Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1085401	06/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Amelia Clinical Lab	Ave Ponce De Leon Num 59 Esquina Munoz, Guaynabo, 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 American Association of Bioanalyst Proficiency Testing Program (AABPTP) records (since year 2017) and technical supervisor interview on June 19, 2019 at 10:35 AM, it was determined that the laboratory failed to enroll in an HHS approved Proficiency Testing Program for Complete Cell Count (CBC) tests and white blood cell (WBC) three parameters differential examination since January 2019. The findings include: 1. The laboratory performed the CBC tests and WBC three parameters differential examination by the Sysmex KX21N system and participated in the AABPTP since January 2017. 2. On June 19, 2019 at 10:35 AM, the AABPTP records showed that the laboratory did not participate in the proficiency testing program for the CBC tests and WBC three parameters differential examination for this year 2019. 3. The laboratory did not have records of the AABPTP enrollment for the year 2019. 4. The technical supervisor confirmed on June 19, 2019 at 10:35 AM, that the laboratory did not perform proficiency testing samples for CBC and WBC differential during this year. He stated that the laboratory performed the enrollment in AABPTP for the year 2019 but, the enrollment paid was accredited to another laboratory.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on urinalysis procedure manual, annual calibration records for the Clay Adams centrifuge and interview with the technical supervisor on June 19, 2019 at 10:55 AM, it was determined that the laboratory failed to follow written procedures for the step-by-step performance of the urine microscopic examination when 1,093 out of 1,093 urine microscopic examinations were performed and reported from June 15, 2018 to June 19, 2019. The findings include: 1. The procedures manual instructed the laboratory to centrifuge the urine specimens at 1,500 rpm for 5 minutes for the urine microscopic examination. 2. On June 19, 2019 at 10:55 AM, the records showed that the centrifuge used by the laboratory to processed the urine specimens was calibrated at 3,360 rpm on June 15, 2018. 3. The technical supervisor confirmed on June 19, 2019 at 10:55 AM, that the the laboratory to processed the urine specimens in the Clay Adams centrifuge at 3,360 rpm since June 15, 2018. 4. The laboratory performed and reported 1,093 out of 1,093 urine urine microscopic examinations from June 15, 2018 to June 19, 2019.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on American Association of Bioanalyst Proficiency Testing Program (AABPTP) records (since year 2017), urinalysis procedure manual, annual calibration records for the Clay Adams centrifuge and technical supervisor interview on June 19, 2019 at 10:35 AM, it was determined that the laboratory director failed to fulfill his

	responsibilities and duties to ensure compliance with the laboratory Proficiency Testing Program and the analytical system requirements. Refer to D 6088. Refer to D 6093.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must 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 Bioanalyst Proficiency Testing Program (AABPTP) records (since year 2017) and technical supervisor interview on June 19, 2019 at 10:35 AM, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved Proficiency Testing Program for Complete Cell Count (CBC) tests and white blood cell (WBC) three parameters differential examination since January 2019. Refer to D 2000.
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 urinalysis procedure manual, annual calibration records for the Clay Adams centrifuge and interview with the technical supervisor on June 19, 2019 at 10:55 AM, it was determined that the laboratory director failed to ensure that the laboratory follow written procedures for the step-by-step performance of the urine microscopic examination when 1,093 out of 1,093 urine microscopic examinations were performed and reported from June 15, 2018 to June 19, 2019. Refer to D 5403.
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 urinalysis procedure manual, annual calibration records for the Clay Adams centrifuge and interview with the technical supervisor on June 19, 2019 at 10:55 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems (urine microscopic examinations). Refer to D 5403 (The laboratory failed to follow written procedures for the step-by-step performance of the urine microscopic examination when 1,093 out of 1,093 urine microscopic examinations were performed and reported from June 15, 2018 to June 19, 2019).