Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0933356	(X3) Date Survey Completed 01/24/2018
Name of Provider or Supplier Laboratorio Clinico Aquarium	**Street Address, City, State** Centro Comercial Plaza Aquarium, Local 21, Toa Alta, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of Proficiency testing record , bacteriology patient records review and general supervisor interview on January 24, 2018 at 9:10 AM, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for the following bacteriology tests results : urine no growth cultures and urine colony count tests (Non-waived method) when 5 out of 5 patients urine cultures were processed and reported from January 20, 2018 to January 22, 2018. The findings include: 1. The laboratory did not have records of Proficiency testing results for the following bacteriology tests results : urine no growth cultures and urine colony count tests (Non-waived method) since January 20, 2018. 2. The general supervisor confirmed on January 24, 2018 at 9:15 AM, that the laboratory did not enroll nor participate in an HHS approved Proficiency Testing Program for those tests since January 20, 2018. She stated that the laboratory establishes a comparison protocol to verify twice a year those tests. 3. The laboratory processed and reported 5 out of 5 patients urine cultures patients specimens for urine no growth cultures results and urine colony count tests from January 20, 2018 to January 22, 2018: patient specimen # 1173525 and patient specimen #1173492 on January 20, 2018 and patient specimen

	# 1193002 , patient specimen # 1193001 and patient specimen # 1193024 on January 22, 2018.
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 lack of Proficiency testing record , bacteriology patient records review and general supervisor interview on January 24, 2018 at 9:10 AM, it was determined that the laboratory director failed to ensure that the it is enrolled in an HHS approved proficiency testing program for the following bacteriology tests results : urine no growth cultures and urine colony count tests (Non-waived method) from January 20, 2018 to January 22, 2018. The finding includes: 1. The laboratory director did not comply with the requirement of Proficiency testing for the following bacteriology tests results : urine no growth cultures and urine colony count tests (Non-waived method) from January 20, 2018 to January 22, 2018. Refer to D 6015.
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 lack of Proficiency testing record , bacteriology patient records review and general supervisor interview on January 24, 2018 at 9:10 AM, it was determined that the laboratory director failed to ensure that the it is enrolled in an HHS approved proficiency testing program for the following bacteriology tests results : urine no growth cultures and urine colony count tests (Non-waived method) from January 20, 2018 to January 22, 2018. Refer to D2000. (The laboratory processed and reported patients specimens for the following bacteriology tests results : urine no growth cultures and urine colony count tests (Non-waived method) from January 20, 2018 to January 22, 2018. However, the laboratory was not enrolled in an HHS-approved proficiency testing program for those tests.