

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1072692	(X3) Date Survey Completed 05/20/2026
Name of Provider or Supplier Laboratorio Clinico Bio Tech Ii	Street Address, City, State Carr Pr 3 Km 28 Hm 6 Calle 1 Bloque A-15, Rio Grande, 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Bio Tech II on May 20, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on May 20, 2026.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of the laboratory refrigerator #2, lack of refrigerator #2 temperature records, manufacturer's instructions, and interview with the laboratory director on May 20, 2026 at 9:04 AM, the laboratory failed to monitor and document the refrigerator #2 temperature. The findings include: 1. On May 20, 2026 at 9:04 AM, direct observation of the laboratory refrigerator #2 showed that it was being used to store chemistry reagents. The refrigerator had the following reagents: 4 Triglycerides, 5 Urea, 4 HDL (High density lipoprotein), 2 Normal saline, 4 ALKP (Alkaline phosphatase), 5 Glucose, 5 Cholesterol, 4 AST (Aspartate aminotransferase), 5 ALT (Alanine aminotransferase), 3 Microalbumin, 1 BUN (Blood urea nitrogen), 1 Creatinine, 1 Human Assayed Multi-sera Level 2 control, 1</p>

Human Assayed Multi-sera Level 3 control, 1 Liquid urine control level 2, 1 Liquid urine control level 3, 1 Direct LDL (Low density lipoprotein)/HDL (High density lipoprotein) Calibrator, and 1 Microalbumin Calibrator set. 2. On May 20, 2026 at 9:10 AM, review of the manufacturer's instructions showed that all chemistry reagents stored in the refrigerator #2 temperature range must be between 2-8 C. 3. On May 20, 2026 at 9:15AM, the refrigerator #2 temperature records were requested. The laboratory director stated that refrigerator #2 was acquired on February 28, 2026, and that the laboratory did not document refrigerator #2 temperature records from February 28, 2026 to May 20, 2026, when they processed and reported 4,868 patient chemistry tests. 4. The laboratory director confirmed on May 20, 2026 at 9:20 AM, that the laboratory did not monitor and document the refrigerator #2 temperature, when they used the stored reagents to process and report 4,868 patient chemistry samples from February 28, 2026 to May 20, 2026.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of the chemistry Randox Imola instrument performance verification results, and laboratory director interview on May 20, 2026 at 10:49 AM, the laboratory failed to evaluate the instrument's performance verification obtained results. The findings include: 1. On May 20, 2026 at 10:49 AM, review of the chemistry Randox Imola instrument performance verification results did not reflect the evaluation and signature of the laboratory director prior to begin to test chemistry patient samples. 2. On May 20, 2026 at 10:52 AM, laboratory supervisor stated that the chemistry Randox Imola instrument was used to perform patient testing since December 1, 2025. 3. The laboratory director confirmed on May 20, 2026 at 10:59 AM that the laboratory director did not evaluate and sign the performance verification of the chemistry Randox Imola instrument. 4. The laboratory processed and reported 13,402 chemistry tests on the Randox Imola instrument from December 1, 2025 to May 20, 2026.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on direct observation of the laboratory refrigerator #2, lack of refrigerator #2 temperature records, lack of evaluation of the chemistry instrument performance verification results, manufacturer's instructions, and interview with the laboratory

director on May 20, 2026 at 10:59 AM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the chemistry quality control requirements. Refer to D5413 and D5421.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

This STANDARD is not met as evidenced by:

Based on direct observation of the laboratory refrigerator #2, lack of refrigerator #2 temperature records, manufacturer's instructions, and interview with the laboratory director on May 20, 2026 at 10:59 AM, the laboratory testing personnel failed to perform and document all quality control activities to ensure compliance with the chemistry quality control requirements. Refer to D5413 and D5421.