

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0965559	<b>(X3) Date Survey Completed</b>  08/10/2022
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Almirante Norte Corp Ii	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing records review ( 2021-2022 ) and laboratory general supervisor interview on August 10,2022 at 10:00 A.M., it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2021 to July 2022. ( ( review at 10:00 A.M. ) 2. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2021. ( review at 10:05 A.M.) 3. The laboratory general supervisor confirmed on August 10,2022 at 10:10 A.M that the laboratory director and testing personnel failed to sign the attestation statements since 2021. ( review at 10:15 A.M.)</p>
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

This STANDARD is not met as evidenced by:  
 Based on Puerto Rico Proficiency Testing Program ( PRPTP ) records review ( 2021-2022) and laboratory general supervisor interview on August 10, 2022 at 9:30 A.M., it was determined that the laboratory failed to verify the accuracy of the hematology specialty when the PRPTP did not have hematology samples in the second testing event performed in June 2021. The findings include: 1. Proficiency testing records were reviewed from February 2021 to July 2022. ( review at 9:30a.m. ) 2. In the Hematology second testing event performed in June 2021 , the Puerto Rico Proficiency Testing office sent to the laboratory a letter that oriented them that in absence of an event the regulation establishes that the laboratory must be verify the accuracy of the tests ( platelet, white blood cells, red blood cells, hemoglobin, hematocrit ) . 3. The proficiency testing records showed that the laboratory did not verify the accuracy of the hematology specialty tets in June 2021. review at 9:35 a.m. ) 4. The general supervisor stated on August 10, 2022 at 9:40 A.M. that the laboratory did not have a mechanism to verify the accuracy of the hematology tests.

**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 ( years 2021-2022 ) and laboratory general supervisor interview on August 10, 2022 at 10:50 A. M, it was determined that the laboratory director failed to evaluate any problems relate to PT performance. The findings include: 1. The laboratory director failed to verify the accuracy of the hematology specialty when the PRPTP did not have hematology samples in the second testing event performed in June 2021. Refer to D5215. ( review at 9:30 a.m ) 2. The laboratory director and testing personnel failed to sign the attestation statements. Refer to D2009. ( review at 10:50a.m. )