Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658036	02/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Pavia Caguas	Ave Luis Munoz Marin Urb Mariolga, Caguas, 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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of quality control of culture media and interview with the laboratory testing personnel on February 15, 2023 at 11:31 AM; it was determined that the laboratory processed 25 out of 25 patient's with a Hektoen enteric agar culture media with exceeded the expiration date from April 28, 2022 to May 19, 2022. The findings include: a. The laboratory used a Hektoen enteric agar for stool culture. b. On February 15, 2023 at 11:28 AM, the cultures media quality control were reviewed. The quality control record showed that the Hektoen enteric agar lot # 441343 with expiration date of April 27, 2022 was used from april 28, 2022 to May 19, 2022. The records showed that a new lot # 488733 was received on May 20, 2022. c. On February 15, 2023 at 11:31 AM, the laboratory testing personnel stated that the laboratory used an expired Hektoen agar culture media to perform and process 25 patient's out of 25 patient's stool culture from April 28, 2022 to May 19, 2022. d. The laboratory did not check the positivity and negativity of culture media nor the ability to support growth, when they used the expired culture media with patient samples.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records review (year 2021-2022) and interview with the laboratory technical consultant on February 15,2023, at 1:20 P. M., it was determined that the laboratory failed to perform at least , every six months, the calibration verification procedures for the glycosylated hemoglobin test processed by the Tosoh G8 HPLC Analyzer. The findings include: 1.The laboratory used the Tosoh G8 HPLC Analyzer for glycosylated hemoglobin test. 2. The review of routine chemistry calibration verification records showed that the calibration verification procedures for the glycosylated hemoglobin test was performed each six months. 2.On February 15, 2023 at 1:25 P.M. review the routine chemistry calibration verification records showed that the glycosylated hemoglobin test calibration verification procedure was performed for year 2022 on November 15,2022. The laboratory failed to performed the glycosylated hemoglobin calibration verification procedure in May 2022. 3.On February 15,2023 at 1:30 P.M., the technical consultant confirmed that the glycosylated hemoglobin calibration verification procedure was performed for year 2022 on November 15,2022. 4.The laboratory processed a total of 4,324 glycosylated hemoglobin patient test from July,2022 to October,2022
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 laboratory comparison test results records review (year 2022) and interview with the laboratory technical consultant on February 15,2023, at 2:00 P.M., it was determined that the laboratory failed to perform and evaluate, twice a year, the relationship of the following tests performed by the Dxl 800 Access and Access 2 : CK-MB, Troponin I, Estradiol, Hcg and TSH tests during year 2022. The findings include: 1.The laboratory used the Dxl 800 Access and Access 2 to perform CK-MB (creatine kinase- MB) , Troponin I, Estradiol, (human chorionic hormone) and TSH (

	thyroid stimulating hormone) tests. 2.On February 15, 2023, at 2:05 P.M., review of the laboratory comparison test results showed that the laboratory performed the comparison of tests results for: CK-MB, Troponin I, Estradiol, Hcg and TSH tests only on June 8, 2022. 3. On February 15,2023, at 2:10 P.M., the technical consultant confirmed that the laboratory failed to perform and evaluate twice a year . 4.The laboratory processed and reported a total of 2,703 patient's test since June 8, 2022.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on manufacturer's storage instructions for chemistry controls and calibrators (Uni Cell Beckman Coulter DxC-800 system) , chemistry's freezer temperature records reviewed (years 2022 and 2023) and interview with general supervisor on February 15, 2023, at 11:15 A.M., it was determined that the laboratory failed to take and document corrective action when the chemistry freezer temperature was out of the established range (-15 to -20 C) 303 days out of 365 days of year 2022 and 13 days out 46 days of year 2023. The findings include: 1. The laboratory use the a Uni Cell Beckman Coulter DxC-800 system to processed routine chemistry tests and use Synchron controls and calibrators. 2.On February 15, 2023, at 11:15 A.M., review the chemistry controls and calibrators manufacturer's instructions instructed the laboratory to store the controls and calibrators at a temperature a ranges of -15 C to -20 C. 3. On February 15,2023 at 11:20 A.M., review of the chemistry freezer temperature records showed a temperature range of -4 C to-13C from January 1, 2022, to December 31,2022. (303 days out of 365 days below established ranges) 4.On February 15,2023 at 11:20 A.M., review of the chemistry freezer temperature records showed a temperature ranges of -11 C to -14 C and -21C to -23.9 C from January 1, 2023 to February 15,2023. (13 days out of 46 days below and over establishes ranges) 5. On February 10,1023, at 11:45 A.M., the general supervisor confirmed that the laboratory failed to take and document corrective action when the chemistry freezer temperature were out of the required storage temperature range. 6.The laboratory processed and reported a total of 1,904,183 patient samples for chemistry from January 1, 2022, to February 15,2023.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on quality control records review (year 2021-2022) , laboratory supervisor and laboratory technical supervisor interview on February 15, 2022 at 2:50 P.M., it was determined that the technical consultant failed to ensure compliance with the

	requirements for analytic systems. Refer to D5775 (failed to perform twice a year the comparison test results between Dxl 800 Access and vs Access 2)
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 laboratory quality control records review (year 2021-2022) and interview with the laboratory director on February 15, 2023 at 2:30 P.M. , it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. The findings include: 1. The laboratory processed and reported 25 out of 25 patient's with a Hektoen enteric agar culture media with exceeded the expiration date from April 28, 2022 to May 19, 2022. Refer to D5417. 2.The laboratory failed to perform at least every six months the calibration verification procedures for the glycosylated hemoglobin test processed by the Tosoh G8 HPLC Analyzer. Refer to D5439. 3. The laboratory failed to perform twice a year the comparison results (correlation) between Dxl 800 Access vs Access 2 for the CK-MB, Troponin I, Estradiol, Hcg and TSH tests. Refer to D5775. 4. The laboratory failed to take and document corrective action when the chemistry freezer temperature was out of the established range (-15 to -20 C). Refer to D5785.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of quality control of culture media records and interview with the laboratory testing personnel on February 15, 2023 at 11:31 AM, it was determined that the technical supervisor failed to ensure that culture media with exceeded expiration were use by the testing personnel , also did not establish any quality control procedure to be perform when they used the expired reagents. The findings include: a. The testing personnel used an Hektoen enteric agaa expired culture media from April 28, 2022 to May 19, 2022. No quality control procedure was established by the TS when the laboratory had in used the expired material.
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 laboratory quality control records review (year 2022) and interview with the laboratory general supervisor on February 15, 2023 at 2:40 P.M. , it was determined that the laboratory supervisor did not comply with his daily supervisor duties, when the testing personnel used expired culture media, did not perform calibration verification procedures and did not ensure that the storage temperatures of the chemistry control and calibrator material were within the established manufacturer's range. Refer to D5417 (use of expire culture media) Refe to D5439 (did not perform calibration verification procedures Refer to D5785 (store control and calibrator material outside the established temperature range)
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on quality control records review (year 2021-2022) , laboratory supervisor and testing personnel interview on February 15, 2022 at 2:50 P.M., it was determined that testing personnel failed to ensure compliance with the requirements for analytic systems. Refer to D5417 (the testing personnel used expire culture media) Refe to D5439 (the testing personnel did not perform calibration verification procedures) Refer to D5785 (the testing personnel did not ensure that the control and calibrator material were stored under the required temperature range)