

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658285	(X3) Date Survey Completed 08/23/2019
Name of Provider or Supplier Lab Clinico Amyr	Street Address, City, State 524 Juan J Jimenez St, Hato Rey, 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, urinalysis procedure manual, centrifuges annual calibration records(years 2018 and 2019) review, testing personnel and laboratory director interview on August 23, 2019 at 10:00 AM, it was determined that the laboratory failed to follow written procedures for the step-by-step performance when 382 out of 382 patients specimens for urine microscopic examination were performed and reported from April 26, 2019 to August 23, 2019. The findings include: 1. On August 23, 2019 at 10:00 AM, it is observed that the laboratory used the Compact centrifuge to centrifuge the urine specimens to perform the urine microscopic</p>

examination. 2. The procedures manual instructed the laboratory to centrifuge the urine specimens from 1,500 to 2,000 rpm for 5 minutes for the performance of the urine microscopic examination. 3. The centrifuges annual calibration records showed that the Compact centrifuge was calibrated at 3,375 rpm on April 26, 2019. 4. The laboratory director and the testing personnel confirmed on August 23, 2019 at 10:00 AM, that the laboratory centrifuges the urine specimens for the microscopic examination by this centrifuge at 3,375 rpm from April 26, 2019 to August 23, 2019. 5. The laboratory processed and reported 382 out of 382 urine patients specimens for urine microscopic examination from April 26, 2019 to August 23, 2019. .

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 direct observation, urinalysis procedure manual, centrifuges annual calibration records(years 2018 and 2019) review, testing personnel and laboratory director interview on August 23, 2019 at 10:00 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for urine microscopic examination from April 26, 2019 to August 23, 2019. Refer to D 5405 (The laboratory failed to follow written procedures for the step-by-step performance when 382 out of 382 patients specimens for urine microscopic examination were performed and reported from April 26, 2019 to August 23, 2019).

D6177

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1495(b)(3)

Each individual performing high 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 direct observation, urinalysis procedure manual, centrifuges annual calibration records(years 2018 and 2019) review, testing personnel and laboratory director interview on August 23, 2019 at 10:00 AM, it was determined that the testing personnel failed to follow quality control requirement for urine microscopic examination from April 26, 2019 to August 23, 2019. Refer to D 5405 (The laboratory failed to follow written procedures for the step-by-step performance when 382 out of 382 patients specimens for urine microscopic examination were performed and reported from April 26, 2019 to August 23, 2019).