

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0885142	(X3) Date Survey Completed 02/13/2020
Name of Provider or Supplier Lab Clinico Lorimar	Street Address, City, State Calle Pedro Santos, Num 65, Moca, 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
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 ASI manufacturer's instruction, syphilis serology testing records (year 2019) review and testing personnel interview at 11:35 AM on February 13, 2020, it was determined that the laboratory failed to follow the manufacturer's instruction for quality control when 825 out of 825 patient's specimen were tested for syphilis serology from September 4, 2019 to December 31, 2019 by the ASI Rapid plasma reagin (RPR) method. The findings include: 1. The laboratory performed the RPR tests by the ASI method from September 4, 2019 to December 31, 2019. 2. The ASI manufacturer's instruction establishes that three levels of control materials (Reactive, Weak Reactive and NonReactive) must be included each day of testing. 3. At 11:35 AM on February 13, 2020, the syphilis serology testing records showed that the laboratory did not include each day of RPR testing the Weak Reactive control from September 4, 2019 to December 31, 2019. 4. The technical supervisor confirmed at 11:35 AM on February 13, 2020, that the laboratory did not include each day of RPR testing the Weak Reactive control from September 4, 2019 to December 31, 2019 . 5. The laboratory processed and reported 825 out of 825 patient's specimen were tested for syphilis serology from September 4, 2019 to December 31, 2019 by the ASI (RPR) method.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</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.

This STANDARD is not met as evidenced by:

Based on ASI manufacturer's instruction, syphilis serology testing records (year 2019) review and testing personnel interview at 11:35 AM on February 13, 2020, it was determined that the laboratory director failed to comply with the analytic system requirement (syphilis serology (RPR) tests. Refer to D 5405 (The laboratory failed to follow the manufacturer's instruction for quality control when 825 out of 825 patient's specimen were tested for syphilis serology from September 4, 2019 to December 31, 2019 by the ASI Rapid plasma reagin (RPR) method).

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of personnel records files and interview with the laboratory director at 12:35 PM on February 13, 2020, it was determined that the laboratory director did not ensure that policies and procedures are established for monitoring the competence of the technical supervisor (MT#2) since February 13, 2018. The findings include: 1. At 12:35 PM on February 13, 2020, the technical supervisor (MT#2) personnel file did not include her competence since February 13, 2018. 2. The laboratory director confirmed at 12:35 PM on February 13, 2020, that the technical supervisor competence was not performed.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records files and interview with the laboratory director at 12:35 PM on February 13, 2020, it was determined that the laboratory director did not specify the duties of the laboratory technical supervisor (MT#2). The findings include: 1. At 12:35 PM on February 13, 2020, the technical supervisor (MT#2) personnel file did not include her written duties and responsibilities. 2. The laboratory

director confirmed at 12:35 PM on February 13, 2020, that the written duties and responsibilities were not included in her personal file.

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 ASI manufacturer's instruction, syphilis serology testing records (year 2019) review and testing personnel interview at 11:35 AM on February 13, 2020, it was determined that the technical supervisor failed to ensure compliance with the requirements for analytic systems for syphilis serology tests. Refer to D 5405 (The laboratory failed to follow the manufacturer's instruction for quality control when 825 out of 825 patient's specimen were tested for syphilis serology from September 4, 2019 to December 31, 2019 by the ASI Rapid plasma reagin (RPR) method).

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 ASI manufacturer's instruction, syphilis serology testing records (year 2019) review and testing personnel interview at 11:35 AM on February 13, 2020, it was determined that the testing personnel failed to follow the manufacturer's instruction for quality control when 825 out of 825 patient's specimen were tested for syphilis serology from September 4, 2019 to December 31, 2019 by the ASI Rapid plasma reagin (RPR) method. Refer to D 5405.