Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0883089	05/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cdt Del Municipio De Canovanas	Calle Corchado Final, Canovanas, 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 (PRPTP) records review and laboratory general supervisor interview on May 21, 2021 at 9:24 AM, 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 March 2021. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent in syphilis serology (qualitative) tests in May 2020 (PRPTP first testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on May 21, 2021, that the laboratory did not take corrective actions in these testing events.
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 (PRPTP) records review from February 2020 to March 2021 and laboratory general supervisor interview at 9:34 AM on May 21, 2021, 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 March 2021. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 0 percent in Creatine Kinase and Lipase test in February 2020 (PRPTP first testing event), 0 percent in Alanine Aminotranferase (ALT), Amylase, Aspartate Aminotranferase (AST), Calcium, Chloride, Creatinine Kinase, Glucose, Potassium, Sodium and Urea Nitrogen (BUN) tests in June 2020 (PRPTP - second testing event) and 0 percent in Alanine Aminotranferase (ALT), Amylase, Aspartate Aminotranferase (AST), Calcium, Chloride, Creatinine Kinase, Glucose, Potassium, Sodium and Urea Nitrogen (BUN) tests in October 2020 (PRPTP - third testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on May 21, 2021, that the laboratory did not take corrective actions on those testing events.
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 (PRPTP) records review and laboratory general supervisor interview on May 21, 2021 at 9:40 AM, 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 (PRPTP) records and results were reviewed from February 2021 to March 2021. 2. Review of Proficiency Testing records showed that the laboratory obtained unsatisfactory results of 16 percent in Differential White Blood Cell for 5 parameter instrument, 0 percent in Red Blood Cell (RBC), 20 percent in Hematocrit (HCT), 20 percent in Hemoglobin (HGB), 0 percent in White Blood Cell (WBC) and 20 percent in Platelets tests on July 2021 (PRPTP second testing event) and 80 percent in Differential White Blood Cell for 5 parameter Instrument in November 2020 (PRPTP third testing event) and February 2021 (PRPTP first testing event). No remedial actions were taken. 3. The general supervisor confirmed on May 21, 2021, that the laboratory did not take corrective actions in those testing events.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235

	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review and laboratory general supervisor interview on May 21, 2021 at 10:05 AM, it was determined that the laboratory failed to follow the established schedule for testing personnel competence evaluation. The findings include: a. The laboratory general supervisor stated that personnel competence evaluation must be performed every year. b. Review of the Clinical Consultant (CC # 14589) personnel files did not include competence evaluations. c. The last competence evaluation of the CC was in year 2019.
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 syphilis serology quality control records review from February 23, 2021 to May 21, 2021 and laboratory general supervisor interview at 10:25 AM on May 21, 2021, it was determined that the laboratory failed to perform syphilis serology test as required by manufacturer's instructions by the ASI RPR method. The findings include: 1. The laboratory syphilis serology (Rapid Plasma Reagin - RPR) quality control were review from February 23, 2021 to May May 21, 2021. 2. The manufacturer's requires that the laboratory must perform the needle calibration, needle preventive maintenance, verify the rotator rpm, rotator circumference and monitor the room temperature in the laboratory. 3. From February 23, 2021 to May 21, 2021, the syphilis serology quality control showed that the laboratory did not document nor verify the needle calibration, rotator rpm, rotator circumference, the room temperature monitoring in the RPR (Rapid Plasma Reagin) testing area in those days. 4. The laboratory processed and reported sixty seven (67) RPR (Rapid Plasma Reagin) patient's samples tests from February 23, 2021 to May 21, 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 (PRPTP) records review from February 2020 to March 2021 and laboratory general supervisor interview on May 21, 2021 at 10:05 AM, it was determined that the laboratory director failed to establish and follow a 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 March 2021. 2. Review of Proficiency Testing (PRPTP) records showed that the laboratory obtained unsatisfactory results of : a. 0 percent in syphilis serology (qualitative) tests in May 2020 (PRPTP first testing event). No remedial actions were taken. b. 0 percent in Creatine Kinase and Lipase test in February 2020 (PRPTP first testing event), 0 percent in Alanine Aminotranferase (ALT), Amylase, Aspartate Aminotranferase (AST), Calcium, Chloride, Creatinine Kinase, Glucose, Potassium, Sodium and Urea Nitrogen (BUN) tests in June 2020 (PRPTP - second testing event) and 0 percent in Alanine Aminotranferase (ALT), Amylase, Aspartate Aminotranferase (AST), Calcium, Chloride, Creatinine Kinase, Glucose, Potassium, Sodium and Urea Nitrogen (BUN) tests in October 2020 (PRPTP - third testing event). No remedial actions were taken. c. 16 percent in Differential White Blood Cell for 5 parameter instrument, 0 percent in Red Blood Cell (RBC), 20 percent in Hematocrit (HCT), 20 percent in Hemoglobin (HGB), 0 percent in White Blood Cell (WBC) and 20 percent in Platelets tests on July 2021 (PRPTP second testing event) and 80 percent in Differential White Blood Cell for 5 parameter Instrument in November 2020 (PRPTP third testing event) and February 2021 (PRPTP first testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on May 21, 2021, 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 February 23, 2021 to May 21, 2021 and laboratory general supervisor interview at 10:25 AM on May 21, 2021, it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems (syphilis serology test RPR quality control as required by manufacturer's instructions). The findings include: 1. The laboratory did not document nor verify the needle calibration, rotator rpm, rotator circumference, the room temperature monitoring in the RPR (Rapid Plasma Reagin) testing from February 23, 2021. Refer to D5411.