Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1046214	01/23/2020
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Olympic Plaza	Extension Centro Comercial, Caribbean Shopping, Las Piedras, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records (years 2018 and 2019) reviewed and interview with the laboratory director at 9:40 AM on January 23, 2020, it was determined that the laboratory failed to enroll in an HHS approved proficiency program for wight blood cell (WBC) 5 parameters differential from January 2018 to December 31, 2019. The laboratory processed and reported 8,046 out of 8,046 patient's specimens for WBC 5 parameters differential during this period of time. The findings include: 1. The laboratory processed and reported patient's specimens for WBC 5 parameters differential by the Sysmex 1000i system. 2. At 9:40 AM on January 23, 2020, the PRPTP records showed that the laboratory did not to enroll in an HHS approved proficiency program for WBC 5 parameters differential since January 2018. 3. The laboratory director confirmed on January 23, 2020 at 9:40 AM, that the laboratory was not enrolled in an HHS proficiency program for WBC 5 parameters differential since January 2018. 4. The laboratory processed and reported 8,046 out of 8,046 patient's specimens for WBC 5 parameters differential from January 2018 to December 31, 2019 by the Sysmex 1000i system.

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 Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma IGM testing and quality control records (from July 1, 2019 to January 3, 2020) reviewed and interview with the laboratory director at 10:30 AM on January 23, 2020, it was determined that the laboratory failed to meet the requirements of the General Immunology (for qualitative Mycoplasma IgM tests). Refer to D 5405 (The laboratory did not follow manufacturer's instruction for test procedure when 240 out of 240 patient's specimens were tested and reported for qualitative Mycoplasma IgM tests from July 1, 2019 to January 3, 2020 , by the Immuno Card Mycoplasma method). Refer to D5449 (The laboratory director at 10:20 AM on January 23, 2020, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 240 out of 240 patient's specimens were tested and reported for qualitative Mycoplasma IgM tests from July 1, 2019 to January 3, 2020 , by the Immuno Card Mycoplasma method).
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 IGM testing records (from July 1, 2019 to January 3, 2020) reviewed and interview with the laboratory director at 10:30 AM on January 23, 2020, it was determined that the laboratory failed to follow manufacturer's instruction for test procedure when 240 out of 240 patient's specimens were tested and reported for qualitative Mycoplasma IgM tests from July 1, 2019 to January 3, 2020 , by the Immuno Card Mycoplasma method. The findings include: 1. The Immuno Card Mycoplasma manufacturer instructed the laboratory to incubate at 22 to 25 C the Test Card during the test procedures. 2. At 10:30 AM on January 23, 2020, the Mycoplasma IGM quality testing records showed that the laboratory did not monitor nor recorded the room temperature when it processed the patient's specimens from July 1, 2019 to January 3, 2020. 3. The laboratory director confirmed at 10:30 AM on January 23, 2020, that the laboratory did not document the room temperature when it processed the patient's specimens for qualitative Mycoplasma IgM tests from July 1, 2019 to January 3, 2020 , by the Immuno Card Mycoplasma method. 4. The laboratory tested and reported 240 out of 240 patient's specimens for qualitative Mycoplasma IgM tests from July 1, 2019 to January 3, 2020 by the Immuno Card Mycoplasma method.
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 Mycoplasma IGM quality control records (from July 1, 2019 to January 3, 2020) reviewed and interview with the laboratory director at 10:20 AM on January 23, 2020, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 240 out of 240 patient's specimens were tested and reported for qualitative Mycoplasma IgM tests from July 1, 2019 to January 3, 2020 , by the Immuno Card Mycoplasma method. The findings include : 1. At 10:20 AM on January 23, 2020, the Mycoplasma IGM quality control records showed that the laboratory did not include each day of testing the negative nor the positive control materials from July 1, 2019 to January 3, 2020. 2. The laboratory director confirmed at 10:20 AM on January 23, 2020, that the laboratory did not include the negative nor the positive control materials each day of qualitative Mycoplasma IgM testing, instead the laboratory includes a negative and a positive control materials when it places in routine use every new lot or new shipping of the Immuno Card Mycoplasma reagents Kit. 4. The laboratory tested and reported 240 out of 240 patient's specimens for qualitative Mycoplasma IgM tests from July 1, 2019 to January 3, 2020 by the Immuno Card Mycoplasma method.
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 PRPTP records (years 2018 and 2019), Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma IGM testing and quality control records (from July 1, 2019 to January 3, 2020) reviewed and interview with the laboratory director at 10:30 AM on January 23, 2020, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the Proficiency Testing Program and with the analytic requirements of the General Immunology (for qualitative Mycoplasma IgM tests). Refer to D 6015. (The laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the WBC 5 parameters differential from January 2018 to December 31, 2019). Refer to D 6020 (The laboratory director did not comply with the analytic requirements of the General Immunology (for qualitative Mycoplasma IgM tests).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on PRPTP records (years 2018 and 2019) reviewed and interview with the laboratory director at 9:40 AM on January 23, 2020, it was determined that the laboratory director failed to ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the WBC 5 parameters differential from January 2018 to December 31, 2019. Refer to D 2000 (The laboratory did not enroll in an approved proficiency program for wight blood cell (WBC) 5 parameters differential from January 2018 to December 31, 2019. The laboratory processed and reported 8,046 out of 8,046 patient's specimens for WBC 5 parameters differential during this period of time.
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: Based on Immuno Card Mycoplasma manufacturer's instructions, Mycoplasma IGM testing and quality control records (from July 1, 2019 to January 3, 2020) reviewed and interview with the laboratory director at 10:30 AM on January 23, 2020, it was determined that the laboratory director failed to comply with the analytic requirements of the General Immunology (for qualitative Mycoplasma IgM tests). Refer to D 5014.