

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0965559	(X3) Date Survey Completed 08/06/2026
Name of Provider or Supplier Laboratorio Clinico Almirante Norte Corp Ii	Street Address, City, State Carr 140, Km 6, Hm 2, Sector Abra Del Pimiento, Barceloneta, 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 Central de Levittown IV on August 6, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on August 6, 2026.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on daily maintenance, temperatures, voltage and relative humidity records review (2025-2026) on August 6, 2026 at 10:22 A.M. and general supervisor interview , the laboratory failed to maintain accurate and timely documentation of the required environmental monitoring,equipment temperature monitoring and equipment maintenance activities. The findings include: 1. During the survey conducted on August 6, 2026 at 10:22 A.M. , it was observed that records of the following required monitoring and maintenance activities were documented until August 8, 2026, two days after the survey date: room temperature, voltage, relative humidity, bleeding area temperature, refrigerator temperature, freezer temperature, centrifuge maintenance and microscope maintenance. 2. The general supervisor confirmed on August 6, 2026

	at 11:00 A.M. that the laboratory maintenance records contain documentation dated August 8, 2026 which was two days in advance of the survey date. (August 6, 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 hematology performance specifications records (2026) and laboratory general supervisor (testing personnel) interview on August 6, 2026 at 10:10 A.M., the laboratory failed to complete the evaluation of the performance specifications of the new hematology system. The findings include: 1. The laboratory acquired on May 2026 a new system to perform hematology tests (Cell Dyn Ruby). 2. The performance specifications records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 3. The laboratory general supervisor (testing personnel) confirmed on August 6, 2026 at 10:10 A.M., that the laboratory did not verify if the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population prior to begin to test patient's samples. 4. The laboratory processed and reported approximately 648 hematology tests performed by Cell Dyn Ruby system since May 2026.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the Urinalysis (Mission U500) , hematology (Cell Dyn Ruby) daily maintenance records(2025-2026) and the manufacturer's instructions, the laboratory failed to perform and accurately document the daily maintenance as required by the manufacturer. Review of the maintenance records on August 6, 2026 at 10:12 A.M., showed that daily maintenance entries for future dates had already been completed, dated, and signed before the required maintenance activities could have been performed. The findings include: 1. The laboratory used the Mission U 500 system to perform urinalysis sample. a. The urinalysis system (Mission U 500) maintenance log showed that the urinalysis system required daily maintenance. b. Review of the daily maintenance records on August 6, 2026 at 10:12 A.M., showed that maintenance entries for August 7, 2026, through August 8, 2026 had already been completed, dated, and signed. c.The laboratory failed to accurately document the daily maintenance activities as they were performed. d. The laboratory general supervisor confirmed on August 6, 2026 at 10:12 A.M., that the testing personnel failed to accurately document the daily maintenance activities as they were performed. 2. The

	laboratory used the Cell Dyn Ruby system to perform hematology sample. a. The hematology system maintenance log showed that the system required daily , weekly and monthly maintenance. b. Review of the maintenance records on August 6, 2026 at 10:10 A.M, showed that maintenance entries for August 7, 2026, through August 8, 2026 had already been completed and dated. c.The laboratory failed to accurately document the daily, weekly and monthly maintenance activities as they were performed. d. The laboratory general supervisor confirmed on August 6, 2026 at 10: 10 A.M., that the testing personnel failed to accurately document the daily, weekly and monthly maintenance activities as they were performed.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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: 1. Based on daily maintenance, temperatures, voltage and relative humidity records review , Urinalysis (Mission U500) , hematology (Cell Dyn Ruby) daily maintenance records (2025-2026), the laboratory director failed to ensure that the testing personnel maintain accurate and timely documentation of the required environmental monitoring,equipment temperature monitoring and equipment maintenance activities. Refer to D5413, D5429. 2. Based on hematology performance specifications records review (2026) and interview with the laboratory supervisor on August 6, 2026 at 11:00 A.M, the laboratory director failed to ensure that the evaluation of the performance specifications of the new hematology system begin to use on May 2026 was completed. Refer to D5421.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) (b)(3) Adhere to the laboratorys 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 daily maintenance, temperatures, voltage and relative humidity records review , Urinalysis (Mission U500) , hematology (Cell Dyn Ruby) daily maintenance records (2025-2026), the laboratory testing personnel failed to ensure that the testing personnel maintain accurate and timely documentation of the required environmental monitoring,equipment temperature monitoring and equipment maintenance activities. Refer to D5413, D5429.