Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0697893	07/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Borinquen-Escorial	Local 17 Y 18, Escorial Shopping Village, Carolina, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on OraSure Quick Flu Influenza A & B results reports records review and interview with the general supervisor on July 31, 2018 at 11:00 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 3 out of 3 patients specimens were tested and reported for Influenza A & B results from July 20 2018 to July 25, 2018. The findings include: 1. The OraSure Quick Flu Influenza A & B manufacture instructed the laboratory that the negative test results are presumptive and it is recommended these results be confirmed by viral culture; negative results do not preclude influenza virus infection and should not be used as sole basis for treatment or other management decision. 2. On July 31, 2018 at 11:00 AM, the Influenza A & B results reports records showed that 3 out of 3 patients specimens tested with the OraSure Quick Flu Influenza A & B reagent kit were reported without the manufacturer required report information from July 20 2018 to July 25, 2018: patients # 8376503, #8383194 and #8383418. Those tests reports were reported as negative. 3. The general supervisor confirmed on July 31, 2018 at 11:00 AM, that those reports did not include the manufacturer required information for tests report.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of

	the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, written procedures manual review, laboratory personnel who perform the patient sample collection and general supervisor interview on July 31, 2018 at 12:40 PM, it was determined that the laboratory failed to follow written polices for the specimen collection of prothrombin time (PT) and partial trombin time (PTT) tests. The findings include: 1. The laboratory collected (in blue top tube) and referral patients specimens for the PT and PTT tests since July 31, 2016. 2. The sample collection procedures manual instructed the laboratory to ensure that the sample collection supplies must not be used when they have exceed their expiration date. 3. On July 31, 2018 at 12:40 PM, it was observed in the laboratory sample collection station #1, 8 out of 8 blue top tubes (lot 7256762) that had exceeded their expiration date (on June 30, 2018). Also, the laboratory had in storage an opened box of the same blue top tubes lot. This box did not include the date of opened and showed that the laboratory used 15 blue top tubes. 4. The general supervisor and laboratory personnel who perform the patient sample collection confirmed on July 31, 2018 at 12:40 PM, that those blue top tubes have exceeded their expiration date and confirmed that the laboratory did not document the date when it opened this box. The laboratory personnel who perform the patient sample collection stated that the laboratory can not ensure that the laboratory used the 15 blue top tubes with exceeded expiration date for the collection of PT and PTT patients samples. 5. The laboratory collected 21 patients specimens for PT and PTT tests from July 2, 2018 to July 30, 2018.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on DXH600 system preventive maintenance records review and general supervisor interview on July 31, 2018 at 9:20 AM, it was determined that the laboratory failed to follow manufacturer's instruction for preventive maintenance when 2100 complete blood cell count (CBC) were processed in April 2018 and June 2018. The findings include: 1. The DXH600 system preventive maintenance records showed that the laboratory did not performed the monthly preventive maintenance of the system in April 2018 and June 2018. 2. The general supervisor confirmed that the preventive maintenance records did not include the required preventive maintenance. She stated that the laboratory performed the preventive maintenance but not recorded. 3. The laboratory processed and reported 303 patients CBC specimens in April 2018 and 1,797 patients CBC in June 2018.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Polymedco manufacture's instructions, direct observation and interview with the general supervisor on July 31, 2018 at 9:35 AM, it was determined that the laboratory failed follow the manufacturers instructions for storage of the Sed-chek control materials from July 20, 2018 to July 31, 2018. The findings include: 1. The Polymedco manufacturer instructed the planetary to storage avoid prolonged exposure to light the open vials of the Sed-chek control materials. 2. On July 31, 2018 at 9:35 AM, it was observed that the laboratory maintained the Sed-chek control materials over the counter exposure to light (lot 11503171A and lot 11503171N). Those lots of control materials were opened on July 20, 2018. 3. The general supervisor confirmed that the laboratory maintained the Sed-chek control material over the counter from July 20, 2018 to July 31, 2018. She stated that the laboratory did not avoid prolonged exposure to light of the opened control material vials. 4. The laboratory processed and reported 10 out 10 patients blood specimens for sedimentation rate procedures form July 20, 2018 to July 31, 2018.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 DXH600 system preventive maintenance records review, Polymedco manufacture's instructions, direct observation and general supervisor interview on July 31, 2018 at 9:35 , it was determined that the laboratory director failed to ensure that the laboratory comply with the analytic system requirements. Refer to D 5429 (The laboratory did not performed the monthly preventive maintenance of the DXH600 system). Refer to D 5479 (The laboratory failed follow the manufacturers instructions for storage of the Sed-chek control materials).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on DXH600 system preventive maintenance records review, Polymedco manufacture's instructions, direct observation and general supervisor interview on

	July 31, 2018 at 9:35 , it was determined that the technical supervisor failed to ensure that the laboratory comply with the analytic system requirements. Refer to D 5429 (The laboratory did not performed the monthly preventive maintenance of the DXH600 system). Refer to D 5479 (The laboratory failed follow the manufacturers instructions for storage of the Sed-chek control materials).
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on DXH600 system preventive maintenance records review, Polymedco manufacture's instructions, direct observation and general supervisor interview on July 31, 2018 at 9:35 , it was determined that the general supervisor failed to perform the day-to-day supervision to ensure that the laboratory comply with the analytic system requirements. Refer to D 5429 (The laboratory did not performed the monthly preventive maintenance of the DXH600 system). Refer to D 5479 (The laboratory failed follow the manufacturers instructions for storage of the Sed-chek control materials).