Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0950922	01/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Bayamon Oeste	Bayamon Oeste Shopp Center Carr 2, Bayamon, 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 hematology procedures manual, Cell Dyn 3200 system calibration records (year 2018 and 2019) review and laboratory director interview at 10:10 AM on January 16, 2020, it was determined that the laboratory failed to perform every six months the calibration procedures for the complete blood count (CBC) tests processed by the Cell Dyn 3200 system when the laboratory reported 10, 981 out of 10, 981 patient's CBC tests during the year 2018 and 10,039 out of 10,039 patient's CBC tests during the year 2019. The findings include: 1. The laboratory uses a Cell Dyn 3200 system to process and report the patient's CBC specimens. 2. The hematology

	procedures manual instructed the laboratory to perform every six month the calibration of the Cell Dyn 3200 system. 3. At 10:10 AM on January 16, 2020, the Cell Dyn 3200 system calibration records showed that the laboratory did not perform every six months the calibration of the Cell Dyn 3200 system during the years 2018 and 2019. The laboratory calibrated the Cell Dyn 3200 system on May 1, 2018, December 7, 2018 and on July 1, 2019. 4. The laboratory director confirmed at 10:10 AM on January 16, 2020, that the laboratory did not perform at least 6 months the calibration procedures for Cell Dyn 3200 system. 5. The laboratory processed and reported the following CBC tests: 10, 981 out of 10, 981 patient's CBC tests during the year 2018 and 10,039 out of 10,039 patient's CBC tests during the year 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 hematology procedures manual, Cell Dyn 3200 system calibration records (year 2018 and 2019) review and laboratory director interview at 10:10 AM on January 16, 2020, it was determined that the laboratory director failed to comply with the analytic requirements for the CBC tests. Refer to D 5403. (The laboratory did not perform every six months the calibration procedures for the CBC tests processed by the Cell Dyn 3200 system).