Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2089661	02/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Plaza Del Carmen Medical Services Inc	Carr 891, Km 1 Hm 7 Bo Pueblo, Corozal, 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
D2072	SYPHILIS SEROLOGY CFR(s): 493.835(d) (1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review and laboratory director interview, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in syphilis serology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2020 to February 2022. 2. Review of Proficiency Testing records on February 16, 2022 at 9:28 AM, showed that the laboratory obtained unsatisfactory results of 0 percent in syphilis serology (qualitative) tests in May 2020 (first testing event). No corrective actions were taken. 3. The laboratory director confirmed on February 16, 2022 at 11:48 AM, that the laboratory did not take corrective actions in the first testing event of syphilis serology specialty in May 2020.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score,

	remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review from February 2020 to February 2022 and laboratory director interview, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2020 to February 2022. 2. Review of Proficiency Testing records on February 16, 2022 at 9:42 AM, showed that the laboratory obtained unsatisfactory results of 0 percent in CO 2 tests in October 2021 (third testing event). No remedial actions were taken. 3. The laboratory director confirmed on February 16, 2022 at 11: 48 AM, that the laboratory did not take corrective actions on November 2021 (third testing event).
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review from February 2020 to February 2022 and laboratory director interview, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed from February 2020 to February 2022. 2. Review of Proficiency Testing records on February 16, 2022 at 9: 28 AM, showed that the laboratory obtained unsatisfactory results of 60 percent in Platelet Count tests in November 2020 (third testing event). No remedial actions were taken. 3. The laboratory director confirmed on February 16, 2022 at 11: 48 AM, that the laboratory did not take corrective actions in the third testing event on November 2020.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, syphilis serology quality control records review

	from January 7, 2021 to December 14, 2021 and laboratory director interview, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by Detector Immunostics RPR method. The findings include: 1. The manufacturer's establishes that the RPR (Rapid Plasma Reagin) test must be performed at room temperature between 23 C to 29 C . 2. Review of syphilis serology records from January 2019 to February 2019 on February 16, 2022 at 10:58 AM, showed that the laboratory processed and reported 102 RPR (Rapid Plasma Reagin) patient's tests that was performed at temperatures below 23 C during 64 of 73 days. 3. The laboratory director confirmed on February 16, 2022 at 11:15 AM, that the laboratory performed RPR (Rapid Plasma Reagin) tests below the range established by the manufacturer's 64 of 73 days from January 7, 2021 to December 14, 2021.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review and laboratory director interview, it was determined that the laboratory director failed to follow the corrective action plan when the laboratory obtained unsatisfactory results. The findings include: 1. Puerto Rico Proficiency Testing Program records and results were reviewed since February 2020 to February 2022. 2. Review of Proficiency Testing records on February 16, 2022 at 9:48 AM, showed that the laboratory obtained unsatisfactory results of 0 percent in Syphilis serology (qualitative) tests in May 2020 (first testing event), 0 percent in CO 2 tests in October 2021 (third testing event) and 60 percent in Platelets cell count tests in November 2020 (third testing event). No remedial actions were taken. 3. The laboratory director confirmed on February 16, 2022 at 11:48 AM, that the laboratory did not take corrective actions on those testing events. Refer to D2072, D2094 and D2128.
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 syphilis serology quality control records review from January 7, 2021 to December 14, 2021 and laboratory director interview on February 16, 2022 at 11:50 AM, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer to D5411 (did not monitor nor record the room temperature when patient's specimens were tested for RPR (Rapid Plasma Reagin by Detector Immunostics method).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's

	quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on syphilis serology quality control records review from January 7, 2021 to December 14, 2021, laboratory director and testing personnel interview on February 16, 2022 at 11:48 AM, it was determined that testing personnel failed to perform syphilis serology test (RPR) as required by manufacturer's instructions by Detector Immunostics RPR method. Refer to D5411 (failed to perform syphilis serology test (room temperature) as required by manufacturer's instructions by Detector Immunostics RPR method).