Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2044188	10/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Domus	Carretera 486 Km 1 Hm 9 Barrio Zanjas, Camuy, 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
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 (PRPT) records review (year 2021-2022) 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 test. The findings include: 1. Proficiency testing records review from February 2021 to September 2022. (review on 10/21/22 at 9:30 a.m.) 2. The PRPT review on 10/21/22 at 9:30 a.m. , showed that the laboratory did not take and document corrective actions when it obtained an unsatisfactory results in the first testing event performed in February 2022 . Tests with unsatisfactory results: 40 % - Chloride, 40 % - phosphorus, 60 % - Sodium 3. The laboratory director confirmed on October 21, 2022 at 9:45 a.m., that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry tests.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this

	section. This STANDARD is not met as evidenced by: Based on prothrombin time (PT) quality control records (year 2021-2022) , patients worksheet records (2021-2022) and interview with the laboratory director on October 21, 2022 , it was determined that the laboratory did not verify the normal patients prothrombin time (PT) mean of the tromboplastin PT reagent prior to report patient's INR (International Normalized ratio) results. The findings include: 1. On October 21, 2022 at 12:20 p.m. , the patients worksheet records showed that the laboratory used the thromboplastin reagent lot number L02B-L035A (expiration date: 2/3/24) from 9/15/2021 to 2/17/2022 and from 7/30/2022 to 10/21/2022. 2. The PT quality control records showed that the laboratory did not calculate nor incorporates the current and pertinent normal patient PT mean for this reagent lot, when it reports 192 out of 192 patient's INR (International Normalized ratio) results from 9/15/2021 to 2/17/2022 and from 7/30/2022 to 10/21/2022. 3. The PT patients worksheet records showed that the laboratory used the former normal patient PT mean of 12.1 seconds to calculate and report the INR from 9/15/2021 to 2/17/2022 and from 7/30/2022 to 10/21 /2022. This mean was calculated for the tromboplastin reagent lot number 373323 that was placed in routine use on 10/27/2021. 4. The laboratory director confirmed on October 21, 2022 at 12:30 P.M., that the laboratory did not calculate nor incorporate the normal patient PT mean for the thromboplastin reagent in use lot number L02B-L035A (expiration date: 2/3/24) from 9/15/2021 to 2/17/2022 and from 7/30/2022 to 10/21/2022.
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, QA assessment records review (year 2021-2022) and interview with the laboratory director interview , 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 the patient's final test reports. The findings include: 1. Review of the quality assessment program showed that evaluations related to the laboratory turn around time and the patient's final test reports. must be evaluated each six month. The evaluations and findings , if any, must be documented in the QA records.(review on October 21, 2022 at 10:45a.m.) 2. Review of the quality assessment record showed that the last turn around time and patient's final test reports evaluation was performed on 2021. (review on October 21, 2022 at 10:50a.m.) 3. The laboratory director confirmed on October 21, 2022 at 10:55a.m., that the laboratory failed to perform the evaluations of turn around time and the patient's final test reports.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

	This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (2021-2022) and laboratory director interview on October 21, 2022 at 1:00 p.m. it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2094 (the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in routine chemistry test).
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 PT quality control records review (year 2021-2022) and laboratory director interview on October 21, 2022 at 12:50 p.m., it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5545 (the laboratory did not verify the normal patients prothrombin time (PT) mean of the tromboplastin PT reagent prior to report patient's INR (International Normalized ratio) results).