

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0690738	(X3) Date Survey Completed 01/19/2018
Name of Provider or Supplier Lab Clin Referencia Cima	Street Address, City, State Calle Saturnino Rodriguez #7, Yabucoa, 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
D2082	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review and laboratory general supervisor interview on January 19, 2018 at 9:15 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in general immunology serology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to December 2018. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Antistreptolysin O (ASOT - qualitative) tests in December 2016 (third testing event - PRPTP). No remedial actions were taken. 3. The general supervisor confirmed on January 19, 2018, that the laboratory did not take and document these corrective action.</p>
D5002	<p>BACTERIOLOGY CFR(s): 493.1201</p> <p>If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299.</p>

This CONDITION is not met as evidenced by:
Based on bacteriology quality control records review from January 1, 2016 to January 19, 2017 and laboratory general supervisor interview on January 19, 2018 at 10:34 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology. Refer to D5507 (to check, with the appropriate control organisms, each day the antimicrobial susceptibility tests were performed by the Microscan method). This deficiency was cited on February 10, 2016 survey.

D5479

CONTROL PROCEDURES
CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on manufacturer's instructions, general immunology quality control records review from January 5, 2016 to December 15, 2017 and laboratory general supervisor interview on January 19, 2018 at 11:15 AM, it was determined that the laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Monocol/lex method. The findings include: 1. The Monocol /lex manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 saline dilution due to a prozone phenomena. 2. From January 5, 2016 to December 15, 2017, the general immunology quality control records showed that the laboratory did not check 20 out of 24 patient's specimens at a 1:10 dilution before it reported as negative Monotest. 3. The laboratory general supervisor confirmed on January 19, 2018, that the laboratory processed and reported twenty (20) negative patient's samples without 1:10 saline dilution retest. 4. This deficiency was cited on February 10, 2016 survey.

D5507

BACTERIOLOGY
CFR(s): 493.1261(b)(c)

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on bacteriology quality control records review, laboratory general supervisor and testing personnel interview on January 19, 2018 at 10:12 AM, it was determined that the laboratory failed to check (with the appropriate control organisms) each day the antimicrobial susceptibility tests were performed by the Microscan method. The

findings include: 1. The bacteriology quality control records showed that the laboratory performed the antimicrobial susceptibility tests for gram positive organism and gram negative organism by the Microscan method from January 1, 2016 to December 31, 2017. 2. The bacteriology quality control records showed that the laboratory did not check each day with the appropriate control organisms the antimicrobial susceptibility tests from January 1, 2016 to December 31, 2017. Instead, the laboratory checked weekly with the appropriate control organisms the Microscan's antimicrobial susceptibility tests from January 1, 2016 to December 31, 2017. 3. The laboratory general supervisor confirmed on January 19, 2018, that the laboratory did not perform the check of antimicrobial susceptibility tests each day of testing. She stated that the laboratory performed the check weekly. 4. The bacteriology quality control records showed that the laboratory performed and reported 3425 patients culture specimens for the antimicrobial susceptibility tests by the Microscan method from January 1, 2016 to December 31, 2017. 5. This deficiency was cited on February 10, 2016 survey.

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 and laboratory general supervisor interview on January 19, 2018 at 11:54 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. Review of the laboratory quality assessment manual showed that for each analytic process a log sheet was designate to keep track of the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic systems: a. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Immuno /lex - IM method. Refer to D5479. b. to check, with the appropriate control organisms, each day the antimicrobial susceptibility tests were performed by the Microscan method. Refer to D5507.

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 Puerto Rico Proficiency Testing Program (PRPTP) records review, quality control records review and laboratory general supervisor interview on January 19, 2018 at 11:55 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the proficiency testing requirements, laboratory analytical system and quality assessment requirements. The finding includes: 1. The laboratory director failed to take and document corrective

actions. Refer to D6092. 2. The laboratory director did not comply with the requirement for analytical systems and quality assessment requirements. Refer to D6093 and D6094.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review and laboratory general supervisor interview on January 19, 2018 at 10:52 AM, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2016 to December 2017. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 60 percent in Antistreptolysin O (ASOT) tests in December 2016 (PRPTP third testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on February 19, 2018, that the laboratory did not take corrective actions on these testing events. Refer to D2082.

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 quality control records review and laboratory general supervisor interview on January 19, 2018 at 11:55 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Immuno/lex - IM method. Refer to D5479. b. to check (with the appropriate control organisms) each day the antimicrobial susceptibility tests were performed by the Microscan method. Refer to D5507.

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 on January 19, 2018 at 11:48 AM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The finding

includes: 1. The laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. Refer to D5791.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on personnel records review and laboratory general supervisor interview on January 19, 2018 at 9:45 AM, it was determined that the laboratory failed to follow the established schedule for testing personnel and clinical consultant competence evaluation. The findings include: 1. The laboratory schedule for testing personnel and clinical consultant competence evaluation showed that it must be performed every year. 2. The laboratory did not perform the testing personnel (MT # 1, MT #2) and clinical consultant (MD # 9799) competence evaluation since January 2016. 3. The general supervisor confirmed on January 19, 2018, that the competence evaluation were not performed as established.

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 quality control records review and laboratory general supervisor interview on January 19, 2017 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: a. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Immuno/lex - IM method. Refer to D5479. b. to check (with the appropriate control organisms) each day the antimicrobial susceptibility tests were performed by the Microscan method. Refer to D5507.

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 quality control records review and laboratory general supervisor interview

on January 19, 2017 at 11:48 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel did not evaluate aspects regarding: a. to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest by Immuno/lex - IM method. Refer to D5479. b. to check (with the appropriate control organisms) each day the antimicrobial susceptibility tests were performed by the Microscan method. Refer to D5507.