Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0912763	08/29/2018
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
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 testing records review (2017-2018) and laboratory general supervisor interview on August 29, 2018 at 9:00 A.M., it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were review from February 2017 to July 2018. 2. The laboratory director and testing personnel did not sign the attestation statements of the Proficiency testing records since February 2017. 3. The laboratory general supervisor confirmed on August 29, 2018 at 9:00 A.M that the laboratory director and testing personnel failed to sign the attestation statements since 2017.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on Hematology quality control records reviewed (2017-2018) and laboratory general supervisor interview on August 29, 2018 at 11:40 A.M., it was determined

	that the laboratory failed to retain the hematology quality control records. The findings include: 1. The laboratory performed hematology tests by the Cell Dyn 3200 system. 2. The laboratory did not have available the hematology quality control records from October 7, 2017 to November 26, 2017. 3. The laboratory processed and reported 270 CBC patient samples those days. 4. The laboratory general supervisor confirmed on August 29, 2017 at 11:40 A.M. , that the laboratory failed to retain the hematology quality control tests from October 7, 2017 to November 26, 2017.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records review (2017-2018) and laboratory general supervisor interview on August 29, 2018 at 11:15 A. M., it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests processed by the Chem Well -T system. The findings include: 1. The laboratory began to use the new routine chemistry system Chem Well-T on April 2017. The laboratory performed glucose and lipid panel by this system. 2. The laboratory did not perform the calibration verification procedures of the system since April 2017. 3. The laboratory performed and reported 20,365 routine chemistry patient samples (glucose, cholesterol, triglycerides and high density lipoprotein) since April 2017. 4. The laboratory general supervisor confirmed on August 29, 2018 at 11:15 A.M. that the laboratory failed to perform the calibration verification of the new system since April 2017.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control records review (2017-2018), manufacturer's instructions and laboratory general supervisor interview on August 29, 2018 at 11:40 A.M., it was determined that the laboratory failed to include three levels of control when complete blood count (CBC) patient samples test were performed by the Cell Dyn 3200 system. The findings include: 1. The laboratory uses the Cell Dyn 3200 system to perform Complete blood count (CBC) patient samples. 2. The manufacturer's establishes that three levels of control material (low, normal and high) must be included each day of testing. 3. Hematology quality control records were reviewed from January 2017 to July 2018. 4. The laboratory processed hematology patient samples from October 7, 2017 to November 26, 2017 and did not have evidence that include the three levels of control. 5. The laboratory processed and reported 270 CBC patient samples those days. 6. The laboratory general supervisor confirmed on August 29, 2018 at 11:40 A.M. , that the laboratory did not have evidence that include the three levels of control those days.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on routine chemistry quality control records review (2017-2018) and laboratory general supervisor interview on August 29, 2018 at 11:30 A.M., it was determined that the laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. The findings include: 1. The laboratory performed routine chemistry patient samples by Chem Well-T system. 2. Quality control records were reviewed from April 2017 to July 2018. 3. Review of quality controls showed that the laboratory failed to take corrective actions when the control material exceeded the laboratory acceptable limits the following days: a. Triglycerides test (level 1) exceeded the laboratory acceptable limits (over 2 sd) three consecutive days: 8/2/17, 8/3/17 and 8/4/17. The laboratory processed and reported 35 patient samples those days. b. High density lipoprotein test (level 2) exceeded the laboratory acceptable limits (over 2 sd) two consecutive days (4 /17/18 and 4/19/18 . Five patient samples were processed and reported on 4/19/18. c. High density lipoprotein test (level 2) exceeded the laboratory acceptable limits (over 2 sd) two consecutive days (4/25/18 and 5/1/18. Five patient samples were processed and reported on 5/1/18. d. Cholesterol test (level 2) exceeded the laboratory acceptable limits (over 2 sd) three consecutive days (3/5/18, 3/7/18 and 3/9/18. Twenty five patient samples were processed and reported on 3/7/18 and 3/9/18. 4. The laboratory general supervisor confirmed on August 29, 2018 at 11:30 A.M. that no corrective actions were taken.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on Quality Assessment records (2017-2018) review and laboratory general supervisor interview on August 29, 2018 at 10:00A.M., it was determined that the laboratory failed to follow Quality Assessment Program to monitor and evaluate the following requirements for post analytic systems: test report The findings include: 1. The Quality Assessment Program establishes that evaluations of the laboratory test report must be performed annually. 2. The laboratory did not perform the test report evaluations since June 2017. 3. The laboratory general supervisor confirmed on August 29, 2018 at 10:00 A.M., that the laboratory failed to perform the evaluations of the laboratory test report annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 hematology and routine chemistry quality control records review , lack of routine chemistry calibration verification records (2017-2018) , and laboratory general supervisor interview on August 29, 2018 at 12:00 P.M., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests processed by the Chem Well -T system. Refer to D5439. 2 .The laboratory failed to include three levels of control when complete blood count (CBC) patient samples test were performed by the Cell Dyn 3200 system. Refer to D5447. 3. The laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. Refer to D5783.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 Quality Assessment records (2017-2018) review and laboratory general supervisor interview on August 29, 2018 at 12:00 P.M., it was determined that the

	laboratory director did not ensure to comply with the QA requirements. The finding includes: 1. The QA records showed that the laboratory director did not comply with the establishment QA Program evaluations. Refer to D5891.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on testing personnel records review and laboratory general supervisor interview on August 29, 2018 at 10:00 A.M., it was determined that the laboratory technical supervisor failed to perform the bi annual competency for the new testing personnel . The findings include: 1. The laboratory hired a new testing personnel # 1 on October 2017. 2. The laboratory did not perform the bi annual competency of the new testing personnel # 1 that was hired on October 2017. 3. The general supervisor confirmed that the laboratory failed to perform the bi annual competency of the new testing personnel # 1 .
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on hematology and routine chemistry quality control records review, lack of routine chemistry calibration verification records (2017-2018) , and laboratory general supervisor interview on August 29, 2018 at 12:00 P.M., it was determined that the laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests processed by the Chem Well -T system. Refer to D5439. 2. The laboratory failed to include three levels of control when complete blood count (CBC) patient samples test were performed by the Cell Dyn 3200 system. Refer to D5447. 3. The laboratory failed to take and document remedial actions when control results failed to meet the laboratory's criteria for acceptability. Refer to D5783.