 1/13/21, 1/14,21, 1/15/21, 1/18/21, 1/20/21, 1/23/21, 1/25 /21, 1/26/21. patient samples reported: 40 date reported : January 28, 2021 3. The test report records showed that from January 22,2021 to January 26, 2021, the laboratory did not report the SARS-Co-rapid tests patients results in the required frequency (24 hrs) by the Bioportal. Patient date report : 1/22/21, 1/23/21, 1/25/21. patient samples reported: 14 date reported : January 27, 2021 4. The test report records showed that from February 15, 2021 to February 18, 2021, the laboratory did not report the SARS-Co-rapid tests patients results in the required frequency (24 hrs) by the Bioportal. Patient date report : 2/15/2021, 2/16/2021, 2/17/2021, 2/18/2021. patient samples reported: 10 date reported : February 20, 2021 5. The laboratory general supervisor confirmed on April 16, 2021 at 10:30 AM, that those results of SARS-CoV 2 tests were not reported in 24 hrs.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on endocrinology quality control records review (2020-2021) and laboratory general supervisor interview at 10:50 a.m. on April 16, 2021, it was determined that the laboratory did not evaluate a new lot of hCG- (human chorionic gonadotropin test) for positive and negative reactivity prior to placed it in routine use. The findings include: a. The laboratory quality control records were review from 1/2020 to 4/2021. b. The laboratory received the following reagent kit and no evaluation of their reactivity was performed: Test Lot Expiration Date First day of use hCG 072343 9/30 /2021 7/3/2020 F910013 10/23/2021 11/3/2020 c. The laboratory processed and reported 36 hCG patient samples during those days.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (2019-2020) and laboratory general supervisor interview on April 16, 2021 at 9:15 A.M., it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2122.
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 endocrinology quality control records review (years 2019-2021) and laboratory general supervisor interview at 9:00 A.M on April 16, 2021, it was found that the laboratory director did not assure that quality control procedures related evaluation of new reagents lots were followed. The finding includes: 1. The laboratory did not evaluate the new hCG reagent . Refer to D5471.