

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0693411	(X3) Date Survey Completed 03/01/2018
Name of Provider or Supplier Lab Garcia, Corp	Street Address, City, State Calle 65 Infanteria #67, Anasco, 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
D5479	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by:</p> <p>A. Based on manufacturer's instructions, general immunology quality control records review (2016-2018) and laboratory general supervisor interview at 10:10 a.m. on March 1, 2018, 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 laboratory uses Monocol/lex method to perform Monotest patient's samples. 2. The Monocol/lex method manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 saline dilution due to a prozone phenomena. 3. Review of records from January 2016 to February 2018, the records showed that the laboratory did not dilute nineteen (19) patient's specimens before it reported as negative Monotest. 4. The laboratory general supervisor confirmed on March 1, 2018 that the laboratory did not dilute nineteen (19) patient's specimens before it reported as negative Monotest. 5. The laboratory processed and reported nineteen (19) negative Monotest patient's samples without 1: 10 saline dilution retest. B. A. Based on manufacturer's instructions, general immunology quality control records review (2016-2018) and laboratory general supervisor interview at 10:10 a.m. on March 1, 2018, it was determined that the laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative C-reactive protein by Detector/lex crp method. The findings include: 1. The laboratory uses Detector/lex crp method to perform C-reactive protein patient's samples. 2. The Detector/lex crp method manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 glicine dilution due to a</p>

prozone phenomena. 3. Review of records from January 2016 to February 2018, the records showed that the laboratory did not dilute fifty eight (58) patient's specimens before it reported as negative C-reactive protein. 4. The laboratory general supervisor confirmed on March 1, 2018 that the laboratory did not dilute fifty eight (58) patient's specimens before it reported as negative C-reactive protein. 5. The laboratory processed and reported fifty eight (58) negative C-reactive protein patient's samples without 1:10 glicine dilution retest.

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 in 2016-2018 and laboratory general supervisor interview on March 1, 2018 at 10:10 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 finding includes: 1. The laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest and C-reactive protein. Refer to D5479.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate 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 general imunology quality control records review in 2016-2018 and laboratory general supervisor interview on March 1, 2018 at 10:10 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest and C-reactive protein. Refer to D5479.

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 general immunology quality control records review from January 2016 to

February 2018 and laboratory general supervisor interview at 10:10 AM on March 1, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5479.

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 in 2016-2018 and laboratory general supervisor interview at 10:10 a.m. on March 1, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.

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 general immunology quality control records review in 2016-2018 and laboratory general supervisor interview on March 1, 2018 at 10:10 AM, it was determined that the general supervisor failed to follow quality control procedures. The finding includes: 1. The laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative Monotest and C-reactive protein. Refer to D5479.