

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1102757	(X3) Date Survey Completed 07/20/2023
Name of Provider or Supplier Laboratorio Clinico Marielys Inc	Street Address, City, State Calle 13 G 52 Santa Monica, 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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on routine chemistry operator's manual, quality control records review and interview with the laboratory director on July 20, 2023 at 10:50 AM; it was determined that the laboratory failed to follow operator's manual instructions for the preventive maintenance of Cobas c111 since January 2022. The findings include: 1. The laboratory performed only glucose test in the routine chemistry specialty in the cobas c111 by Roche Diagnostics. 1. On July 20, 2023 at 10:40 AM the preventive maintenance of routine chemistry was requested and showed that the laboratory did not perform the annual preventive maintenance of the cobas c111 system in the years 2022 and 2023. 2. On July 20, 2023 at 10:46 AM the operator's manual was reviewed. The operator's manual has established in the chapter 8 section C-7 that the preventive maintenance has to be done annually. 3. On July 20, 2023 at 10:50 AM the laboratory director confirmed that the preventive maintenance was not performed in the years 2022 and 2023. The laboratory processed and reported 373 patient's sample for glucose test in the year 2022 and 2023.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:
Based on routine chemistry quality control records review (year 2022 and 2023), operator's manual of cobas c111 and interview with the laboratory director on July 20, 2023 at 10:50 AM; it was determined that the laboratory director failed to ensure that the quality control program and the operator's manual instruction were follow when processed and reported 373 patient's sample for glucose test. Refer to D5429.