

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2126781	(X3) Date Survey Completed 04/16/2021
Name of Provider or Supplier Laboratorio Clinico Costa Isabela Ii	Street Address, City, State Bo Palmar, Carr 111, Km 1, Hm 8, Aguadilla, 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
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2019-2020) and laboratory director interview on April 16, 2021 at 11:30 A.M., it was determined that the laboratory failed to participate in the routine chemistry (urinalysis and urine sediment) third testing event performed in October 2020. The findings include: 1. Proficiency testing records were reviewed from February 2019 to March 2021. 2. The laboratory obtained a score of 0 % in the third testing event of routine chemistry (urinalysis, urine sediment) perform in October 2020 due the laboratory did not participated in the P.R. Proficiency Testing Program for this event. 3. The laboratory director confirmed on April 16, 2021 at 11:30 A.M., that the laboratory failed to participate in the third testing event of routine chemistry specialty (urinalysis, urine sediment) in October 2020.</p>
D2100	<p>ENDOCRINOLOGY CFR(s): 493.843(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a</p>

score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program records reviewed (2019-2020) and laboratory director interview on April 16, 2021 at 11:30 A.M., it was determined that the laboratory failed to participate in the endocrinology (human chorionic gonadotropin- hCG) third testing event performed in October 2020. The findings include: 1. Proficiency testing records were reviewed from February 2019 to March 2021. 2. The laboratory obtained a score of 0 % in the third testing event of endocrinology (human chorionic gonadotropin- hCG) perform in October 2020 due the laboratory did not participated in the P.R. Proficiency Testing Program for this event. 3. The laboratory director confirmed on April 16, 2021 at 11:30 A.M., that the laboratory failed to participate in the third testing event of endocrinology (hCG) in October 2020.

D2121

HEMATOLOGY
CFR(s): 493.851(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Based on AAB Proficiency Testing Program records review (2019-2020) and laboratory director interview on April 16, 2021 at 12:00 P.M., it was determined that the laboratory failed to attain a satisfactory results in hematology event. The findings include: 1. AAB Proficiency Testing Program records and results were reviewed from February 2019 to March 2021. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 % in the following tests : hemoglobin and hematocrit in the first testing event. 3. The laboratory director confirmed on April 16, 2021 at 12:00 P.M., that the laboratory failed to attain a satisfactory results in the first hematology testing event of AAB program.

D5024

HEMATOLOGY
CFR(s): 493.1215

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299.

This CONDITION is not met as evidenced by:
Based on hematology quality control records review (2019-2021) and interview with the laboratory director on April 16,2021 at 12:50 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for

hematology. Refer to D5447 (the laboratory did not include any control material when performed hematology patient samples).

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(g)

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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
1. Based on lack of hematology quality control records review (2019-2021), manufacturer's instructions review and laboratory director interview on April 16, 2021 at 12:30 P.M., it was detemined that the laboratory failed to include control material when performed CBC (Complete blood count) tests since January 20, 2020. The findinds include: a. The laboratory uses Cell Dyn 1700 system to perform hematology tests (CBC). b. The manufacturer establishes that three levels control material (low, normal and abnormal) must be included each day of testing for glucose test. c. Review of records from January 20, 2020 to December 2020, the lack of records showed that the laboratory did not include any level of control each day of testing for hematology test since January 2020. d. The laboratory director confirmed on April 16, 2021 at 12: 30 P.M., that the laboratory did not have evidence that included any level of control each day of testing for hematology test since January 2020. d. The laboratory processed and reported four hundred eleven (411) CBC patient's samples during 2020.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on review of laboratory final test report and laboratory director interview on April 16, 2021 at 1:15 P.M., it was determined that the laboratory failed to include the laboratory name and address where the test was performed. The findings include: 1. During the survey the laboratory director stated that Laboratory Clinic Costa Isabela II did not performed any type of Covid test. 2. Several test reports showing as testing facility for Covid antigen and antibody test, the laboratory Costa Isabela II, Clia # 40D2126781. 3.On April 16, 2021, the laboratory patient tests reports files were review by the surveyor and showed that the laboratory perform and report the following Covid test: id sample date report 2150 - SARS- ANTIGEN 2/20/2021 2156 - Covid rapid test Ig G/ IgM 2/22/2021 2003- Covid rapid test Ig G/ IgM 3/10/2021

	<p>2175 - SARS- ANTIGEN 3/15/2021 4. The laboratory director was interview about the finding, she stated that the test were performed at Laboratory Costa Isabela (40D1084371) 5. The laboratory did not include the correct testing location.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p> <p>1. Based on review of laboratory director qualifications and laboratory director interview on April 16, 2021 at 12:30 P.M. it was determined that the laboratory director a current professional registry, as required by the state law. The findings include: a. The laboratory director record showed that the director failed to renew the current professional registry in 2019. b. The MT licence # 6358 and registry # 103691) expired on November 10, 2019. Refer to D6028. 2. Based on lack of hematology quality control records, manufacturer's instructions review and laboratory director interview on April 16, 2021 at 12:30 P.M. it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems requirements. Refer to D 6020. 3. Based on Puerto Rico Proficiency testing records review (2019-2020) and laboratory director interview on April 16, 2021 at 12:00 P. 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 D2089, D2100 and D2121.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing records review (2019-2020) and laboratory director interview on April 16, 202189 and D2121 at 11:00 AM, it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2089, D2100 and D2121.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on hematology quality control records review (2019-2020) and laboratory director interview on April 16, 2021 at 1:00 P.M., it was determined that laboratory director failed to ensure compliance with the hematology requirements for analytic systems. The finding includes: 1. The laboratory did not include control material when performed CBC tests since January 20, 2020. Refer to D5447. 2. The laboratory director confirmed on April 21, 2021 at 1: 00 P.M., that the laboratory failed to ensure compliance with the hematology requirements for analytic systems.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on review of personnel records and laboratory director interview on April 16, 2021 at 12:20 P.M., it was determined that the laboratory director failed to renew a current professional registry, as required by the state law. The finding include: 1. The laboratory personnel records reviewed showed that the laboratory director state professional registry (# 103691) was due since November 10, 2019.