Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1102757	08/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Marielys Inc	Calle 13 G 52 Santa Monica, Bayamon, 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
D2105	ENDOCRINOLOGY CFR(s): 493.843(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP)records (years 2018 and 2019) review and testing personnel interview on August 2, 2019 at 1:00 PM, it was determined that the laboratory failed to take and document remedial actions when it obtained an unsatisfactory results for hCG test in the first 2019's proficiency testing event. The findings include: 1. The PRPTP records showed that the laboratory obtained a 40 percent score for the hCG test in the first 2019's proficiency testing event (February 2019). However, the laboratory did not have available the documentation of the remedial action for this unacceptable analyte result. 2. The testing personnel confirmed on August 2, 2019 at 1:00 PM, that the laboratory did not have available the documentation of the remedial action for this result. She stated that occurred a data entry mistake in this event.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not

	provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Streck ESR-Chez Plus manufacturer's instruction and erythrocytes sedimentation rate (ESR) testing records (years 2018 to 2019) review and testing personal interview on August 2, 2019 at 11:40 AM, it was determined that the laboratory failed to follow manufacturer's instruction for control materials handling when 21 patients specimens for ESR were processed and reported from July 3, 2019 to August 2, 2019 by the Mini-Cube system. The findings include: 1. The laboratory processed and reported the patients ESR specimens by the Mini Cube system and run each day of testing the ESR-Chex Plus control materials (two levels). 2. The ESR-Chex Plus manufacturer define the open-vial stability (OVS) as the maximum number of continuous days a vial can be brought to room temperature and mixed for analysis on this system. Vials must be discarded at the lot expiration or the OVS expiration, whichever come first. The OVS is 7 days. 3. The ESR testing records showed that the laboratory had in used the ESR-Chex Plus controls lot 439 and open the controls vials on June 23, 2019. The laboratory used these controls vials with exceeded OVS from July 3 ,2019 to August 2, 2019. 4. The testing personnel confirmed on August 2, 2019 at 11:40 AM, that the laboratory used the ESR-Chex Plus controls lot 439 with with exceeded OVS from July 3 ,2019 to August 2, 2019. 5. The laboratory processed and reported 21 patients specimens for ESR from July 3, 2019 to August 2, 2019 by the Mini-Cube system.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on PRPTP records (years 2018 and 2019) review and testing personnel interview on August 2, 2019 at 1:00 PM, it was determined that the laboratory director failed to ensure that an approved corrective action plan is followed when the laboratory obtained an unsatisfactory results in hCG test in the first 2019's proficiency testing event. Refer to D 2105.
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 Streck ESR-Chez Plus manufacturer's instruction and ESR testing records (years 2018 to 2019) review and testing personal interview on August 2, 2019 at 11: 40 AM, it was it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the ESR test when 21 patients

	specimens were reported from July 3, 2019 to August 2, 2019 by the Mini-Cube system. Refer to D 5405 (The laboratory failed to follow manufacturer's instruction for ESR-Chez Plus control materials handling).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on Streck ESR-Chez Plus manufacturer's instruction and ESR testing records (years 2018 to 2019) review and testing personal interview on August 2, 2019 at 11: 40 AM, it was determined that testing personnel failed to follow manufacturer's instruction for the handling of the ESR-Chez Plus control materials. Refer to D 5405 (The laboratory failed to follow manufacturer's instruction for the ESR-Chez Plus control materials).