Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0912763	07/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico San Juan Inc	Plaza Olmedo # 1790, Ave Lomas Verdes, Rio Piedras, 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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (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 General Immunology procedural manual of C-Reactive Protein test (CRP), worksheet review from January 2022 to July 2022, manufacturer's instructions and interview with the laboratory supervisor, it was determined that the laboratory did no include in the written procedure manual the new kit that was in use (ASI C-Reactive Protein slide test) and run a wrong dilution for the prozone effect when 34 patients was diluted 1:10 from May 27, 2022 to July 13, 2022. The findings include: 1. During the review of the procedure manual on July 14, 2022 at 10:20 am, it was found that

	the written procedure manual stated: a. Analytic phase principle: a.1. "Immunolex/ CRP reagent..." b. Procedure "Screening": b.1. Make sure that all reagents are at room temperature. b.2. Process positive and negative controls, included every time of testing or as necessary. b.3. Mix gently the CRP reactive, filling and emptying the container before use. b.4. Dispense one drop of reagent in the slide. b.5. Using the pipet included, add one drop of serum. b.6. Serve one drop of each control in the indicated area. b.7. Mix both drops with the stirring pipet. b.8. Mix for two minutes in the rotator or manually. b.9. Look for the presence or absence of macroscopic agglutination using the indirect source of light. c. Limitation of procedure c.1. The strong agglutination reaction is not indicative of the CRP concentration. Weak reactions can occur with slightly or markedly elevated concentrations. The prozone phenomenon (excess of antigen) can cause false negatives. For this reason it is advertise to verify the negative serum and do it again with a 1:10 dilution. Reactions with more time than specified (four minutes) can produce apparently false reactions due to the drying effect. 2. The laboratory uses ASI C-Reactive Protein slide test kit. The manufacturer's instruction did not establish any specific dilution for the prozone effect. Reviewed the Worksheet record of CRP on July 14, 2022 at 10:02 am, the laboratory established a 1:10 dilution to rule out prozone effect. 3. The laboratory supervisor confirmed on July 14, 2022 at 10:15 am that they run a 1:10 dilution based on the procedure manual that was established before she arrived. The Laboratory supervisor confirmed on July 14, 2022 at 10:25 am that the procedure manual was not updated with the ASI C-Reactive Protein kit manufacturer's instructions when 34 patients were diluted 1:10 from May 27, 2022 to July 13, 2022.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on C-reactive protein (CRP) test quality control record (January 2022 to July 2022) review, manufacturer's instructions, procedure manual review and interview with the laboratory supervisor on July 14, 2022 at 10:15am, it was determined that the laboratory director failed to establish the acceptable dilution for the prozone effect for the ASI C-Reactive Protein slide test method. Refer to D5403.