Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1007051	06/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hrp Labs-Laboratorio Clinico	Avenida Domenech 300 Y 302, Hato Rey, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the lack of daily checks records of temperature's and interview with the laboratory director on June 13, 2024 at 12:43 PM; it was determined that the laboratory fail to monitor and document the temperature of the transport cooler used for the storage of patient samples referred from other laboratories. The laboratory transport from other laboratories 11,984 patient samples in the year 2023 and 8,674 from January to June 2024. The findings include: a. On June 13, 2024 at 10:56 AM; the daily checks of the cooler temperature was requested and it was not available. b. On June 13, 2024 at 12:43 PM; the laboratory director confirmed that the laboratory fail to monitor and document the transport cooler temperature where the patient samples were transported to HRP LABS-Laboratorio Clinico (year 2023 and 2024). The laboratory transport from other laboratories 11,984 patient samples in the year 2023 and 8,674 from January to June 2024.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for

	specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on endocrinology Levy-Jennings quality control graphs, laboratory written procedure manual, Bio rad immunoassay plus control insert and laboratory director interview on June 13, 2024 at 2:38 PM, it was determined that the laboratory did not include, in the written procedure manual what corrective action they will be taken and document when Free thyroxine (Free T4) quality control graphs showed a trend from October 1, 2023 to October 31, 2023, and April 1, 2024 to April 30, 2024. The laboratory processed and reported 59 for the Free T4 test on October 2023 and 82 patients on April 2024. The findings include: a. The laboratory performed Free T4 in the Access 2 immunoassay system by Beckman Coulter. b. On June 13, 2024 at 2:02 PM the quality control records were reviewed from January 2023 to May 2024. Review of the quality control graphs of October 2023 and April 2024, showed that the laboratory failed to take corrective actions when the three control material levels for Free T4, showed a trend with more than 10 points below the established mean. c.The laboratory procedure manual was reviewed on June 13, 2024 at 2:20 PM, and it showed that the laboratory did not include what corrective action they will be taken and document when the quality control of the three levels of controls were 10 points below or above the established mean. d .The laboratory director confirmed on June 13, 2024 at 2:38 PM, that the written procedure manual did not include what corrective actions were taken when the three control material levels for Free T4 showed a trend with more than 10 points below the established mean from October 1, 2023 to October 31, 2023, 59 patients were processed and reported for the Free T4 test, and from April 1, 2024 to April 30, 2024, 82 patients were processed and reported for the Free T4 test.
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: 1. Based on laboratory freezer termperature records (year 2024), manufacturer's instructions review, tour of the laboratory facilities and laboratory director interview

	on June 13, 2024 at 1:50 PM; it was determined that the laboratory did not take any remedial actions, when thre freezer charts showed temperature outside the manufacturer's instructions established ranges for free T4 calibrator, total T4 calibrator, human chorionic gonadotropin quantitative calibrator, CA-19-9 calibrator and Vitamin D total calibrator. The freezer was out of the manufacturer storage temperature range in 69 out of 136 days from January 2024 to June 2024. The findings include: a. On June 13, 2024 at 8:57 AM, the tour of the laboratory was performed. The freezer thermometer was observed, showing a temperature of -9 C. b. On June 13, 2024 at 1:25 PM, the laboratory frezeer temperature records were reviewed from January, 2024 to June, 2024. c. The manufacturer's instructions showed the following required storage temperature ranges: for free T4 calibrator until -20 C, for total T4 calibrator until -15C, for human chorionic gonadotropin quantitative calibrator until -20C, for CA-19-9 calibrator until -20C and for Vitamin D total calibrator from - 30C- -15C d. The laboratory director confirmed on June 13, 2024 at 1:50 PM, that the laboratory did not take any remedial actions when the freezer temperatures were outside of the manufacturer's range. 2. Based on chemistry lipid linearity kit manufacturer's instruction, tour of the laboratory facilities and laboratory director interview on June 13, 2024 at 10:30 AM; it was determined that the laboratory failed to follow the manufacturer's requirements for the conditions of storage for the lipid linearity kits. The lipid linearity kit was storage out of manufacturer's temperature range 11 days out of 11 days. a. On June 13, 2024 at 8:57 AM, the tour of the laboratory was performed and showed that the lipids linearity kits were stored on the freezer at -9 C. b. The lipid test linearity kit (Lot. 07041 exp. 11/29 /2025) box was observed. The box showed as storage temperature 2-8C. The lipid linearity kit was received on June 3, 2024. c. The laboratory director confirmed on June 13, 2024; that the laboratory failed to follow the conditions of storage that was established by the manufacturer's instruction. The lipid linearity kit was storage out of manufacturer's temperature range 11 days out of 11 days.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on the room temperature and humidity preventive maintenance records and interview with the laboratory director on June 13, 2024 at 10:10 AM; it was determined that the laboratory use whiteout when making corrections on the room temperature and humidity records in the year 2024. The findings include: a. On June 13, 2024 at 10:00 AM the room temperature and humidity records were reviewed and showed that the laboratory used whiteout to make corrections during the year 2024. b. On June 13, 2024 at 10:10 AM, the laboratory director confirmed that the laboratory use whiteout to make corrections in the preventive maintenance records.
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 review of the chemistry procedure manual, evaluation of calculated data records and interview with the laboratory testing personnel on June 13, 2024 at 1:20 PM, it was found that the laboratory did not evaluate the calculated data for chemistry test since June 30, 2023. The findings include: a. The laboratory included in the chemistry procedure manual, the quality assessment (QA) evaluations to be performed. As part of the QA program, the laboratory must evaluated their calculated data; biannually. (reviewed on June 13, 2024 at 12:25 PM) b. Review of the evaluation of chemistry calculated data showed that, in the year 2023, the laboratory only performed the evaluation of calculated data on June 30, 2023. c. The laboratory testing personnel stated on June 13, 2024 at 1:20 PM that the evaluations were not performed biannually in the year 2023.
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 chemistry and endocrinology quality control records review, and interview with the laboratory director on June 13, 2024 at 2:45 PM it was determined that the laboratory director did not ensure that the quality control procedures were performed as established by the manufacturer's instructions and as their procedure manual established. Refer to D5311, D5403, D5411.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on chemistry quality control records review, procedure manual and laboratory general director interview on June 13, 2024 at 2:40 PM, it was determined that the general supervisor failed to ensure compliance with the requirement for analytic systems and postanalytic systems. Refer to D5787, D5891