Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0977871	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Obymar	Carr 420 Km 04 Barrio Voladoras, Moca, 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
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 syphilis serology quality control review (year 2021-2022) , manufacturer's instructions and laboratory general supervisor interview on January 25, 2023 at 10:10 a.m., it was determined that the laboratory failed to follow the manufacturer's instruction when 31 out 31 patient specimen were tested for RPR (Rapid plasma reagin) by ASI syphilis/rpr method. The findings include: 1. The syphilis serology quality control records were reviewed since 1/2022. (review on 1/25/23 at 10:10 a.m.) 2. On December 19, 2022 the syphilis serology records showed that the laboratory began to use a new method for RPR test (ASI) . 3. The manufacturer's instruction of the new method establishes that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. (review on 1 /25/23 at 10:15 a.m.) 4. From 12/19/2022 to 1/25/2023, the syphilis serology quality control log showed that the laboratory included only two control material (reactive and non reactive) each day of testing. (review on 1/25/23 at 10:18 a.m.) 5. The general supervisor confirmed on January 25, 2023 at 10:20 a.m., that the laboratory failed to follow the manufacturer's instruction when 31 out 31 patient specimens were tested for RPR by ASI syphilis/rpr 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 General Immunology (Mycoplasma pneumoniae test) quality control records review (years 2022-2023) and laboratory general supervisor interview on January 25, 2023 at 9:26 a.m., it was determined that the laboratory did not include an external negative control material each day when 107 out 107 mycoplasma patient samples were reported and performed. The findings include: 1. The laboratory begin to test Mycoplasma pneumoniae test on October 2022. (review on 1/25/23 at 9:27 a. m.) 2. The quality control records were review since October 2022 to January 24, 2023. (review on 1/25/23 at 9:30 a.m) 3. Review of Mycoplasma pneumoniae quality control record showed that the laboratory did not include an external negative control material each day of patient testing since October 2022. (review on 1/25/23 at 9:30 a. m) 4. The laboratory general supervisor confirmed on January 25, 2023 at 9:40 a.m., that the laboratory failed to include a negative control material each day of testing when performed Mycoplasma pneumonia test. 5. The laboratory did not include a negative control material, when 107 out 107 patient specimen were processed and reported since October 2022. (review on 1/25/23 at 9:35 a.m)
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 and syphilis serology control records review (2021-2023) and laboratory general supervisor interview on January 25, 2023 at 11:00 a.m. it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D5405 - the laboratory failed to follow the manufacturer's instruction when 31 out 31 patient specimen were tested for RPR (Rapid plasma reagin) by ASI syphilis/rpr method. Refer to D5449 - the laboratory did not include an external negative control material each day when 107 out 107 mycoplasma patient samples were reported and performed.
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 and syphilis serology control records review (2021-2023) and laboratory general supervisor interview on January 25, 2023 at 11:00 a.m. it was determined that the laboratory general supervisor failed to comply with the analytic system requirements. Refer to D5405 - the laboratory failed to follow the

	manufacturer's instruction when 31 out 31 patient specimen were tested for RPR (Rapid plasma reagin) by ASI syphilis/rpr method. Refer to D5449 - the laboratory did not include an external negative control material each day when 107 out 107 mycoplasma patient samples were reported and performed.