Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0697545	09/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Ciudad Universitaria	Calle Aa N-16 Ciudad Universitaria, Trujillo Alto, 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 OSOM Ultra Flu A&B manufacturer's instructions, Influenza A&B tests reports records review and laboratory director interview on September 18, 2019 at 10: 35 AM, it was determined that the laboratory failed to follow manufacturer's instruction for report information when 260 out of 260 patients specimens were reported for Influenza A&B tests by OSOM Ultra Flu A&B from March 28, 2018 to September 17, 2019. The findings include: 1 The laboratory uses the OSOM Ultra Flu A&B to detect the Influenza A&B antigen as Waived complexity. 2. OSOM Ultra Flu A&B manufacturer's instructions for the intended uses establish that the negative test results are presumptive it is recommended this results be confirmed by viral culture and establish limitations for the negative test result (included in the insert). 3. On September 18, 2019 at 10:35 AM, the Influenza A&B tests reports records showed that the laboratory did not include the manufacturer required information. The laboratory reported the negative Influenza A or B results as final results. 4. The laboratory director confirmed on September 18, 2019 at 10:35 AM, that the Influenza A&B tests reports did not include the required information. 5. The laboratory reported 260 out of 260 patients specimens for Influenza A&B tests by OSOM Ultra Flu A&B from March 28, 2018 to September 17, 2019.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)

	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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on American Association of Bioanalysts Proficiency Testing Program (AABPTP) record (years 2017 to 2019) , bacteriology testing records (years 2018 and 2019) review and laboratory director interview on September 18, 2019 at 10:15 AM, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for urine no growth cultures and urine colony count tests results (Non-waived method) when it processed 156 out of 156 patients urine culture specimens from September 10, 2018 to December 18, 2018. The findings includes: 1. On September 18, 2019 at 10:15 AM, the AABPTP record showed that the laboratory did not enrolled in the proficiency testing program for urine no growth cultures and urine colony count tests results during the year 2018. 2. The bacteriology testing records showed that the laboratory processed and reported 156 patients urine culture specimens from September 10, 2018 to December 18, 2018. 3. The laboratory director confirmed on September 18, 2019 at 10:15 AM, that the laboratory did not enrolled in a proficiency testing program for urine no growth cultures and urine colony count tests results from September 10, 2018 to December 18, 2018 and processed and reported 156 patients urine culture specimens during this periods.