

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D1072692	<b>(X3) Date Survey Completed</b>  05/07/2024
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Bio Tech Ii	<b>Street Address, City, State</b>  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.		

<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 Proficiency Testing program records review (year 2023) and laboratory director interview on May 7, 2024 at 9:14 AM; it was determined that the laboratory failed to attestated that the proficiency samples were tested in the same manner that they tested the laboratory patient samples. The findings include: 1. On May 7, 2024 at 9: 00 AM, the proficiency testing program record was reviewed. The proficiency attestation statement year 2023 were requested. The laboratory director did not provide any attestation statement of the year 2023. 2. The laboratory director stated, on May 7, 2024 at 9:14 AM, that they no print nor signed the attestation statement of the proficiency program for the year 2023.</p>
<b>D6016</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p>

This STANDARD is not met as evidenced by:  
Based on the review of the proficiency program record and interview with the laboratory director on May 7, 2024 at 9:14 AM, it was determined that the laboratory director fail to meet the required requirements under subpart H. Refer to D2009.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 Proficiency testing program reviewed and laboratory director interview on May 7, 2024 at 9:22 AM, it was determined that the laboratory director failed to evaluate the proficiency testing result of the third event of year 2023 (Diagnostics Immunology). The finding include: 1. On May 7, 2024 at 9:22 AM, the third event of the year 2023 were requested. The laboratory director stated that the third event of the year 2023, that was performed on December 2023, was not printed nor evaluated.