Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0955222	05/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Van Scoy	Carr Pr 167, Ramal 829, Casa 1 Barrio Buena Vista, 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
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) records (years 2017 and 2018) and interview with the laboratory director on May 3, 2018, it was found that the laboratory did not have written procedures to monitor the following: Comparison of test results. The findings include: a. The QA program was reviewed on May 3, 2018 at 12:30 PM. The QA program from years 2017 and 2018 did not include any written instructions in order to evaluate any patient test result inconsistent with the age, sex, diagnostic and others. b. The laboratory director stated that the testing personnel paid attention to the comparison of test results, however no written instructions nor documentation of any finding was performed.
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 Quality Assessment (QA) records (years 2017 and 2018) and

	interview with the laboratory director on May 3, 2018, it was found that the laboratory did not evaluate the following postanalytic activity: Test Report. The findings include: a. The QA program was reviewed on May 3, 2018 at 12:30 PM. b. The QA program from year 2017 did not include evaluations to the laboratory final test reports c . The laboratory did not schedule any evaluation for year 2018. d. The laboratory director stated that they discontinued the final test report evaluation. .
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review and laboratory director interview on May 3, 2018 at 12:30 PM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: a. Quality Assessment records from year 2017 and 2018 showed that the laboratory did not evaluate the following : comparison of test report not final test reports. Refer to D5791 and D5891.