

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0914062	(X3) Date Survey Completed 08/08/2024
Name of Provider or Supplier Laboratori0 Clinico Genesis	Street Address, City, State Carr 111 Km 4-2 Bo Lares, Lares, 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	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Gnesis on August 8, 2024. 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 August 8, 2024.
D6107	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records files and interview with the laboratory supervisor on August 8, 2024 at 11:10 AM, it was determined that the laboratory director did not include the written duties of the laboratory technical supervisor. The finding includes: a. The laboratory personnel files were reviewed on August 8, 2024 beginning at 11:10 AM b. During interview with the general supervisor stated that the personnel designated as technical supervisor was personnel # 2 (as identified on form CMS-209). c. Review of the personnel # 2 file record at 11:15 am, showed that no written duties were included.</p>