Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658225	12/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Centro Medico Wilma N Vazquez	Carr Num 2 Km 39 Hm 5, Vega Baja, 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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on quality assessment procedure manual, quality assessment records review (year 2020 and 2021) and interview with the laboratory general supervisor interview on December 21, 2021 at 10:00A.M. it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests The findings include: a. Review of the quality assessment program showed that evaluations to patient test request must be evaluated every year. b. Review of the quality assessment records on December 21, 2021 at 10:00 A.M., showed that the the laboratory failed to perform the evaluations since January 2021. c. The laboratory general supervisor confirmed on December 21, 2021 at 10:00 A.M., that evaluations to test requests was not performed.
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) testing records review and interview with the laboratory supervisor on December 21, 2021 at 10:48 AM, it was determined that the laboratory did not include an external positive and negative control material each day of patient testing. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. Testing record review show that the laboratory fail to run external control from November 18, 2021 to December 1, 2021. 3. The laboratory supervisor confirmed on December 21, 2021 at 10:48 AM, that the laboratory failed to include each day of patient testing the external negative and positive control material . She stated that the laboratory run the external controls when it received a new reagent kit or new lot. 4. The laboratory processed and reported 135 patients specimens for Mycoplasma pneumoniae from November 18, 2021 to December 1, 2021.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on quality assessment (QA) procedure manual, quality assessment records review (year 2020 and 2021) and interview with the laboratory general supervisor interview on December 21, 2021 at 10:00 A.M. it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for postanalytic systems: turn around time and completeness of the patient's final test reports. The findings include: a. Review of the quality assessment program on December 21, 2021 at 10:00 A.M., showed that evaluations related to the laboratory turn around time and patient's final test reports must be evaluated every year . b. Review of the quality assessment program showed that the laboratory failed to performed the evaluations related to the completeness of the patient's final test reports and turn around time since January 2021. c. The laboratory general supervisor confirmed on December 21, 2021 at 10:00 A.M., that evaluations to post analytic system was not performed.
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 Mycoplasma pneumonia test quality control records and interview with the laboratory supervisor on December 21, 2021 at 10:48 AM, it was determined that the laboratory director did not fulfill his responsabilities to assure that the external control material was run each day of patient testing from November 18 2021, to December 1, 2021 for Mycoplasma pneumonia tests. Refer to D5449.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records review (2020-2021) and laboratory general supervisor interview on December 21, 2021 at 10:30 A.M, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory preanalytic,and postanalytic systems. 2. The laboratory general supervisor confirmed on December 21, 2021 at 10:30 A.M., that the laboratory failed to evaluate the requirements for laboratory preanalytic and postanalytic systems. Refer to D5391 and D5891.