

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0868566	(X3) Date Survey Completed 04/26/2018
Name of Provider or Supplier Clinica Yaguez	Street Address, City, State Calle Ramon Valdes Cobian Num 117, Mayaguez, 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
D5012	<p>SYPHILIS SEROLOGY CFR(s): 493.1207</p> <p>If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on syphilis serology testing records review (years 2017,2018) and general supervisor interview on April 26, 2018 at 11:40 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology quantitative tests. The finding includes: 1. The laboratory did not include at least once a day, a negative control material and a control material with tittered reactivity when 11 out of 11 patient specimen was tested for syphilis serology quantitative test by rapid plasma reagin (RPR) method from July 21, 2017 to April 10, 2018. Refer to D 5451. Based on syphilis serology testing records review (years 2017,2018) and general supervisor interview on April 26, 2018 at 11:40 AM, it was determined that the laboratory failed to include at least once a day, a negative control material and a control material with tittered reactivity when 11 out of 11 patient specimen was tested for syphilis serology quantitative test by rapid plasma reagin (RPR) method from July 21, 2017 to April 10, 2018. The findings include: 1. On April 26, 2018 at 11:40 AM, the syphilis serology testing records showed that the laboratory did not include at least once a day, the negative control material nor the control material with tittered reactivity when 3 out of 3 patient specimen were tested and reported for quantitative RPR on April 7, 2018 (patient specimen # 335210), April 6, 2018 (patient specimen # 334984), and on March 12, 2018 (patient specimen # 331275). 2 . The syphilis serology testing records showed that the laboratory did not include at least once a day, the negative control material when 8 out of 8 patient specimen were tested and reported for quantitative RPR on July 21, 2017 (patient</p>

specimen # 297608), August 1, 2017 (patient specimen # 299515), December 1, 2017 (patient specimen # 315324), December 12, 2017 (patient specimen # 31965), December 30, 2017 (patient specimen # 319236), February 15, 2018 (patient specimen # 327128), March 15, 2018 (patient specimen # 331689) and on April 10, 2018 (patients specimens # 335614). 2. The general supervisor confirmed on April 26, 2018 at 11:40, that the syphilis serology testing records did not include the require control procedures results recorded those days of testing.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on laboratory temperature, humidity and voltage records review and general supervisor interview on April 26, 2018 at 10:20 AM, it was determined that the laboratory failed to monitor and document the room temperature, room humidity, voltage, the refrigerator and freezer temperature from September 20, 2017 to October 14, 2017. The findings include: 1. On April 26, 2018 at 10:20 AM, the following records showed that the laboratory did not monitor nor document the room temperature, room humidity, voltage, the refrigerator and freezer temperature from September 20, 2017 to October 14, 2017. 2. The general supervisor confirmed on April 26, 2018 at 10:20 AM, that the laboratory did not monitor nor document the room temperature, room humidity, voltage, the refrigerator and freezer temperature from September 20, 2017 to October 14, 2017. 3. The laboratory processed and reported the following patients specimens from September 20, 2017 to October 14, 2017: a. 516 out of 516 complete blood cell count (CBC) b. 298 out of 288 urinalysis c. 1038 out of 1038 comprehensive metabolic panel (CMP)

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 Vitamin B12 tests by the Vitors 5600 system and general supervisor interview on April 26, 2018 at 9:40 AM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of this new test on September 16, 2016 before reporting 1828 out of

1828 1 Vitamin B12 tests results from January 1, 2017 to April 25, 2018. The findings include: 1. On April 26, 2018 at 9:40 AM, the validation records of the Vitamin B12 tests showed that the laboratory laboratory performed the validation procedures on September 16, 2016. However the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting test results. 2. The general supervisor stated on April 26, 2018 at 9:40 AM, that the laboratory did not have records to demonstrate that it verified that the Vitamin B12 manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population before reporting 1828 out of 1828 1 Vitamin B12 tests results from January 1, 2017 to April 25, 2018.

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 written procedures, preventive maintenance records review and interview with the general supervisor on April 26, 2018 at 10:20 AM, it was determined that the laboratory failed to follow written instructions for the preventive maintenance of following laboratory equipments and instruments from September 20, 2017 to October 14, 2017: microscope, centrifuges, multitimer and rotator. The findings include: 1. The written procedures showed that the laboratory require twice a weeks the preventive maintenance of the microscope and the weekly preventive maintenance of the following equipments and instruments: centrifuges, multitimer and rotator. 2. Qn April 26, 2018 at 10:20 AM, the preventive maintenance showed that the laboratory did not perform the preventive maintenance of the microscope, centrifuges, multitimer and rotator from September 20, 2017 to October 14, 2017. 3. The general supervisor confirmed on April 26, 2018 at 10:20 AM, that did not perform the preventive maintenance of the microscope, centrifuges, multitimer and rotator from September 20, 2017 to October 14, 2017. 4. The laboratory processed and reported the following patients specimens from September 20, 2017 to October 14, 2017: a. 516 out of 516 complete blood cell count (CBC) b. 298 out of 288 urinalysis c. 1038 out of 1038 comprehensive metabolic panel (CMP)

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 reviewed and general supervisor interview on April 26, 2018 at 10:10 AM, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the sodium (Na), potassium (K) and chloride (Cl) tests during the year 2017 and for the vitamin D the laboratory failed to perform at least every 6 months the calibration verification procedures test since January 1, 2017; all the tests are processed by the Vitros 5600 system. The findings include: 1. On April 26, 2018 at 10:10 AM, the routine chemistry calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Na, K and Cl tests during the year 2017 by the the Vitros 5600 system. The laboratory processed the calibration verification procedures for the Na, K and Cl tests in February 2017 during the year 2017. 2. The routine chemistry calibration verification records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for vitamin D test since January 1, 2017 by the the Vitros 5600 system. 3. The general supervisor confirmed on April 26, 2018 at 10:10 AM, that the laboratory did not have the requiere calibration verification records for those tests. 4. The laboratory processed 11,243 out of 11,243 electrolytes from August 2017 to April 12, 2018. 5. The laboratory processed 5563 out of 5563 vitamin D tests from January 2017 to April 26, 2018.

D5451

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(iii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on syphilis serology testing records review (years 2017,2018) and general supervisor interview on April 26, 2018 at 11:40 AM, it was determined that the laboratory failed to include at least once a day, a negative control material and a control material with tittered reactivity when 11 out of 11 patient specimen was tested for syphilis serology quantitative test by rapid plasma reagin (RPR) method from July 21, 2017 to April 10, 2018. The findings include: 1. On April 26, 2018 at 11:40 AM, the syphilis serology testing records showed that the laboratory did not include at least once a day, the negative control material nor the control material with tittered reactivity when 3 out of 3 patient specimen were tested and reported for quantitative RPR on April 7, 2018 (patient specimen # 335210), April 6, 2018 (patient specimen # 334984), and on March 12, 2018 (patient specimen # 331275). 2 . The syphilis

serology testing records showed that the laboratory did not include at least once a day, the negative control material when 8 out of 8 patient specimen were tested and reported for quantitative RPR on July 21, 2017 (patient specimen # 297608), August 1, 2017 (patient specimen # 299515), December 1, 2017 (patient specimen # 315324), December 12, 2017 (patient specimen # 31965), December 30, 2017 (patient specimen # 319236), February 15, 2018 (patient specimen # 327128), March 15, 2018 (patient specimen # 331689) and on April 10, 2018 (patients specimens # 335614). 2. The general supervisor confirmed on April 26, 2018 at 11:40, that the syphilis serology testing records did not include the require control procedures results recorded those days of testing.

D5545

HEMATOLOGY
CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on PT Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) quality control records review and general supervisor interview on April 26, 2018 at 10:45 AM, it was determined that the laboratory failed to include two levels of control material each 8 hours of operation since June 7, 2017. The findings include: 1. On April 26, 2018 at 10:45 AM, the PT and PTT quality control records showed that the laboratory did not include two levels of control material each 8 hours of operation since June 7, 2017. 2. The general supervisor confirmed on April 26, 2018 at 10:45 AM, that the laboratory did not include two levels of control material each 8 hours of operation. He stated, that the laboratory includes two levels of control material in the first shift from Monday to Friday and if the laboratory received samples in the second or the third shift, then the laboratory includes the two control materials. Also, he stated that during Sunday and Saturday, the laboratory only includes the two levels of control material in the shift when the laboratory received the patients samples. 3. From June 7, 2017 to January 13, 2018, the PT and PTT quality control records showed that the laboratory did not include two levels of control material each 8 hours of operation the following dates: a. On June 7, 2017, the first shift included the two control materials at 6:11 AM. The second shift included the two levels of control at 5:22 PM when the patient specimen number ID 290039 was processed and reported for PT and PTT tests at 5:30 PM. b. On July 5, 2017, the first shifts included the two control materials at 6:37 AM. The second shift included the two levels of control at 7:45 PM when the patient specimen number ID 294778 was processed and reported for PT and PTT tests at 7:49 PM. c. On January 13, 2018, the first shift included the two control materials at 4:50 AM. The second shift included the two levels of control at 3:55 PM when the patient specimen number ID 321445 was processed and reported for PT and PTT tests at 3:59 PM. d. On February 5, 2018, the first shift included the two control materials at 6:14 AM. The seconds shift included the two levels of control at 7:47 PM when the patient specimen number ID 325586 was processed and reported for PT and PTT tests at 8:06 PM. e. On February 13, 2018, the first shift included the two control materials at 6:20 AM. The seconds shift included the two levels of control at 5:34 PM when the patients number ID 326860 was processed and reported for PT and PTT tests at 6:13 PM.

<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on syphilis serology testing records review (years 2017,2018), temperature, humidity and voltage records, validation records of the Vitamin B12, routine chemistry calibration verification records, preventive maintenance records, PT Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) quality control records review and general supervisor interview on April 26, 2018 at 11:40 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system requirements. The finding includes: 1. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology testing records review (years 2017,2018), temperature, humidity and voltage records, validation records of the Vitamin B12, routine chemistry calibration verification records, preventive maintenance records, PT Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) quality control records review and general supervisor interview on April 26, 2018 at 11:40 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements for syphilis serology quantitative tests. D 5012. 2. The laboratory director failed to ensure compliance with the analytic system requirements of routine chemistry tests. Refer to D 5413, D 5421, D 5429 and D 5439. 3. The laboratory director failed to ensure compliance with the requirements of the PT and PTT tests. Refer to D 5545.</p>
<p>D6144</p>	<p>GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology testing records review (years 2017,2018), temperature, humidity and voltage records, validation records of the Vitamin B12, routine chemistry calibration verification records, preventive maintenance records, PT Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) quality control</p>

records review and general supervisor interview on April 26, 2018 at 11:40 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results. Refer to D 5413, D 5421, D 5429, D 5439, D 5451 and D 5545.

D6177

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on syphilis serology testing records review (years 2017,2018), temperature, humidity and voltage records, validation records of the Vitamin B12, routine chemistry calibration verification records, preventive maintenance records, PT Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) quality control records review and general supervisor interview on April 26, 2018 at 11:40 AM, it was determined that the testing personnel failed to follow quality control procedures. Refer to D 5413, D 5421, D 5429, D 5439, D 5451 and D 5545.