

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0861654	<b>(X3) Date Survey Completed</b> 05/08/2026
<b>Name of Provider or Supplier</b> Laboratorio Clinico Pajuil	<b>Street Address, City, State</b> Carretera 490 Km 4 Hm 5, Hatillo, 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>D0000</b>	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced Clinical Laboratory Improvement Amendments (CLIA) recertification survey at Laboratorio Clinico Pajuil on May 8, 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 May 8, 2026.
<b>D2010</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(2)</p> <p>(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of the routine chemistry proficiency samples test results for the first testing event of year 2026, proficiency testing (PT) written procedures and interview with the laboratory director on May 8, 2026, at 8:15 a.m., the laboratory failed to test routine chemistry PT samples in the same number of times that it routinely tested patient specimens. The laboratory processed the routine chemistry PT samples on February 4, 2026, February 5, 2026, and February 6, 2026. The findings include: 1. On May 8, 2026, at 8:15 a.m., the routine chemistry PT records for the first testing event of 2026 were reviewed. 2. On May 8, 2026, at 8:20 a.m., review of the routine chemistry PT samples test results showed that the laboratory processed each PT sample in triplicate, as follows: a. PT sample ID PROF #1 was processed on February 4, 2026, at 3:04 p.m.; February 5, 2026, at 2:22 p.m.; and February 6, 2026, at 11:42 a.m. b. PT sample ID PROF #2 was processed on February 4, 2026, at 3:06 p.m.; February 5, 2026, at 2:24 p.m.; and February 6, 2026, at 11:44 a.m. c. PT sample ID PROF #3 was processed on February 4, 2026, at 3:08 p.m.; February 5, 2026, at 2:26 p.m.; and February 6, 2026, at 11:47 a.m. d. PT sample ID PROF #4 was processed on February 4, 2026, at 3:10 p.m.; February 5, 2026, at 2:28 p.m.; and February 6, 2026,</p>

at 11:49 a.m. e. PT sample ID PROF #5 was processed on February 4, 2026, at 3:12 p. m.; February 5, 2026, at 2:30 p.m.; and February 6, 2026, at 11:51 a.m. 2. On May 8, 2026, at 8:28 a.m., the PT written procedures were reviewed. The written procedures stated that PT samples must be repeated the same number of times as patient specimens. The laboratory director stated that only patient specimens with critical values were repeated, while patient specimens with normal values were not repeated. 3. On May 8, 2026, at 8:35 a.m., laboratory director confirmed that the routine chemistry PT samples for the first testing event of 2026 were processed more than once. Laboratory director confirmed that the first run was performed on February 4, 2026, the second run was performed on February 5, 2026, and the third run was performed on February 6, 2026.

**D2128**

**HEMATOLOGY**  
CFR(s): 493.851(e)

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:  
Based on review of the Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2025 - 2026), Certification and Survey Provider Enhanced Reports (CASPER) 0155D, and interview with the laboratory director on May 8, 2026, at 8:45 a.m., the laboratory failed to take and document corrective action when it obtained an unsatisfactory proficiency testing score for hemoglobin (Hgb) in the specialty of hematology during the second proficiency testing event of 2025. The laboratory processed and reported 245 out of 245 Hgb patient test results from March 2025 through June 2025. The findings included: 1. The PRPTSP scores and CASPER Report 0155D were reviewed for the period of January 2025 through February 2026. 2. Review of PRPTSP scores and CASPER Report 0155D showed that the laboratory obtained an unsatisfactory score of 60 % (percent) for the Hgb analyte in the second proficiency testing event of 2025 and failed to take or document any remedial or corrective action. 3. The laboratory processed and reported 245 out of 245 patient test results for Hgb from March 2025 through June 2025. 4. On May 8, 2026, at 8:50 a.m., the laboratory director confirmed during interview that the laboratory did not take or document corrective action for the unsatisfactory Hgb proficiency testing score.

**D6016**

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

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of PRPTSP routine chemistry PT printouts, PT protocol, and interviews on May 8, 2026, at 12:00 p.m., the laboratory director failed to ensure compliance with PT testing requirements when the laboratory processed each routine

chemistry PT sample three times on three separate dates, in the first proficiency testing event of 2026. Refer to D2010.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) 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; and

This STANDARD is not met as evidenced by:

Based on review of the Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2025), Certification and Survey Provider Enhanced Reports (CASPER) 0155D, and laboratory director interview on May 8, 2026, at 12:00 p.m., the laboratory director failed to ensure compliance with proficiency testing requirements when the laboratory obtained an unsatisfactory score for the Hgb analyte during the second proficiency testing event of 2025 and failed to take and document corrective action. Refer to D2128.