

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0872956	<b>(X3) Date Survey Completed</b>  12/27/2023
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Garnier	<b>Street Address, City, State</b>  Barrio Guaraguao Abajo Carr 174, Km 5, Hm 7, 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 records review, laboratory supervisor and laboratory director interview on December 27, 2023 at 10:04 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results, for the following test: cholesterol, total protein and sodium, in the first proficiency testing event of the year 2023. For the test Alanine Transaminase (ALT), sodium and Urea nitrogen (BUN) in the second proficiency testing event and the third proficiency testing event of the year 2023 the following test: albumin and sodium. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since January 2023. 2. Review of Proficiency Testing records on December 27, 2023 at 9:55 AM, showed that the laboratory obtained unsatisfactory result of 60 % percent in the first proficiency testing event of cholesterol, total protein and sodium tests in the year 2023. For the second proficiency testing event of the year 2023 the laboratory obtained unsatisfactory result of 20 % percent, in Alanine Transaminase (ALT), 60 % percent, in sodium, 0% percent in BUN. For the third proficiency testing event of the year 2023 the laboratory obtained unsatisfactory result of 60 % percent in Albumina and Sodium. No remedial actions were taken nor document. 3. The laboratorysupervisor</p>

and laboratory director confirmed on December 27, 2023 at 10:04 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained in the first, second and third proficiency testing event of routine chemistry in the year 2023.

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review, laboratory supervisor and the laboratory director interview on December 27, 2023 at 10:15AM, it was determined that the laboratory obtained an unsuccessful performance for sodium analyte. The laboratory obtained three consecutive unsatisfactory testing score. The laboratory processed and reported 433 patient samples for the sodium test from May 1, 2023 to December 26, 2023. The findings include: 1. The Puerto Rico Proficiency Testing Program (PRPTP) records was review on December 27, 2023 at 9:55 AM. The PRPTP records showed that the laboratory obtained unsuccessful test results of 60 % in the first (february 2023), 60 % second (May 2023) and 60% third testing (October 2023) event of the year 2023. 2. On a letter sent on August 7, 2023, the Puerto Rico State Office informed to the laboratory that their sodium test was decertified until they have two consecutives satisfactory test result. During the survey performed on December 27, 2023 at 10:00 AM, it was observed that the facility did not stop to test patient samples for sodium. Since May 2023 the laboratory perform 433 patient samples for sodium test. 3. The laboratory supervisor and the laboratory director confirmed on December 27, 2023 at 10:15 AM that the laboratory fail to stop processing the sodium patient samples when the test scores were received on May 2023. They stated that the laboratory continue to perform the sodium test.

**D2128**

**HEMATOLOGY**

CFR(s): 493.851(e)

(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.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program records review, laboratory supervisor and laboratory director interview on December 27, 2023 at 10:04 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in the White Blood Cell (WBC) test in the first event of the year 2023 and for hematocrit (Hct) test in the second hematology event of year 2023. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since January 2023. 2. On December 27, 2023 at 9:

55 AM, the Proficiency Testing records was review and showed that the laboratory obtained unsatisfactory result of 60 % percent in the first proficiency testing event of WBC and 40 % in the second proficiency testing event of Hct tests in the year 2023. No remedial actions were taken nor document. 3. The laboratory supervisor and laboratory director confirmed on December 27, 2023 at 10:04 AM that the laboratory failed to take or document the corrective action when an unsatisfactory score was obtained 60 % percent in the first proficiency testing event of WBC and 40 % in the second proficiency testing event of Hct tests in the year 2023. This deficiency was cited in the previous survey performed on February 4, 2022.

**D6091**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:  
Based on Puerto Rico Proficiency Testing Program records review ( year 2023 ), laboratory supervisor and the laboratory director interview on December 27, 2023 at 11:00 A M, it was determined that the laboratory director failed to evaluate any problems relate to the proficiency testing event of routine chemistry and hematology performance in the year 2023. Refer to D2094, D2096, D2128.