Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0692386	11/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Rios Lisojo	#4 Calle Palmer, Las Marias, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on facility records review in years 2017-2018 and laboratory general supervisor interview at 11:00 AM on November 2, 2018, it was determined that the laboratory failed to be in compliance with the State laboratory requirements. The findings include: 1. The laboratory Biomedical Generator Number #DBR-RM-43-13-02-0032 was due since August 20, 2018. 2. The laboratory general supervisor confirmed on November 2, 2018, that the Biomedical Generator Number was due since August 20, 2018.
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 hematology quality control records review in years 2017-2018 and laboratory general supervisor interview at 10:30 AM on November 2, 2018, it was determined that the laboratory failed to perform at least every six months the calibration verification procedures for the hematology tests processed by the Cell Dyn 3200 hematology system. The findings include: 1. The laboratory uses a Cell Dyn 3200 system to perform the Complete Blood Count (CBC) patient's samples tests. 2. Review the hematology quality control records from January 2017 to October 2018, the records showed that the laboratory did not perform at least every six months the calibration verification procedures for the hematology tests processed by Cell Dyn 3200 system since January 2017. 3. The laboratory general supervisor stated on November 2, 2018 that the laboratory did not perform at least six months the calibration verification procedures for the hematology tests processed by Cell Dyn 3200 system.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on endocrinology quality control records review in years 2017-2018 and laboratory general supervisor interview at 10:00 AM on November 2, 2018, it was determined that the laboratory failed to include negative and positive control material when performed hCG test (Human Chorionic Gonadotropin) by Aim One Step Method. The findings include: 1. The laboratory performed hCG (Human Chorionic Gonadotropin) by Aim One Step Method. 2. Endocrinology quality control logs were reviewed from January 2017 to October 2018. 3. The records showed that the laboratory did not include nor document a negative and a positive control material in the following days: Date # samples 1/3/2018 1 1/4/2018 1 1/11/2018 1 1/12/2018 2 1 /20/2018 1 1/23/2018 1 1/26/2018 1 2/1/2018 2 2/6/2018 1 2/7/2018 1 2/28/2018 1 3 /13/2018 1 3/15/2018 1 4/11/2018 1 4/12/2018 1 4/17/2018 1 5/9/2018 2 7/18/2018 1 7 /19/2018 3 7/21/2018 1 7/30/2018 1 8/13/2018 1 8/25/2018 1 8/31/2018 1 9/4/2018 1 9 /5/2018 2 9/6/2018 1 9/13/2018 1 9/15/2018 1 9/20/2018 1 9/26/2018 1 4. The laboratory processed and reported thirty seven hCG patient's samples during those days. 5. The laboratory general supervisor confirmed on November 2, 2018 that the laboratory did not include nor document a negative and a positive control material during those days.

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 endocrinology and hematology quality control records review from January 2017 to October 2018 and laboratory general supervisor interview at 11:30 AM on November 2, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5439 and D5449.
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 endocrinology and hematology quality control records review in 2017-2018 and laboratory general supervisor interview on November 2, 2018 at 11:30 AM, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory failed to perform at least every six months the calibration verification procedures for the hematology tests processed by the Cell Dyn 3200 hematology system. Refer to D5439. 2. The laboratory failed to include negative and positive control material when performed hCG test (Human Chorionic Gonadotropin) by Aim One Step Method. Refer to D5449.