

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0705731	(X3) Date Survey Completed 01/24/2025
Name of Provider or Supplier Laboratorio Clinico Santana	Street Address, City, State Calle 25 De Julio #45, Guanica, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced CLIA Recertification survey was conducted at the Laboratorio Clinico Santana on January 24, 2025 by the Puerto Rico State Agency. 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 January 24, 2025.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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) and laboratory director interview on January 24, 2025 at 10:30 AM, it was determined that the laboratory failed to follow the established schedule for competence evaluation for the clinical consultant. The finding includes: 1. The laboratory written policies for personnel competence procedures showed that the competence procedures performed annually. (Reviewed at 10:30 AM) 2. The laboratory director did not perform, as established (annually), the competence evaluation for the clinical consultant during years 2023-2024. (Reviewed at 10:35 AM) 3. During the interview with the laboratory director on January 24, 2025 at 10:40 AM, the laboratory director stated that the clinical consultant competence evaluation was not performed.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure</p>

that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on personnel records review (years 2023-2024) and laboratory director interview on January 24, 2025 at 10:30 AM, it was determined that the laboratory director failed to follow the established schedule to monitor and ensure the competency evaluation of the laboratory clinical consultant. Refer to D5209.