Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2058614	09/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Plaza Caparra	Centro Comercial Plaza Caparra, Carretera 23, Guaynabo, 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
D5002	BACTERIOLOGY CFR(s): 493.1201 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. This CONDITION is not met as evidenced by: Based on bacteriology culture media plates quality control records review (from January 1, 2018 to September 11, 2019) and laboratory director and testing personnel on September 11, 2019 at 11:20 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of bacteriology. The finding includes: 1. The laboratory did not check each batch of cultures media plates used at the laboratory for ability to support growth, selectivity and or inhibition and biochemical response from January 1, 2018. Refer to D 5477.
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 general immunology (Mycoplasma pneumoniae IgM) quality control records (from December 14, 2019 to September 11, 2019) review and laboratory director interview on September 11, 2019 at 10:45 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements of

	General immunology. The finding includes: 1. The laboratory did not include each day of testing a negative and a positive control material when patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method. Refer to D 5449.
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 IgM) quality control records (from December 14, 2018 to September 11, 2019), Mycoplasma pneumoniae IgM worksheets review and interview with the laboratory director at 10:45 AM on September 11, 2019, it was determined that the laboratory failed to include each day of testing a negative and a positive control material when patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method. The findings include: 1. The laboratory performed the IgM to Mycoplasma pneumoniae qualitative test by the Mycoplasma Immuno Card method. 2. The General Immunology serology (IgM to Mycoplasma pneumoniae) quality control records showed that the laboratory place in use the following lots of Mycoplasma Immuno Card: December 14, 2019 (lot # 709030K020), February 18, 2019 (lot # 709030K035), February 23, 2019 (lot # 709030K042), March 13, 2019 (lot # 709030K042), April 3, 2019 (lot # 709030K042) and September 9, 2019 (lot # 709030L046). 3. The Mycoplasma IGM quality control records showed that the laboratory did not include each day of testing a negative and a positive control material when 115 out of 115 patients serum specimens tested for qualitative Mycoplasma pneumoniae IgM by the Immuno Card Mycoplasma method from December 14, 2018 to September 11, 2019. The worksheets showed that 31 patients serum specimen tests were positive for Mycoplasma pneumoniae IgM and 84 patients serum tests were negative. 3. The laboratory director and testing personnel confirmed on September 11, 2019 at 10:45 AM, that the laboratory did not include each day of testing a negative and a positive control material when patients serum specimens were tested for qualitative Mycoplasma IgM. The laboratory director stated that the laboratory included a negative and a positive control material when they placed in use a box (same lot) or new lot of the Immuno Card Mycoplasma reagents kit.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on bacteriology culture media quality control records review (from January 10, 2018 to September 11, 2019), bacteriology worksheets and laboratory director and testing personnel interview on September 11, 2019, it was determined that the laboratory failed to check each batch of cultures media plates used at the laboratory for ability to support growth, selectivity and or inhibition and biochemical response since January 1, 2018. The findings include: 1. Review of the bacteriology culture media quality control records showed that the following agar plates were being used: Blood Agar (BA) and Mac Conkey. 2. From January 10, 2018 to September 11, 2019, the laboratory received the following: Media Total of different lot numbers a. Blood Agar (BA) 22 lots b. Mac Conkey 19 lots 3. The laboratory processed 756 patients samples for urine cultures from January 1, 2018 to September 11, 2019. The worksheets showed that 133 patients samples for urine cultures were positive and 623 patients samples for urine cultures were negative. 4. The laboratory director and testing personnel stated that no evaluation of the ability to support growth was performed from January 1, 2018 to September 11, 2019.
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 bacteriology (culture media plates) and general immunology (Mycoplasma pneumoniae IgM) quality control records review (from January 1, 2018 to September 11, 2019) and laboratory director interview on September 11, 2019 at 1:42 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the analytic system requirements of bacteriology and general immunology. 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: Based on bacteriology and general immunology quality control (from January 1, 2018 to September 11, 2019) records review and laboratory director and testing personnel interview on September 11, 2019 at 1:50 PM, it was determined that the laboratory director did not establish quality control procedures for Mycoplasma pneumoniae test nor for bacteriology culture media plates. The findings include: 1. The laboratory did not include each day of testing a positive and negative control materials for Mycoplasma pneumoniae tests. Refer to D 5449. 2. The laboratory did not check the ability to support growth, inhibitor and or selectivity of the culture media plates. Refer to D5477.