Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0901302	05/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Vivianette	Carr 459 Km 01 Bo Corrales, Aguadilla, 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
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory Quality Assessment (Q.A.) Program and interview with the technical supervisor on May 8, 2018, it was found that the laboratory did not follow the established policy regarding the evaluation of the final test report. The findings include: a. The QA Program was reviewed on May 8, 2018 at 11:45 AM. b. The QA Program established that evaluation to the laboratory final test report must be done every year. c. The laboratory did not evaluate the final test report since year 2016. d. The laboratory technical supervisor stated on May 8, 2018 that the evaluations were not performed since year 2016.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on testing personnel records review and technical supervisor interview on May 8, 2018, it was found that the laboratory director did not make sure that the testing

	personnel # 3292, had the necessary training before beginning to perform patient tests. The findings include: a. The testing personnel # 3292 was hired and performed patient testing since January 2018. b. The laboratory did not have any document related to testing personnel training. c. The laboratory technical supervisor stated on May 8, 2018 at 9:30 AM that the laboratory did not document the testing personnel training prior to perform patient tests.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of competence records and interview with the technical supervisor on May 8, 2018 , it was determined that the laboratory director did not establish procedures for the competence evaluation of the laboratory technical supervisor. The findings include: a. The laboratory director designated as technical supervisor (TS) the medical technologist # 3039. b. The personnel competence since year 2016 files were reviewed on May 8, 2018 at 9:00 AM, however no competence were found for the TS # 3039. c. The TS # 3039 stated that the laboratory director did not established competence procedures for the technical supervisor position.