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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 40D0667272 | (X3) Date Survey Completed 04/24/2018 |
| Name of Provider or Supplier Laboratorio Clinico Licer | Street Address, City, State Calle Degetau F-16, 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 |
|---------------------------|--|
| 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 quality control records (years 2017, 2018), syphilis serology testing records(years 2017, 2018) review and general supervisor interview on April 24, 2018 at 10:40 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory did not follow the Immunostix-rpr manufacturer's instruction when 6 out of 6 patients specimens were tested and reported for syphilis serology tests by the rapid plasma reagin (RPR) method from April 17, 2017 to April 20, 2018. Refer to D 5405.</p> |
| D5405 | <p>PROCEDURE MANUAL CFR(s): 493.1251(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on syphilis serology quality control records (years 2017, 2018), syphilis serology testing records(years 2017, 2018) review and general supervisor interview on April 24, 2018 at 10:40 AM, it was determined that the laboratory failed to follow the</p> |

manufacturer's instruction when 6 out of 6 patients specimens were tested and reported for syphilis serology by Rapid plasma reagin (RPR) Immunostics method from April 17, 2017 to April 20, 2018. The findings include: 1. The Immunostics RPR manufacturer's instruction establishes that three levels of control materials (non reactive, minimal to moderate and reactive) must be included each day of testing. 2. On April 24, 2018 at 10:40 AM, the syphilis serology quality control records and the syphilis serology testing records showed that the laboratory did not include the three levels of control materials when it tested and reported 6 out of 6 patients specimens for syphilis serology by the RPR Immunostics method from April 17, 2017 to April 20, 2018: Date Patients specimens ID June 16, 2017 # 175412 June 16, 2017 #5414 June 26, 2017 #5056 July 19, 2017 #6653 July 19, 2017 #6691 April 20, 2018 #14129 3. The general supervisor interview confirmed on April 24, 2018 at 10:50, that the syphilis serology quality control records did not include the three levels of control materials those days. She stated that the laboratory performed the quality control procedures but not recorded.

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 prothrombin time (PT) quality control records (2017, 2018), normal patient PT mean records (2017), thromboplastin reagent log records (2017, 2018) review and interview with the general supervisor on April 24, 2018 at 9:30 AM, it was determined that the laboratory did not calculate nor incorporates the current and pertinent normal patient PT mean when it reports 253 out of 253 patient's INR (International Normalized ratio) results from February 6, 2018 to April 23, 2018. The findings include: 1. On April 24, 2018 at 9:30 AM, the thromboplastin reagent log records showed that the laboratory used the thromboplastin reagent lot number N0160407 since February 6, 2018. 2. The PT quality control records showed that the laboratory did not calculate nor incorporates the current and pertinent normal patient PT mean for this reagent lot, when it reports 253 out of 253 patient's INR (International Normalized ratio) results from February 6, 2018 to April 23, 2018. 3. The PT quality control records showed that the laboratory used the former normal patient PT mean of 11.5 seconds to calculate and report the INR from February 6, 2018 to April 23, 2018. This mean was calculated for the tromboplastin reagent lot number N1243676 that was placed in routine use on May 22, 2017. 4. The general supervisor confirmed on April 24, 2018 at 9:40 AM, that the laboratory did not calculate nor incorporate the normal patient PT mean for the thromboplastin reagent in use (lot number N0160407) from February 6, 2018 to April 23, 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 syphilis serology quality control records (years 2017, 2018), syphilis serology testing records (years 2017, 2018), prothrombin time (PT) quality control records (2017, 2018), normal patient PT mean records (2017), thromboplastin reagent log records (2017, 2018) review and interview with the general supervisor on April 24, 2018 at 10:40 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 for the syphilis serology tests not the INR test results. Refer to D 6093.

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 syphilis serology quality control records (years 2017, 2018), syphilis serology testing records (years 2017, 2018), prothrombin time (PT) quality control records (2017, 2018), normal patient PT mean records (2017), thromboplastin reagent log records (2017, 2018) review and interview with the general supervisor on April 24, 2018 at 10:40 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for the syphilis serology and the INR test results. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements of syphilis serology tests. Refer to D 5012. 2. The laboratory director failed to ensure compliance with the analytic system requirements of INR test results. Refer to D 5545.

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 syphilis serology quality control records (years 2017, 2018), syphilis serology testing records (years 2017, 2018), (PT) quality control records (2017, 2018), normal patient PT mean records (2017), thromboplastin reagent log records (2017, 2018) review and interview with the general supervisor on April 24, 2018 at 10:40 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems of the syphilis serology and the INR tests results. Refer to D 5405 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 quality control records (years 2017, 2018), syphilis serology testing records (years 2017, 2018), (PT) quality control records (2017, 2018), normal patient PT mean records (2017), thromboplastin reagent log records (2017, 2018) review and interview with the general supervisor on April 24, 2018 at 10:40 AM, it was determined that testing personnel failed to follow quality control procedures for the syphilis serology and the INR tests results. Refer to D 5405 and D 5545.