Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0673305	01/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Hosp Metropolitano San German	Calle Javilla #8, San German, 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
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on hematology quality control records review (years 2018-2019) and laboratory general supervisor interview at 9:00 AM on January 16, 2020, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for body fluids cell counts. Refer to D 5543.
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 quality control records review (years 2018-2019) and laboratory director general supervisor interview at 11:00 AM on January 16, 2020, it was determined that the laboratory failed to perform at least every 6 months the calibration verification procedures for the Arterial Blood Gases (pH, pCO2, P02) tests processed by the Cobas b221 system. The findings include: 1. The laboratory uses a Cobas b221 system for Arterial Blood Gases (pH, pCO2, P02) tests. 2. From January 2018 to January 2020, the records showed that the laboratory did not perform at least every 6 months the calibration verification procedures for the Arterial Blood Gases (pH, pCO2, P02) tests processed by the Cobas b221 system. 3. The laboratory processed and reported three hundred seventy six (3,076) Arterial Blood Gases (pH, pCO2, P02) patient's samples tests those days. 3. The laboratory general supervisor stated on January 16, 2020, that the laboratory did not perform at least 6 months the calibration verification procedures for Arterial Blood Gases (pH, pCO2, P02) tests processed by the Cobas b221 system.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on hematology body fluids count testing records review (years 2018-2019) , lack of quality control records and laboratory general superivsor interview on January 16, 2020 at 9:00 AM, it was determined that the laboratory failed to include one control material each 8 hours of operation when manual body fluids (ascitic, pleural and Cerebro Spinal fluids) cell counts were performed by hemocytometer. The findings include: 1. The records showed that the laboratory performed manual cell counts (ascitic, pleural and Cerebro Spinal fluids) by the hemocytometer. 2. From January 2018 to January 2020, the records showed that the laboratory did not include one control material each 8 hours of operation when 13 out 13 body fluids patients specimens were processed for (ascitic, pleural and Cerebro Spinal fluids) cells counts by the hemocytometer. 3. The laboratory processed and reported thirteen (13) body fluids patients specimens were processed for (ascitic = 6, pleural = 4 and Cerebro Spinal fluids = 3) cells counts. 4. The laboratory general supervisor confirmed on January 16, 2020, that the testing record not show any documentation of the control procedure.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on hematology and routine chemistry quality control records review (years 2018-2019) and laboratory general supervisor interview at 11:30 AM on January 16, 2020, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control and quality assessment requirements. Refer to D 6093.
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 hematology and routine chemistry quality control records review (years 2018-2019) and laboratory general supervisor interview at 11:30 AM on January 16, 2020, it was found that the laboratory director did not assure that quality control procedures were follow related to calibration verification for Cobas b221 (ABG) and any control material when cell counts were performed by hemocytometer. The findings include: 1. The laboratory failed to perform at least every 6 months the calibration verification procedures for the Arterial Blood Gases (pH, pCO2, P02) tests processed by the Cobas b221 system. Refer to D5439. 2. The laboratory failed to include one control material each 8 hours of operation when manual body fluids (ascitic, pleural and Cerebro Spinal fluids) cell counts were performed by hemocytometer. Refer to D5543.
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 hematology and routine chemistry quality control records review (years 2018-2019) and laboratory general supervisor interview at 11:30 AM on Janjuary 16, 2020, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. Refer to D5439 and D5543.
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 hematology and routine chemistry quality control records review (years 2018-2019) and laboratory geneal supervisor interview on January 16, 2020 at 11:30 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D5439 and D5543.