Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1094840	02/26/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Villa Ana	Carr 1, Km 27, Hm 8 Rio Canas,, Caguas, 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, syphillis serology quality control records review (years 2017-2019) and laboratory director interview at 10:30 AM on February 26, 2019, it was determined that the laboratory failed to perform syphillys serology test as required by manufacturer's instructions by Detector RPR method. The findings include: 1. The manufacturer's establishes that the RPR (Rapid Plasma Reagin) test must be performed at room temperature between 23 C to 29 C . 2. From February 2018 to February 25, 2019, showed that the laboratory performed RPR (Rapid Plasma Reagin) patient's samples test during seventeen (17) days. 3. The records showed that a total of eighty six samples patient's were processed and reported with temperatures outside the acceptable range:: Date temp.C # samples 2/10/18 22.0 1 4/7/18 22.0 14 5 /16/18 22.0 2 6/25/18 22.0 2 7/20/18 22.0 3 8/8/18 22.0 27 8/14/18 22.0 2 9/6/18 22.0 13 9/18/18 22.0 6 10/9/18 22.0 1 10/13/18 22.0 2 10/23/18 22.0 5 11/26/18 22.0 1 12/8 /18 22.0 1 1/14/19 22.0 3 1/26/19 22.0 1 2/8/19 22.0 2 4. The laboratory director confirmed that the laboratory performed RPR (Rapid plasma reagin) tests below the range established by the manufacturer's those days.
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 manufacturer's instructions, hematology quality control records review (years 2017-2019) and laboratory director interview on February 26, 2019 at 10:00 AM, it was determined that the laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the ABX Pentra 60 C+ system. The findings include: 1. The laboratory uses a ABX Pentra 60 C+ hematology system for CBC (Complete blood count) patient's tests. 2. The manufacturer's instructions showed that for the ABX Pentra 60 C+ system establish that the laboratory must perform the calibration verification procedures each six months. 3. Review hematology records from March 2017 to February 2019, showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the ABX Pentra 60 C+ hematology system. The laboratoy performed the calibration verification for ABX Pentra 60 C+ system on March 2017 and September 2018, once a year. 4. The laboratory director stated on February 26, 2019, that the laboratory did not perform at least 6 months the calibration verification procedures for ABX Pentra 60 C+ system.
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 manufacturer's instructions, syphillis serology quality control records review (years 2017-2019) and laboratory director interview at 11:00 AM on February 26, 2019, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory failed to perform syphillys serology test as required manufacturer's instructions by Detector RPR method. Refer to D5411. 2. The laboratory failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer

	(each six months) for the hematology tests performed by the ABX Pentra 60 C+ system. Refer to D5439.
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 syphillis serology quality control records review in 2017-2019 and laboratory director interview at 11:00 AM on February 26, 2019, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory supervisor failed to perform syphillys serology test as required by manufacturer's instructions by Detector RPR method. Refer to D5411. 2. The laboratory supervisor failed to perform the calibration verification procedures with at least the frequency recommended by the manufacturer (each six months) for the hematology tests performed by the ABX Pentra 60 C+ system. Refer to D5439.