

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0717803	(X3) Date Survey Completed 12/26/2019
Name of Provider or Supplier Laboratorio Clinico Universitario	Street Address, City, State C/2 J-12 Ext Hermanas Davila, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lipid panel tests reports records (years 2018 and 2019) reviewed and laboratory director interview on December 26, 2019 at 10:00 AM, it was determined that the laboratory failed to indicate the name and address of the laboratory location where the cholesterol and triglycerides tests were performed when 3 out 3 lipid panel tests results were reported from January 16, 2019 to September 26, 2019. The findings include: 1. The Laboratorio Clinico Universitario referred the patient's specimens for cholesterol and triglycerides tests to the Laboratorio Clinico M. Landron, Inc, located at Calle JJ Acosta #46, Vega Baja, PR. 2. On December 26, 2019 at 10:00 AM, the lipid panel reports showed that the Laboratorio Clinico Universitario did not included the name nor the address of the Laboratorio Clinico M. Landron, Inc in where the cholesterol and triglycerides tests were performed and included in the lipid panel results reports. 3. The laboratory director confirmed on December 26, 2019 at 10:00 AM, that the laboratory did not include the name nor the address of the laboratory where the cholesterol and triglycerides tests were performed and reported in the lipid panel report. 4. The laboratory reported 3 out 3 lipid panel from January 16, 2019 to September 26, 2019: patient # 24172 on 01/16/2019, patient #24205 on 05/07/2019 and patient #24750 on 09/26/2019.</p>

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on lipid panel tests reports records (years 2018 and 2019) reviewed and laboratory director interview on December 26, 2019 at 10:00 AM, it was determined that the laboratory failed to indicate the pertinent normal values in the cholesterol and triglycerides test when 3 out of 3 lipid panel tests results were reported from January 16, 2019 to September 26, 2019. The findings include: 1. The Laboratorio Clinico Universitario referred the patient's specimens for cholesterol and triglycerides tests to the Laboratorio Clinico M. Landron, Inc, . The cholesterol and triglycerides tests reports showed that the normal values for the cholesterol test is 50-to 200 mg/dl and the normal values for the triglycerides test is 40 to 160 mg/dl. 2. On December 26, 2019 at 10:00 AM, the lipid panel reports showed that the Laboratorio Clinico Universitario utilized the cholesterol and triglycerides tests results (processed at Laboratorio Clinico M. Landron, Inc,) and the laboratory information system modified the normal values of the cholesterol test as 120 to 200 mg/dl and the normal values of the triglycerides as 40 to 150 mg/dl. 3. The laboratory director confirmed on December 26, 2019 at 10:00 AM, that the laboratorio Clinico Universitario utilized the cholesterol and triglycerides tests results (processed at Laboratorio Clinico M. Landron, Inc,) and the laboratory information system modified the normal values of those tests reported in the lipid panel. 4. The laboratory reported 3 out of 3 lipid panel from January 16, 2019 to September 26, 2019: patient # 24172 on 01/16/2019, patient #24205 on 05/07/2019 and patient #24750 on 09/26/2019.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(8)

The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

This STANDARD is not met as evidenced by:

Based on lipid panel tests reports records (years 2018 and 2019) reviewed and laboratory director interview on December 26, 2019 at 10:00 AM, it was determined that the laboratory director failed to ensure that the cholesterol and triglycerides tests reports include the required information. Refer to D 5805. Refer to D 5807.