Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0693515	03/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Camuy	Calle Infanzon # 4, Camuy, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, syphilis serology quality control records review in 2017-2018 and laboratory director interview at 10:45 AM on March 16, 2018, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by Immunostics and Aim RPR method. The findings include: 1. The manufacturer's establishes that the RPR (Rapid plasma reagin) test must be performed at room temperature between 20 C to 30 C . 2. Syphilis serology records were reviewed from January 2017 to March 15, 2018, the records showed that the laboratory room temperature was below 20 C during the following months: August 2017- 9 of 21 days (66 RPR patients) December 2017 -5 of 15 days (15 RPR patient samples) January 2018- 8 of 17 days (16 RPR patient samples) February 2018- 13 of 17 days (72 RPR patient samples) March 2018 - 4 of 9 days (9 RPR patient samples) 3. The laboratory processed and reported 177 RPR patient samples during those months. 4. The laboratory general supervisor confirmed that the laboratory performed RPR (Rapid plasma reagin) tests below the range established by the manufacturer's .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on hematology quality control records review and laboratory general supervisor interview at 11:15 a.m. on March 16, 2018, it was determined that the laboratory used the CBC (complete blood count) controls materials that have exceeded their expiration date. The findings include: 1. The laboratory analyzed and reported CBC (complete blood count) patient's specimens by the Sysmex 800 i system. 2. The laboratory used Sysmex 800i control material lot 6290804, exp. date : 1/5/17 to perform CBC from 1/15/17 to 1/24/17. 3. The laboratory used Sysmex 800i control material lot 635500804, exp. date : 3/12/17 to perform CBC from 3/12/17 to 3/27/17. 4. The laboratory processed and reported 170 patient samples those days for CBC test. 5. The laboratory general supervisor confirmed on March 16, 2018 at 11:15 A.M. that the laboratory used hematology control material that exceed their expiration date.
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 routine chemistry calibration verification records review and laboratory general supervisor interview at 11:45 a.m. on March 16, 2018, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by the Dimension system. The findings include: 1. The laboratory uses a Dimension system for routine chemistry tests. 2. From March 2016 to March 2018, the routine chemistry calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by Dimension system. 3. The laboratory general supervisor confirmed on March 16, 2018 at 11:45 A.M. that the last calibration verification for electrolytes tests was performed on November 2016.

D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review in 2016/2018 and laboratory general supervisor interview on March 16, 2018 at 11:30 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by Immunostics and Aim RPR method. Refer to D5411. 2. The laboratory used the CBC (complete blood count) controls materials that have exceeded their expiration date. Refer to D5417. 3. The laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by the Dimension system. Refer to D5439.
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 , syphilis serology and routine chemistry quality control records review and interview with the laboratory general supervisor on March 16, 2018 at 11: 30 A.M. , it was found that the laboratory director did not fulfill his responsibilities. The findings include: 1. The laboratory failed to perform syphilis serology test as required by manufacturer's instructions by Immunostics and Aim RPR method. Refer to D5411. 2. The laboratory used the CBC (complete blood count) controls materials that have exceeded their expiration date. Refer to D5417. 3. The laboratory failed to perform at least every 6 months the calibration verification procedures for the routine chemistry (Lytes) tests processed by the Dimension system. Refer to D5439.
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 review and laboratory general supervisor interview at 11:45 a.m. on March 16, 2018 , it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.

D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on hematology, syphilis serology and routine chemistry quality control records review (2016-2018) and laboratory general supervisor interview on March 16, 2018 at 11:50 AM, it was determined that the general supervisor failed to follow quality control procedures. The finding includes: 1. The laboratory general supervisor did not evaluate aspects regarding: control procedures. Refer to D5411, D5417 and D5439.