Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0709713	06/20/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Caleb	Ave Borinquen 2100 Box 14511, San Juan, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Stambio Glycohemoglobin (Pre-Fail) manufacturer's instructions, Stat Fax Operator's manual, lack of Stat Fax linearity verification records, lack of calibration verification records for the Stambio Glycohemoglobin tests, procedure manual, glycohemoglobin patients's list, glycohemoglobin testing records and interview with the laboratory director on June 20, 2019 at 10:25 AM, it was determined that the laboratory failed to meet the analytic system requirements for glycohemoglobin tests. Refer to D5405(1) (The laboratory failed to follow manufacturer's instructions when 1,012 out of 1,012 patient's specimens were tested and reported for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018). Refer to D5429 (The laboratory failed to follow manufacturer's instructions for the preventive maintenance of the Stat Fax spectrophotometer when 1,012 out of 1,012 patient's specimens were tested and reported for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018). Refer to D5439 (The laboratory director on June 20, 2019 at 10:25 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the glycohemoglobin tests from June 27, 2017 to December 31, 2018).
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must

	meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Coulter Act 5 diff manufacturer's instructions, Complete Blood Count (CBC) quality control records review (years 2018-2019) and technical supervisor interview on June 20, 2019 at 2:00 PM, it was determined that the laboratory failed to meet the analytic system requirements for Hematology specialty (CBC tests). Refer to D 5405 (1). (The laboratory failed to follow manufacturer's instructions for quality control procedures when 10 out of 10 patient specimens were tested for CBC from April 13, 2019 to May 19, 2019 by the Coulter Act 5 diff system).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: 1. Based on Stambio Glycohemoglobin (Pre-Fil) manufacturer's instructions, procedure manual, glycohemoglobin patients's list, glycohemoglobin testing records and interview with the laboratory director on June 20, 2019 at 10:25 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 1,012 out of 1,012 patient's specimens were tested and reported for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018. The findings include: a. The laboratory tested and reported the glycohemoglobin patient's specimens by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018. b. The Stambio Glycohemoglobin (Pre-Fil) manufacturer instructed the laboratory to include two control materials (normal and abnormal) with each series of assays. c. The procedures manual establish to use normal and abnormal control material. However, the procedures manual did not include the name of the control materials, the manufacturer's of the control materials nor instructions for the storage and stability of the control materials. d. On June 20, 2019 at 10:25 AM, the glycohemoglobin patients's list showed that the laboratory reported the following patients specimens: 25 patients specimens on September 15, 2017, 12 patients specimens on July 18, 2017 and 7 patients specimens on July 27, 2017. However, no normal nor abnormal control values were recorded for those days. e. The glycohemoglobin testing records showed the control values for the normal and the abnormal control materials for the assays performed from June 27, 2017 to December 31, 2018. However, the laboratory did not have available the control materials package inserts for those years. f. The manufacture procedures establish to read absorbance of the standard, patient's specimens and controls vs water at 415 nm within 60 minutes, to calculate the test value. g. The glycohemoglobin testing records showed that the laboratory perform the following procedures to calculate the test value: read 4 times the standards and made a media; read 4 to 6 times the patient's specimens and made a media, then calculated the test value with the standard's media and the patients's specimens media. The testing records did not include the time, the laboratory did not assure that the absorbance reading were performed within 60 minutes. This laboratory practice were not included in the laboratory procedures

	manual. h. The laboratory director confirmed on June 20, 2019 at 10:25 AM, that the control materials package inserts were not available in the laboratory and stated that he performed this test and includes the normal and abnormal control materials with each series of assays. i. The laboratory tested and reported 1,012 out of 1,012 patient's specimens for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) from June 27, 2017 to December 31, 2018. 2. Based on Coulter Act 5 diff manufacturer's instructions, Complete Blood Count (CBC) quality control records review (years 2018-2019) and technical supervisor interview on June 20, 2019 at 2:00 PM, it was determined that the laboratory failed to follow manufacturer's instructions for quality control procedures when 10 out of 10 patient's specimens were tested for CBC from April 13, 2019 to May 19, 2019 by the Coulter Act 5 diff system . The findings include: a. The laboratory performed the CBC tests by the Coulter Act 5 diff system since January 2017. b. The Act 5 diff system manufacturer establishes that three levels of control material (low, normal and high) must be included each day of CBC testing. c. On June 20, 2019 at 2:00 PM, the CBC quality control records showed that the laboratory did not include the three levels of control materials when the laboratory tested 10 out of 10 patient specimens for CBC by the Coulter Act 5 diff system from April 13, 2019 to May 19, 2019: on April 15, 2019 (patient's specimens #7162, #7163, #7156, #7157 and # 7158); on May 16, 2019 ((patient's specimens #7605 and #7606) and on May 17, 2019(patient's specimen #7640). Also, the laboratory did not include the normal level control material on April 13, 2019 when patient's specimens were tested (#7151 and # 7158). d. The technical supervisor stated on June 20, 2019 at 2:00 PM, that the quality control data of those days were lost.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on Stat Fax Operator's manual, lack of Stat Fax linearity verification records, glycohemoglobin testing records and interview with the laboratory director on June 20, 2019 at 10:25 AM, it was determined that the laboratory failed to follow manufacturer's instructions for the preventive maintenance of the Stat Fax spectrophotometer when 1,012 out of 1,012 patient's specimens were tested and reported for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018. The findings include: 1. The Stat Fax Operator's manual establish that a periodic verification of the instrument linearity is advisable and it can be done using Redi-Check calibration check set. 2. The laboratory did not perform the periodic verification of the Stat Fax linearity since June, 2017. 3. The laboratory director confirmed on June 20, 2019 at 10:25 AM, that the laboratory did not verify the Stat Fax linearity since June, 2017. 3. The laboratory used the Stat Fax spectrophotometer to read the absorbance of the 1,012 out of 1,012 patient's specimens of glycohemoglobin tests that were processed by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the

	laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration verification records for the Stambio Glycohemoglobin (Pre-Fil) tests, procedure manual, glycohemoglobin testing records and interview with the laboratory director on June 20, 2019 at 10:25 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the glycohemoglobin tests from June 27, 2017 to December 31, 2018. The findings include: 1. The laboratory did not perform the calibration verification did not perform at least every 6 months the calibration verification procedures for the glycohemoglobin tests from June 27, 2017 to December 31, 2018. 2. The laboratory director confirmed on June 20, 2019 at 10:25 AM, stated that the laboratory did not perform at least every 6 months the calibration verification procedures for the glycohemoglobin tests from June 27, 2017 to December 31, 2018. 3. The laboratory processed and reported 1,012 out of 1,012 patient's specimens for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) from June 27, 2017 to December 31, 2018.
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 Stambio Glycohemoglobin (Pre-Fail) manufacturer's instructions, Coulter Act 5 diff manufacturer's instructions, Stat Fax Operator's manual, lack of Stat Fax linearity verification records, lack of calibration verification records for the Stambio Glycohemoglobin tests, procedure manual, glycohemoglobin patients's list, glycohemoglobin testing records and interview with the laboratory director on June 20, 2019 at 10:25 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytical system requirements. Refer to D 6093 (The laboratory director failed to ensure compliance with the requirements for the glycohemoglobin and the CBC tests).

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 Stambio Glycohemoglobin (Pre-Fail) manufacturer's instructions, Coulter Act 5 diff manufacturer's instructions, Stat Fax Operator's manual, lack of Stat Fax linearity verification records, lack of calibration verification records for the Stambio Glycohemoglobin tests, procedure manual, glycohemoglobin patients's list, glycohemoglobin testing records and interview with the laboratory director on June 20, 2019 at 10:25 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for the glycohemoglobin tests from June 27, 2017 to December 31, 2018. Refer to D 5405(1) (The laboratory failed to follow manufacturer's instructions when 1,012 out of 1,012 patient's specimens were tested and reported for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018). Refer to D 5405(2). (The laboratory failed to follow manufacturer's instructions for quality control procedures when 10 out of 10 patient's specimens were tested for CBC from April 13, 2019 to May 19, 2019 by the Coulter Act 5 diff system). Refer to D 5429 (The laboratory failed to follow manufacturer's instructions for the preventive maintenance of the Stat Fax spectrophotometer when 1,012 out of 1,012 patient's specimens were tested and reported for glycohemoglobin by the Stambio Glycohemoglobin (Pre-Fil) method from June 27, 2017 to December 31, 2018). Refer to D 5439 (The laboratory failed to perform at least every 6 months the calibration verification procedures for the glycohemoglobin tests from June 27, 2017 to December 31, 2018).
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 Coulter Act 5 diff manufacturer's instructions, Complete Blood Count (CBC) quality control records review (years 2018-2019) and technical supervisor interview on June 20, 2019 at 2:00 PM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems (CBC tests). Refer to D 5405(2). (The laboratory failed to follow manufacturer's instructions for quality control procedures when 10 out of 10 patient's specimens were tested for CBC from April 13, 2019 to May 19, 2019 by the Coulter Act 5 diff system).