

<p><b>Statement of Deficiencies</b></p>	<p><b>(X1) Provider/Supplier/CLIA Identification Number</b></p> <p>40D0658016</p>	<p><b>(X3) Date Survey Completed</b></p> <p>06/06/2025</p>
<p><b>Name of Provider or Supplier</b></p> <p>Laboratorio Clinico Borinquen - Forest Hills</p>	<p><b>Street Address, City, State</b></p> <p>Forest Hills Plaza, Carr Pr-167, Esquina Calle#15, Bayamon, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p><b>(X4) ID Prefix Tag</b></p>	<p><b>Summary Statement of Deficiencies</b></p>
<p><b>D0000</b></p>	<p>The Centers for Medicare &amp; Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clinico Borinquen - Forest Hills on June 6, 2025. 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 June 6, 2025.</p>
<p><b>D2104</b></p>	<p><b>ENDOCRINOLOGY</b> CFR(s): 493.843(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing (PRPT) event scores (years 2024-2025), CASPER Report 0155D, PRPT (year 2024) schedule and laboratory technical consultant interview on June 6, 2025, at 9:00 A.M., it was determined that the laboratory failed to report the Human Chorionic Gonadotropin (hCG) proficiency testing results within the time frame established by the program. The laboratory performed and reported 121 out of 121 hCG patient's testing from November, 2023 to May, 2024. The findings include: 1. The PRPT and CASPER Report were reviewed on June 6, 2025, at 9:00 A.M., from February 2024 to March 2025. 2. The PRPT schedule for the year 2024 showed that the deadline of the first testing event for Endocrinology scores was on February 23, 2024. (Reviewed on June 6, 2025, at 9:05 A.M.) 3. Review of the PRPT scores showed that the laboratory obtained a 0% score in the first testing event, year 2024, for hCG tests. (Reviewed on June 6, 2025, at 9:07 A.M.) 4. The laboratory technical consultant confirmed on June 6, 2025, at 9:15 A.M., that the laboratory failed to report the hCG proficiency testing results of the first testing event within the time frame established by the PRPT. 5. The laboratory</p>

	<p>performed and reported 121 out of 121 hCG patient's testing from November, 2023 to May, 2024.</p>
<b>D6041</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(3)</p> <p>(b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing scores (years 2024-2025) and CASPER Report and laboratory technical consultant interview on June 6, 2025, at 9:20 A.M, it was determined that the laboratory technical consultant failed to report the hCG proficiency testing results within the time frame established by the program. Refer to D 2104.</p>
<b>D6090</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(ii)</p> <p>(e)(4)(ii) The results are returned within the timeframes established by the proficiency testing program;</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing scores (years 2024-2025) and CASPER Report and laboratory technical consultant interview on June 6, 2025, at 9:20 A.M, it was determined that the laboratory director failed to ensure that the laboratory technical consultant submitted the Endocrinology proficiencies testing results within the time frame established by the program. Refer to D6041.</p>