Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1079617	05/15/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Capa	Plaza Quintana Carr Pr-111 Km 11 Hm 5, Moca, 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 (QA) records review (year 2023-2024) and interview with the laboratory testing personnel (MT-7125) interview on May 15, 2024 at 9:00 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests The findings include: 1. Review of the quality assessment program showed that evaluations to patient test request must be evaluated every six month . (review on May 15, 2024 at 9:00 A.M) 2. Review of the quality assessment records showed that the last evaluation to patient test requests was performed in July 2023.(review on May 15, 2024 at 9:03A.M) 3. The laboratory testing personnel confirmed that evaluations to test request scheduled for January 2024 was not performed. (review on May 15, 2024 at 9:04 A.M)
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on human chorionic gonadotropin (hCG) test quality control records review (2023-2024) , and laboratory testing personnel (MT-7125) interview on May 15, 2024 at 10:17 A.M., it was determined that the laboratory did not evaluate the new lots of hCG test for positive and negative reactivity prior to placing it in routine use. The findings include: 1. On May 15, 2024 at 10:17 AM, the laboratory testing personnel stated that the laboratory performs hCG tests. 2. The hCG quality control parallel check worksheet records were reviewed on May 15, 2024 at 11:20 A.M. from January 5, 2023 to mAY 15, 2024 and showed that the laboratory did not evaluate the new lots of hCG test for positive and negative reactivity prior to placing it in routine use. 3. Review of the hCG quality control worksheet records on mAY 15, 2024 at 11: 20 AM showed that the following lots that the laboratory used in 2023 -2024 : lot exp date date in use patient report 23006 3/31/23 1/5/23 18 624190 7/17/24 10/30/23 7 31003 10/31/25 2/28/24 19 4. The laboratory testing personnel confirmed on May 15, 2024 at 10:30 A.M., that the laboratory did not evaluate the new lots of hCG tests for positive and negative reactivity prior to placing it in routine use.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on white blood cells (WBC) differential results comparison records review , (year 2023-2024) and laboratory testing personnel (MT-7125) interview on May 15, 2024 at 9:10 A.M, it was determined that the laboratory failed to evaluate and define each six month the relationship between the manual cell differential and automatic cell differential. The findings include: 1. The laboratory performed automatic cell differential by Sysmex XN -L hematology system. 2. The laboratory establishes that the evaluation of the relationship between the manual cell differential and automatic cell differential was perform each six month. (review on May 15, 2024 at 9:12 A.M) 3. The WBC differential results comparison records showed that the laboratory did not evaluated each six month the relationship of the WBC differential results between the manual method and the Sysmex XN-L system since July 2023.(review on May 15, 2024 at 9:12 A.M) 4. The laboratory testing personnel confirmed on May 15, 2024 at 9:15 A.M, that the laboratory failed to evaluate each six month the relationship between the manual cell differential and automatic cell differential by hematology system since July 2023.
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 records review (year 2023-2024) and interview with the laboratory testing personnel (MT-7125) interview on May 15, 2024 at 9: 05 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 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 May 15, 2024 at 9:08 A.M) 2. Review of the quality assessment record showed that the last turn around time and patient's final test reports evaluation was performed in July 2023. (review on May 15, 2024 at 9:10 A.M) 3. The laboratory testing personnel confirmed on May 15, 2024 at 9:10 A.M., that the laboratory failed to perform the evaluations of turn around time and the patient's final test reports.
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 endocrinology quality control records review (2023-2024) , it was determined that the laboratory director did not ensure that quality control procedures related to hCG quality control procedures were performed as established by the manufacturer's instructions. Refer to D5471.
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 (year 2023-2024) and laboratory director interview on May 15, 2024 at 11: a.m 2:15 P.M., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records (2023-2024) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic and postanalytic systems. (review on May 15, 2024 at 11:10 A.M.) 2. The laboratory testing personnel (MT-7125) confirmed on May 15, 2024 AT 11:10 A.M. , that the laboratory failed to evaluate the requirements for laboratory general systems, preanalytic and postanalytic systems. Refer to D5391 and D5891.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: 1. Based on personnel records review (2023-2024) and laboratory testing personnel (MT-7125) interview on May 15, 2024 at 8:45 A.M., it was determined that the laboratory failed to follow the established schedule for clinical consultant evaluation The findings include: a. The laboratory schedule for clinical consultant competence evaluation showed that it must be performed every year. b. The laboratory did not perform the clinical consultant competence evaluation since 2022. c. The testing personnel stated on May 15, 2024 at 8:50 A.M.that the year 2023 competence evaluation were not available in the laboratory. 2. Based on personnel records review and laboratory testing personnel interview on May 15, 2024 at 8:45 A.M., it was determined that the technical supervisor failed to provide annually the competence evaluation to the testing personnel that performed the high and moderate complexity tests. The findings include: A. The technical supervisor failed to perform the annual competency evaluation to the testing personnel (MT # 7125, 8949 and 9051) that include at least the following requirements since 2022 : a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b. Monitoring, recording and reporting of test results. c. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. d. Direct observation of performance of instrument maintenance and function checks. e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. B. The testing personnel stated on May 15, 2024 at 8:55 A.M.that the year 2023 competence evaluation of the testing personnel were not available in the laboratory.