Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1067613	09/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Metropolitano De La Montana	Calle Isaac Gonzalez, Utuado, 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**
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 normal patient PT (prothrombin time) mean records (2022-2023), thromboplastin reagent log records (2021-2023) review and interview with the laboratory director on September 5, 2023 at 9:10 AM, it was determined that the laboratory did not calculate nor incorporates the current and pertinent normal patient PT mean when it reports 27 out of 27 patient's INR (International Normalized ratio) results from June 12, 2023 to September 4, 2023. The findings include: 1. On September 5, 2023 at 9:10 AM, the thromboplastin reagent log records showed that the laboratory used the thromboplastin reagent lot number 549786,exp. date : 9/24/23 since June 12, 2023. 2. The normal patient PT (prothrombin time) mean 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 27 out of 27 patient's INR (International Normalized ratio) results from June 12, 2023 to September 4, 2023. 3. The normal patient PT (prothrombin time) mean records showed that the laboratory used the former normal patient PT mean of 10.4 seconds to calculate and report the INR from June 12, 2023 to September 4, 2023. This mean was calculated for the tromboplastin reagent lot number 549780 that was placed in routine use on 7/20/2021. 4. The laboratory was decertificated in July 2022 for PTand PTT (partial thromboplastin time) test. The laboratory failed to attain satisfactory performance for these tests in two consecutive testing events (third testing event 2021 and first testing event 2022). 5. The laboratory began to test coagulation test in June 12, 2023 after obtain two consecutive satisfactory results. 6. The laboratory director confirmed on

	September 5, 2023 at 9:30 , that the laboratory did not calculate nor incorporate the normal patient PT mean for the thromboplastin reagent in use (lot number 549786) from June 12, 2023 to September 4, 2023.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on coagulation quality control records review (2022-2023) , and interview with the laboratory director on September 5, 2023 at 11:00A.M., it was determined that the laboratory did not calculate nor incorporates the current and pertinent normal patient PT mean when it reports 27 out of 27 patient's INR (International Normalized ratio) results from June 12, 2023 to September 4, 2023. Refer to D5545