Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2154981	04/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Barrazas, Inc	Avenida Roberto Sanchez Vilella A2, Carolina, 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 review, observation and technical superviosr interview on April 11, 2019 at 9:30 AM, it was determined that the laboratory failed to include the Wright staining protocol for blood smear from November 12, 2018 to April 10, 2019. The findings include: 1. On April 11, 2019 at 9: 30 AM, it is observed that the laboratory had in use the Camco Quick stain for the Wright staining of blood smear. 2. The Hematology procedures manual did not

	include the Wright staining protocol for blood smear from November 12, 2018 to April 10, 2019. 3. The technical superviosr confirmed on April 11, 2019 at 9:30 AM, that the Hematology procedures manual did not include the required protocol.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation records of the Sysmex XS 1000 system and technical supervisor interview on April 11, 2019 at 9:50 AM, it was determined that the laboratory failed to verify that the manufacturer's complete blood count (CBC) reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 478 out of 478 patient CBC from November 12, 2018 to April 10, 2019. The findings include: 1. On April 11, 2019 at 9:50 AM, the Sysmex XS 1000 system validation records showed that the laboratory laboratory performed the validation procedures in September 2018. however, the laboratory did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The technical supervisor confirmed on April 11, 2019 at 9:50 AM, that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting CBC results. 3. The laboratory processed and reported 478 out of 478 patient CBC results from November 12, 2018 to April 10, 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, validation records of the Sysmex XS 1000 system review, observation and technical superviosr interview on April 11, 2019 at 9: 50 AM, it was determined that laboratory director failed to comply with the requirements for analytic systems from November 12, 2018 to April 10, 2019). Refer to D 5403 (The laboratory failed to include the Wright staining protocol for blood smear from November 12, 2018 to April 10, 2019). Refer to D 5421 (The laboratory failed to verify that the manufacturer's complete blood count (CBC) reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 478 out of 478 patient CBC from November 12, 2018 to April 10, 2019).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel file review and laboratory director interview on April 11, 2019 at 12:10 PM, it was determined that the laboratory director failed to ensure that the testing personnel, prior to testing patients' specimens have the appropriate training from November 12, 2018 to April 10, 2019). The findings include: 1. The laboratory processed and reported patients specimens for the following tests and its open since November 12, 2018: CBC, urinalysis, glucose, syphilis serology and qualitative tests. 2. On April 11, 2019 at 12:10 PM, the personnel file of the testing personnel did not include the following test training: urinalysis, glucose, syphilis serology and qualitative tests. 3. The laboratory director stated on April 11, 2019 at 12:10 PM , that the testing personnel have appropriate training for the laboratory tests but were not documented.
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 Hematology procedures manual, validation records of the Sysmex XS 1000 system review, observation and technical superviosr interview on April 11, 2019 at 9: 50 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems. Refer to D 5403 (The laboratory failed to include the Wright staining protocol for blood smear from November 12, 2018 to April 10, 2019). Refer to D 5421 (The laboratory failed to verify that the manufacturer's complete blood count (CBC) reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 478 out of 478 patient CBC from November 12, 2018 to April 10, 2019).