Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0676705	02/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Rincon's Psc	Calle Munoz Rivera #53 Oeste, Rincon, 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
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on virology quality control records (2017-2018) and laboratory general supervisor interview on February 15, 2018 at 11:45 A.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for virology tests (Influenza A & B) . The finding includes: 1. The laboratory did not include a negative nor a positive control material when patients specimens were processed and reported for Influenza A/B by the OSOM method. Refer to D5449.
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 virology quality control records review (years 2017 to 2018) , manufacturer's instructions and interview with the laboratory general supervisor on February 15, 2018 at 11:30 AM, it was determined that the laboratory did not include a negative nor a positive control material when patients specimens were processed and

	reported for Influenza A/B by the OSOM method. The findings include : a. The laboratory performed the Influenza A/B tests by the OSOM since January 17, 2018. b. Review of the manufacturer' insert showed that the test was classified as moderate complexity. c. The virology (Influenza A/B) quality control records were reviewed from January 17, 2018 to February 9, 2018. d. The virology (Influenza A/B) quality control records did not include any external control material since January 17, 2018. e. The laboratory general supervisor stated on February 15, 2018 that the laboratory included external controls only when a new box of reagents was received. f. The laboratory general supervisor stated that 27 Influenza A/B tests were processed and reported since January 17, 2018.
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 quality assessment (QA) records review and technical supervisor interview on February 15, 2018 at 11:45 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The finding includes: 1. The laboratory did not evaluate aspects regarding the analytic system in the following area: virology. Refer to D 5449.
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 Influenza A& B quality control reviews and interview with the general supervisor on February 15, 2018 at 11:30 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system for the subspecialty of Virology test. The finding includes: 1. The laboratory director did not comply with the requirement for analytical systems (virology test) and quality assessment requirements. Refer to D6020 and D6021.
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 virology quality control records review and laboratory general supervisor interview on February 15, 2018 at 11:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory did not include a negative nor a positive control material when patients specimens were processed and reported for Influenza A/B by the OSOM method. Refer to D5449.
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 Quality Assessment (QA) records review in 2016-2018 and laboratory general supervisor interview on February 15, 2018 at 11:45 AM, it was determined that laboratory director failed to ensure compliance with quality assessment requirements. Refer to D5791.
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 virology quality control records review and laboratory general supervisor interview on February 15, 2018 at 11:45 AM, it was determined that the testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel did not include a negative nor a positive control material when patients specimens were processed and reported for Influenza A/B by the OSOM method. Refer to D5449.