

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1043613	(X3) Date Survey Completed 01/31/2020
Name of Provider or Supplier Laboratorio Clinico Ginara	Street Address, City, State 1253 Calle Juan Baez Urb San Martin, Rio Piedras, 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
D2094	<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 and laboratory general supervisor interview on January 31, 2020 at 9:15 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in rutine chemistry specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2018 to December 2019. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent for Albumin tests in February 2019 (first testing event) and 40 percent for Urea Nitrogen (BUN) tests in June 2019 (second testing event). No remedial actions were taken.</p>
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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</p>

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 Program (PRPTP) records review and laboratory general supervisor interview on January 31, 2017 at 9:15 AM, it was determined that the laboratory director failed to follow the written corrective action plan when the laboratory obtained an unsatisfactory result. The finding includes: 1. The laboratory obtained a 0 percent results for Albumin tests in the first testing event of 2019 and 40 percent for Urea Nitrogen (BUN) in the second testing event in 2019. No remedial action was taken nor documented.