

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1072320	<b>(X3) Date Survey Completed</b>  05/22/2018
<b>Name of Provider or Supplier</b>  Cdt Centro De Servicios Medicos Integrados, Llc	<b>Street Address, City, State</b>  Santa Cruz 59, Bayamon, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2094</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (year's 2016, 2017, 2018), laboratory director and general supervisor interview on May 22, 2018 at 9:25 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to February 2018. 2. Review of Proficiency Testing records (year 2017), showed that the laboratory obtained unsatisfactory results of 0 percent in Albumin, Bilirubin, Total, Calcium, Chloride, Cholesterol, Total, Glucose, Sodium, Total Protein, Urea Nitrogen (BUN) and 20 percent in Uric Acid tests in June 2017 (PRPTP second testing event). No remedial actions were taken. 3. Review of Proficiency Testing records (year 2018), showed that the laboratory obtained unsatisfactory results of 40 percent in Albumin, 20 percent in Calcium, 0 percent in Chloride, 20 percent in Cholesterol, Total, 20 percent in Glucose, 0 percent in Sodium, 20 percent in Total Protein, 60 percent in Urea Nitrogen (BUN), 20 percent in Uric Acid, 60 percent in lipase, 60 percent in CO2 tests in February 2018 (PRPTP first testing event). No remedial actions were taken. 4. The laboratory director and general supervisor confirmed on May 22, 2018, that the laboratory did not take remedial actions.</p>

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Records review (year's 2016, 2017, 2018), laboratory director and general supervisor interview on May 22, 2018 at 9:15 AM, it was determined that the laboratory director failed to follow the corrective action plan when the laboratory obtained an unsatisfactory result. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to February 2018. 2. Review of Proficiency Testing records (year 2017), showed that the laboratory obtained unsatisfactory results of 0 percent in Albumin, Bilirubin, Total, Calcium, Chloride, Cholesterol, Total, Glucose, Sodium, Total Protein, Urea Nitrogen (BUN) and 20 percent in Uric Acid tests in June 2017 (PRPTP second testing event). No remedial actions were taken. 3. Review of Proficiency Testing records (year 2018), showed that the laboratory obtained unsatisfactory results of 40 percent in Albumin, 20 percent in Calcium, 0 percent in Chloride, 20 percent in Cholesterol, Total, 20 percent in Glucose, 0 percent in Sodium, 20 percent in Total Protein, 60 percent in Urea Nitrogen (BUN), 20 percent in Uric Acid, 60 percent in lipase, 60 percent in CO2 tests in February 2018 (PRPTP first testing event). No remedial actions were taken. 4. The laboratory director and general supervisor confirmed on May 22, 2018, that the laboratory did not take remedial actions.