Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0673305	01/21/2026
Name of Provider or Supplier	**Street Address, City, State**	
Hosp Metropolitano San German	Calle Javilla #8, San German, 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 the Hospital de la Concepcion San German Pueblo on January 21, 2026. 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 January 21, 2026.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on blood gas procedure manual for referral specimen, review of patients blood

	gas final test report and interview with the laboratory supervisor on January 21, 2026 at 11:25 A.M., the laboratory failed to follow the established procedure for the blood gas patient sample referral since December 20, 2025. 40 out of 75 patients samples were received in the other facility after 35 minutes from the sample collection time. The findings include: 1. During interview with the laboratory supervisor, she informed that the Cobas b221 instrument used to perform blood gas test was out of service since December 20, 2025. She also informed that the blood gas patients samples were referred to another facility that has the same instrument model. 2. Review of the procedure manual showed that the blood gas samples must be received within 35 minutes since the sample collection time. 3. Review of the patients blood gas final test report showed that 40 out of 75 patients samples were received in the other facility after 35 minutes from the sample collection time. The mean transportation time was 41 minutes. 4. The laboratory supervisor confirmed on January 21, 2026 at 2:53 P.M. that the laboratory failed to follow the established procedure manual for blood gas referral time when 40 out of 75 patients samples were received in the other facility after 35 minutes from the sample collection time.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on blood gas procedure manual for referral specimen, patient final test report for blood gas and interview with the laboratory supervisor on January 21, 2026 at 2:53 P.M., the laboratory director failed to fulfill his responsibilities and duties to ensure compliance for the established procedure for the blood gas patients sample referral since December 20, 2025. Refer to D5403.