Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2047664	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Cima Camino Nuevo, Inc	Carretera Pr-901, Km 3 Hm 6 Barrio Camino Nuevo, Yabucoa, 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
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on serum pregnancy qualitative test testing records (years 2017 to 2019) review and and interview with the technical consultant on February 14, 2019 12:05 PM, it was determined that the laboratory failed to meet with the requirement for the subspecialty of Endocrinology (serum pregnancy qualitative tests) from April 22, 2018 to February 11, 2019. Refer to D 5449 (The laboratory did not include each day of testing the negative nor the positive control material when 22 patients specimens were tested and reported for serum pregnancy qualitative test from April 22, 2018 to February 11, 2019).
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 serum pregnancy qualitative test testing records (years 2017 to 2019) review

	and and interview with the technical consultant on February 14, 2019 12:05 PM, it was determined that the laboratory failed to include at least once a day the negative and the positive control materials when 22 patients specimens were tested and reported for serum pregnancy qualitative test from April 22, 2018 to February 11, 2019. The findings include: 1. On February 14, 2019 12:05 PM, the serum pregnancy qualitative test testing records showed that the the laboratory did not include at least once a day the negative nor the positive control materials when 22 patients specimens were tested and reported for serum pregnancy qualitative test from April 22, 2018 to February 11, 2019. 2. The technical consultant confirmed on February 14, 2019 12:05 PM, that the serum pregnancy qualitative tests testing records showed that the laboratory did not include the negative nor the positive control materials results. She stated that those control materials were include each day of testing but the controls results were not recorded each day.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on serum pregnancy qualitative test testing records (years 2017 to 2019) review and and interview with the technical consultant on February 14, 2019 12:05 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system for the subspecialty of Endocrinology (serum pregnancy qualitative tests) from April 22, 2018 to February 11, 2019. Refer to D 6020.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on serum pregnancy qualitative test testing records (years 2017 to 2019) review and and interview with the technical consultant on February 14, 2019 12:05 PM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for serum pregnancy quantitative test from April 22, 2018 to February 11, 2019. Refer to D 6020 (The laboratory director failed to ensure that the laboratory meet the requirement for the subspecialty of Endocrinology (serum pregnancy qualitative tests) from April 22, 2018 to February 11, 2019.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on serum pregnancy qualitative test testing records (years 2017 to 2019) review and and interview with the technical consultant on February 14, 2019 12:05 PM, it was determined that technical consultant failed to ensure compliance with the requirements for analytic systems of serum pregnancy qualitative test from April 22, 2018 to February 11, 2019. Refer to D 5449 (The laboratory did not include at least once a day the negative nor the positive control materials when 22 patients specimens were tested and reported for serum pregnancy qualitative test from April 22, 2018 to February 11, 2019).
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate 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 serum pregnancy qualitative test testing records (years 2017 to 2019) review and and interview with the technical consultant on February 14, 2019 12:05 PM, it was determined that testing personnel failed to follow quality control procedures for serum pregnancy qualitative tests from April 22, 2018 to February 11, 2019. Refer to D 5449 (The laboratory did not include at least once a day the negative nor the positive control materials when 22 patients specimens were tested and reported for serum pregnancy qualitative test from April 22, 2018 to February 11, 2019).