Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0993164	11/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Emanuel	Carr # 2, Km 30 Hm 4, Parcelas 18 C, Vega Alta, 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
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 syphilis serology quality control records review (year 2021-2022) and laboratory director interview on November 10, 2022 at 10:20 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method. The findings include: 1. The manufacturer's instruction establishes that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. (reviewed on 11/10/22 at 10:22a.m.) 2. Since August 23, 2022, the syphilis serology quality control records showed that the laboratory did not include the weakly reactive control material when the laboratory processed and reported 522 out of 522 patients specimens for syphilis serology by RPR method. (reviewed on 11/10/22 at 10:23a.m.) 3. The laboratory director stated on November 10, 2022 at 10:25 a.m. , that the laboratory performed the quality control procedures those days but not included the weakly reactive control .
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 (year 2021-2022) and interview with the laboratory director on November 10, 2022 at 9:45 AM, it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (electrolytes) tests processed by the Dimension Xpand system. The findings include: 1. The laboratory used the Dimension Xpand system to perform routine chemistry tests. 2. Review of the calibration verification records showed that the procedures were performed on January 2021, August 2021, January 2022 and August 2022. (reviewed on 11/10/22 at 9:48 a.m.) 3. The laboratory director confirmed on November 10, 2022 at 9:48 a.m. that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by Dimension Xpand system.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on MAS ChemTrak routine chemistry control materials manufacturer's instructions, routine chemistry quality control records review (year 2022) and interview with the laboratory director at 9:20 AM on November 10, 2022, it was determined that the laboratory failed to follow the establishes manufacturer's ranges

	when performed routine chemistry tests. The findings include : 1. The laboratory processed routine chemistry tests by the Xpand system. 2. The laboratory used the MAS ChemTrak control materials for quality control. (reviewed on 11/10/2022 at 9: 30 a.m.) 3. The Xpand system quality control records showed that the laboratory did not follow the controls values range established by the manufacturer's (lot : CHA22101A , exp. date 10/31/2022 and CHA22103A, exp. date : 7/19/2022) . Since January 2022 to June 2022 the laboratory established its own reference range that is lower 3 SD or over 3 SD. Controls values were reviewed and the values meets with the commercial reference range. (reviewed on 11/10/2022 at 9:35 a.m.) test Level 1 commercial range Alanine aminotransferase (ALT) 32.1-53.1 U/L Uric Acid 3.02-4.54 mg/dl Albumim 3.40-5.10 md/dl alkaline phosphate 34.8-57.8 U//L Direct bili 0.1-0.39 mg/dl total bili 0.56-1.04 mg/dl Blood urea nitrogen (BUN) 14.3-21.4 mg/dl Calcium 5.06-7.58 mg/dl Cholesterol 171-256 mg/dl Creatinine 0.82-1.24 mg/dl High density cholesterol 60.2-90.2 mg/dl Potassium (K) 2.09-3.13 mEq/L sodium (NA) 120-180 mEq/L Aspartate aminotransferase (AST) 30.5-45.8 U/L Total protein 5.85-8.77 g/dl triglycerides 190-285 mg/dl chloride 82.4-124 mEq/L laboratory range Alanine aminotransferase (ALT) 21.6-63.6 U/L Uric Acid 1.8-4.9 mg/dl Albumim 2.59-5.9 mg/dl alkaline phosphate 33-79 U/L Direct bili 0.24-0.6 mg/dl total bili 0.72-1.54 mg/dl Blood urea nitrogen (BUN) 10.7-25.1 mg/dl Calcium 3.8-8.8 mg/dl Cholesterol 129-301 mg/dl Creatinine 0.51-1.51 mg/dl High density cholesterol 45.2-105.2 mg/dl Potassium (K) 1.59-3.67 mEq/L sodium (NA) 91- 211 mEq/L Aspartate aminotransferase (AST) 23.3-54.1 U/L Total protein 4.39-10.2 g/dl triglycerides 150-326 mg/dl chloride 60-145.1 mEq/L test Level 2 commercial range Uric Acid 9.94-14.9 mg/dl Albumim 2.26-3.38 md/dl alkaline phosphate 310-465 U //L Direct bili 2.28-3.42 mg/dl total bili 5.84-8.76 mg/dl Blood urea nitrogen (BUN) 59.5-89.3 mg/dl Calcium 9.86-14.8 mg/dl Cholesterol 55.9-83.8 mg/dl Creatinine 5.43-8.15 mg/dl High density cholesterol 23.2-40.4 mg/dl Potassium (K) 4.87-7.31 mEq/L sodium (NA) 92.7-139 mEq/L Aspartate aminotransferase (AST) 208-312 U /L Total protein 3.90-5.84 g/dl triglycerides 106-159 mg/dl chloride 65.9-98.9 mEq/L test Laboratory range Uric Acid 5.9-15.8 mg/dl Albumim 1.7-3.9 mg/dl alkaline phosphate 200-508 U/L Direct bili 1.3-3.61 mg/dl total bili 3.9-9.75 mg/dl Blood urea nitrogen (BUN) 35.6-95.6 mg/dl Calcium 7.0-16.78 mg/dl Cholesterol 47.2-102.8 mg /dl Creatinine 4.0-9.6 mg/dl High density cholesterol 14.6-49 mg/dl Potassium (K) 3.85-8.77 mEq/L sodium (NA) 68-162 mEq/L Aspartate aminotransferase (AST) 173-381 U/L Total protein 2.7-6.6 g/dl triglycerides 56-164 mg/dl chloride 52-118 mEq/L 4. The laboratory director confirmed on November 10, 2022 ar 9:40 a.m. , that the laboratory failed to used the establishes manufacturer's references ranges and expanded over 3 SD the ranges.
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 routine chemistry and syphilis serology quality control records review (year 2021-2022) and laboratory director interview on November 10, 2022 at 11:00 a.m. , it

	was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D5405 -failed to follow the manufacturer's instruction when patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method Refer to D5439 -the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry (electrolytes) tests processed by the Dimension Xpand system Refer to D5439-the laboratory failed to follow the establishes manufacturer's ranges when performed routine chemistry tests.