Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658293	07/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Almi	1332 San Alfonso Ave Urb Altamesa, Rio Piedras, 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	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, centrifuge's calibration records (year 2018) review and interview with the laboratory director on July 19, 2019 at 12:05 PM, it was determined that the laboratory failed to follow written procedures for the step-by-step performance of the urine microscopic examination. The findings include: 1. The procedures manual instructed the laboratory to centrifuge the urine specimens at 1,800 rpm for 5 minutes for the urine microscopic examination. 2. On July 19, 2019 at 12:05 PM, the centrifuge's calibration records showed that the urinalysis centrifuge was

	calibrated at 3,350 rpm on August 21, 2018. 3. The laboratory director confirmed on July 19, 2019 at 12:05 PM, that the the urinalysis centrifuge was calibrated at 3,350 rpm on August 21, 2018. 4. The laboratory processed and reported 1,811 urine microscopic examinations during the year 2918.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on laboratory complete blood cell (CBC) tests reports records (years 2018, 2019), laboratory annual tests volume records (year 2018) review and general supervisor interview on July 19, 2019 at 1:15 PM, it was determined that the laboratory failed to indicate the address of the laboratory in the CBC the tests results reported by the Mindray BC5394 system since January 2018. The findings include: 1. The laboratory processed and reported the CBC patients specimens by the Mindray BC5394 system since January 2018. 2. On July 19, 2019 at 1:15 PM, the CBC tests reports records showed that the laboratory did not indicate the address of the laboratory in the CBC the tests results reported by the Mindray BC5394 system since January 2018. 3. The general supervisor confirmed on July 19, 2019 at 1:15 PM, that the CBC tests reports did not include the laboratory address. 4. The laboratory annual tests volume records showed that the laboratory reported 11,351 CBC tests results during the year 2018.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assessment QA records (years 2017, 2018 and 2019) review and general supervisor interview on July 19, 2019 at 1:15 PM, it was determined that the laboratory failed to follow written procedures to assess the post analytic system: ensure that all required information were included in the CBC test report since January 2018. The finding includes: 1. The QA records showed that the laboratory evaluated the post analytic system requirements since year 2017. However, the laboratory failed to ensure that the CBC tests reports include the address of the laboratory. Refer to D 5805.
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, centrifuge's calibration records (year 2018) review and interview with the laboratory director on July 19, 2019 at 12:05 PM, it was determined that the laboratory director failed to ensure compliance with the requirements for the urine microscopic examination. Refer to D 5403 (The laboratory failed to follow written procedures for the step-by-step performance of the urine microscopic examination).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 quality assessment QA records (years 2017, 2018 and 2019) review and general supervisor interview on July 19, 2019 at 1:15 PM, it was determined that laboratory director failed to ensure compliance with QA requirements for the post analytic system. Refer to D 5891.
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: D 5403 Based on urinalysis procedure manual, centrifuge's calibration records (year 2018) review and interview with the laboratory director on July 19, 2019 at 12:05 PM, it was determined that the laboratory failed to follow written procedures for the step-by-step performance of the urine microscopic examination.