Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D0912847	**(X3) Date Survey Completed** 05/10/2022
Name of Provider or Supplier Laboratorio Clinico Villa Ana Aguas Buenas Iii	**Street Address, City, State** Carr 174 Km 21 , Hm 7, Aguas Buenas, 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 from February 9, 2021 to May 9, 2022 and laboratory testing personnel interview on May 10, 2022 at 11:14 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: 1. Refer to D5405 - The laboratory did not monitor and record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from February 9, 2021 to May 9, 2022 (review on May 10, 2022 at 9:28 AM). 2. Refer to D5449- The laboratory did not include positive and negative control material when performed Mycoplasma pneumoniae each day of patient testing from February 9, 2021 to May 9, 2022 (review on May 10, 2022 at 9:28 AM).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) 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. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing

	records review from February 9, 2021 to May 9, 2022 and laboratory testing personnel interview, it was determined that the laboratory failed to follow the manufacturer's instruction when 513 out of 513 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from February 9, 2021 to May 9, 2022. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22C to 25C. 2. On May 10, 2022 at 9:28 AM, the Mycoplasma testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from February 9, 2021 to May 9, 2022. 3. The laboratory testing personnel confirmed on May 10, 2022 at 11:14 AM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 513 out of 513 patients specimens for mycoplasma test by Immuno Card Meridian method from February 9, 2021 to May 9, 2022.
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 General Immunology (Mycoplasma pneumoniae test) quality control records review from February 9, 2021 to May 9, 2022 and laboratory testing personnel interview, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing from February 9, 2021 to May 2022. The findings include: 1. General Immunology (Mycoplasma pneumoniae test) quality control records were review on May 10, 2022 at 9:28 AM, from February 9, 2021 to May 9, 2022. 2. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include any control material each day of patient testing since February 9, 2021. 3. The laboratory testing personnel confirmed on May 10, 2022 at 11:14 AM, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test. The testing personnel confirm on May 10, 2022, that the laboratory only run negative and positive control material when change the lots of Mycoplama pneumoniae kits. 4. The laboratory did not include control material each day of run, when 513 out of 513 patient specimen were processed and since February 9, 2021.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on general immunology quality control records review from February 9, 2021

	to May 9, 2022 and laboratory testing personnel interview on May 10, 2022 at 11:14 AM, it was determined that the laboratory director failed to ensure monitor and record the correct room temperature (22C - 25C) when performed Mycoplasma pneumoniae patient's specimens were tested for Mycoplasma pneumoniae by Immuno Card Meridian from February 9, 2021 to May 9, 2022 (513 out of 513 patients specimens for mycoplasma test by Immuno Card Meridian method) and ensure that negative and positive control material, were included by the testing personnel each day of Mycoplasma pneumoniae patient testing from February 9, 2021 to May 9, 2022. The findings include: 1. Refer to D5405 - The laboratory did not monitor and record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from February 9, 2021 to May 9, 2022 (review on May 10, 2022 at 9:28 AM). 2. Refer to D5449- The laboratory did not include positive and negative control material when performed Mycoplasma pneumoniae each day of patient testing from February 9, 2021 to May 9, 2022 (review on May 10, 2022 at 9: 28 AM).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: 1. Based on general immunology (Mycoplasma pneumoniae) quality control testing records review from February 9, 2021 to May 9, 2022 and laboratory testing personnel interview on May 10, 2022 at 11:14 AM, it was determined that the laboratory director failed to ensure that the laboratory follow the manufacturer's instruction for monitor and documented the room temperature when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. The finding includes: a. The laboratory failed to monitor and documented the the room temperature when patient's specimen were tested for Mycoplasma by Immuno Card Meridian method from February 9, 2021 to May 9, 2022. Refer to D5405. 2. Based on general immunology (Mycoplasma pneumonia) quality control records review from February 9, 2021 to May 9, 2022 and laboratory testing personnel on May 10, 2022 at 11:14 AM, it was determined that the laboratory director failed to ensure that negative and positive control material, were included by the testing personnel each day of Mycoplasma pneumoniae patient testing. The finding includes: a. The laboratory did not include a positive and a negative control material when performed Mycoplasma pneumoniae each day of patient testing from February 9, 2021 to May 9, 2022. Refer to D5449.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

	This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma testing records review from February 9, 2021 to May 9, 2022 and laboratory testing personnel interview on May 9, 2022 at 11:14 AM, it was determined that the testing personnel failed to follow the manufacturer's instruction when patient's were tested for Mycoplasma by Immuno Card Meridian Method. The finding includes: 1. The laboratory testing personnel did not follow the manufacturer's instruction for monitor and documented the room temperature from February 9, 2022 to May 9, 2022, when the patient's specimens were tested for Mycoplasma by Immuno Card Meridian method. Refer to D5405.