Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2129969	10/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Villa Ana Aguas Buenas Ii	Calle Dr Rafael Lasa # 48, Aguas Buenas, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review (years 2018,2019 and 2020) and laboratory testing personnel interview on October 6,2020 at 12:20 PM, it was found that the laboratory did not perform the competence of the following personnel: the clinical consultant and the testing personnel. The findings include: 1. The laboratory competence evaluation showed that laboratory personnel competence must be done every year. 2. The personnel records of the clinical consultant showed that the last competence was performed on October 10, 2018. 3. The personnel records of the testing personnel showed that the last competence was performed on October 15, 2018. 4. The testing personnel confirmed on October 6,2020 at 12:20 PM, that not competence records for the years 2019 were available in the laboratory.
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 lack routine chemistry calibration verification records and interview with the testing personnel on October 6, 2020 at 10:07 AM, it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the routine chemistry tests when it processed and reported 10, 395 out of 10, 395 comprehensive metabolic panel (CMP) by the Architect C4000 system from October 6, 2019 to October 6, 2020. The findings include: 1. The laboratory used the Architect C4000 to perform the CMP from October 6, 2019 to October 6, 2020. 2. The laboratory did not perform the calibration verification procedures for the CMP tests by the Architect C4000 system from October 6, 2019 to October 6, 2020. 3. The laboratory testing personnel confirmed on October 6, 2020 at 10:07 AM, that the laboratory did not perform the calibration verification for the routine chemistry tests. She stated that she understood that the laboratory meets the calibration verification standard running three levels of control every day. 4. The laboratory processed and reported 10, 395 out of 10, 395 comprehensive metabolic panel (CMP) by the Architect C4000 system from October 6, 2019 to October 6, 2020.
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 lack routine chemistry calibration verification records and interview with the testing personnel on October 6, 2020 at 10:07 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the routine chemistry tests when the laboratory processed and reported 10, 395 out of 10, 395 CMP by the Architect C4000 system from October 6, 2019 to October 6, 2020. Refer to D 5439.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on personnel records review (years 2018,2019 and 2020) and laboratory testing personnel interview on October 6,2020 at 12:20 PM, it was found that the laboratory director failed to ensure compliance with quality assessment requirements: personnel competence evaluation since October, 2019. Refer to D 5209.