Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0693411	(X3) Date Survey Completed 02/25/2020
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
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Mycoplasma pneumoniae quality control records patient records review (2019) and interview with the laboratory supervisor on February 25, 2020 at 10:40 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: a. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to : 5449- The laboratory did not include positive and negative control material
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of Mycoplasma pneumoniae IgM quality control results (2019) , patient test results records and interview with the laboratory supervisor on February 25, 2020 at 10:40 AM, it was found that the laboratory did not include a positive and a

	negative control material each day of patient testing. The findings include: a. The laboratory began to perform patient's test for Mycoplasma pneumoniae on March 1, 2019. b. Review of the quality control and patient test results records from April 11, 2019 to December 31, 2019, at 10:40 AM, showed that positive and negative controls were included when a new reagent box was opened. c. The quality control and patient test results records showed that from April 11, 2019 to December 30, 2019 the laboratory performed and reported a total of 140 Mycoplasma pneumoniae IgM patient samples. d. The laboratory supervisor confirmed on February 25, 2020 at 10: 45 A.M. that the laboratory failed to include a negative and a positive control material each day of testing, a positive and negative controls were included when a new reagent box was opened.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on general immunology and endocrinology quality control records review (years 2019-2020) and laboratory general supervisor interview at 10:30 AM on February 25, 2020, it was determined that the laboratory did not evaluate the new lot of Rheumatoid factor (RA) , human chorionic gonadotropin (hCG) and C-reactive protein (CRP) for positive reactivity prior to placed it in routine use. The findings include: a. The laboratory quality control records were review from January 2019 to February 2020. b. The laboratory received the following reagent kit for hCG, RA and CRP method and no evaluation of their positive reactivity was performed: Test Lot Date of use RA 9A05D3 4/24/2019 hCG HCG8050217 3/7/2019 hCG HCG9010027 12/11/2019 CRP 9C07C3 6/6/2019 CRP 9D22C3 11/8/2019 c. The laboratory general supervisor confirmed on February 25, 2020 at 11:00 A.M., that the laboratory did not evaluate the new lot of hCG., RA and CRP test for positive reactivity prior to placed it in routine use.
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 quality control records review (2019) and laboratory supervisor interview on February 25, 2020 at 10:40 A.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093

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: 1. Based on Mycoplasma pneumonia rapid test quality control records (2019) , general immunology and endocrinology quality control records review (years 2019-2020) , and interview with the laboratory general supervisor on Fenruary 25, 2020 at 11:00 A.M., it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: a. The Mycoplasma pneumonia rapid test quality control records (2019) showed that no positive neither negative control material were included each day of patient testing. Refer to D5449. b. The general immunology and endocrinology quality control records review (years 2019-2020) showed that the laboratory did not evaluate the new lot of Rheumatoid factor (RA) , human chorionic gonadotropin (hCG) and C-reactive protein (CRP) for positive reactivity prior to placed it in routine use. Refer to D5471.
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 Mycoplasma pneumonia rapid test quality control records (2019) , general immunology and endocrinology quality control records review (years 2019-2020) , and interview with the laboratory general supervisor on Fenruary 25, 2020 at 11:00 A. M., it was determined that the laboratory general supervisor failed to ensure compliance with the requirements for analytic systems. The findings include: a. The Mycoplasma pneumonia rapid test quality control records (2019) showed that no positive neither negative control material were included each day of patient testing. Refer to D5449. b. The general immunology and endocrinology quality control records review (years 2019-2020) showed that the laboratory did not evaluate the new lot of Rheumatoid factor (RA) , human chorionic gonadotropin (hCG) and C-reactive protein (CRP) for positive reactivity prior to placed it in routine use. Refer to D5471.