

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0658040	<b>(X3) Date Survey Completed</b> 03/27/2025
<b>Name of Provider or Supplier</b> Laboratorio Clinico Tropical By Villa Ana	<b>Street Address, City, State</b> Call Intendente Ramirez Num 2, Caguas, 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 CLIA Recertification survey at the Laboratorio Clinico Tropical by Villa Ana on March 27, 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 on March 27, 2025.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on personnel records review (years 2023-2024), written policies for personnel competence procedures and laboratory general supervisor interview on March 27, 2025, at 9:15 AM, it was determined that the laboratory failed to follow written policies to assess the technical supervisor, technical consultant and laboratory general supervisor competence. The findings include: 1. The technical supervisor, technical consultant and laboratory general supervisor's personnel records were reviewed since March 2023. 2.The laboratory written policies for personnel competence procedures showed that competence procedures must be performed annually. (Reviewed on March 27, 2025, at 9:30 AM) 3. The laboratory general supervisor confirmed on March 27, 2025, at 10:00 AM, that the laboratory director failed to perform the annual competence evaluation to the technical supervisor, technical consultant and laboratory general supervisor during the year 2023 and 2024.</p>
<b>D6128</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p>

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on personnel records, personnel competence written policies review and general supervisor interview on March 27, 2025, at 10:00 AM, it was determined that the laboratory technical supervisor did not evaluated the competence of the technical consultant, laboratory general supervisor and testing personnel. Refer to D5209.