Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2083701	10/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Santa Isabel Medical Center	Calle Hostos Final, Carr 153, Santa Isabel, 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 SANTA ISABEL MEDICAL CENTER on October 4, 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 October 4, 2024.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (years 2023-2024) and laboratory testing personnel interview on October 4, 2024, it was determined that the laboratory director and testing personnel failed to sign the proficiency attestation statements. The findings include: 1. Puerto Rico Proficiency testing records from years 2023 and 2024 were reviewed on October 4, 2024 at 10:30 a.m. 2. On October 4, 2024 at 10:35 a.m. the attestation statements (submittion form page 10) instructed the laboratory to print, fill, sing and retain the page for laboratory records and inspection purposes. Review of the attestation statements forms from years 2023 and 2024, showed that none of them were signed by director nor the individual who tested the samples. 3. On Octboer 4, 2024 at 10:40 a.m., the testing pesonnel stated that the attestation statements were never signed by the personnel
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the review of the Puerto Rico Profiency Testing Program (PRPTP) records (2023-2024) and interview with the laboratory testing personnel on October 4, 2024 at 10:30 a.m., it was determined that the laboratory director fail to meet the required requirements under subpart H. Refer to D2009