Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1092622	03/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Irizarry Guasch	Carr Pr-506 Solar 3 Legacy Office Park, Ponce, 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 written procedure manual review, lack of sperm count quality control records and laboratory general supervisor interview on March 21, 2023 at 12: 15 P.M. , it was determined that the laboratory failed to ensure compliance with the analytic system requirements for sperm cell counts. The findings include: 1. The hematology written procedure manual did not include written control procedures for perform sperm count analysis. Refer to D5403. 2. The laboratory failed to include one control material each 8 hours of operation when 25 of 25 patients specimens were processed for sperm count by the Cell -VU system from March 2, 2022 to March 15, 2023. Refer to D5543.
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 Hematology procedure manual review and laboratory general supervisor interview on March 21, 2023 at 11:50 A.M. , it was determined that the laboratory did not include written control procedures for perform sperm count analysis (March 2,2022 to March 21, 2023.) The findings include: 1. The laboratory performed count analysis by Cell - VU system. 2. Review of the hematology procedure manual showed that the laboratory did not included written policies for control procedures when performed sperm count analysis. (review on 3/21/23 at 11:50 a.m.) 3. The general supervisor confirmed on March 21, 2023 at 11:50 AM. that the sperm count written procedures did not include the requirements for control procedures to perform sperm count analysis.
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 statistics laboratory record (march 2022 to march 2023) , lack of sperm count quality control records and general supervisor interview on March 21, 2023 at 12:15 P.M. , it was determined that the laboratory failed to include one control material each 8 hours of operation when 25 of 25 patients specimens were processed for sperm count by the Cell -VU system from March 2, 2022 to March 15, 2023. The findings include: 1. The laboratory performed sperm count testing by Cell -VU system. (review on 3/21/23 at 11:50 a.m.) 2. The review of statistics laboratory record (march 2022 to march 2023) showed that the laboratory performed and reported 25 sperm count patient results from March 2, 2022 and did not include one control material each 8 hours of operation. (review on 3/21/23 at 11:55 a.m.) 3. The laboratory general supervisor confirmed on March 21, 2023 at 12:15 P.M., that the laboratory did not include one control material when performed and reported 25 sperm count patients samples from march 2022 to march 2023 .
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 lack of sperm count quality control records (year 2022-2023) and laboratory general supervisor interview on March 21, 2033 at 12:15 P.M., it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the hematology quality control 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 lack of sperm count quality control material and interview the laboratory supervisor on March 21, 2023 at 12:15 P.M. , it was determined that the laboratory director failed to establish the quality control procedures for the sperm count test. The findings include: 1. The laboratory did not include written control procedures for perform sperm count analysis. Refer to D5403. 2. The laboratory failed to include one control material each 8 hours of operation when 25 of 25 patients specimens were processed for sperm count by the Cell -VU system from March 2, 2022 to March 15, 2023. 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 lack of sperm count quality control material and interview the laboratory supervisor on March 21, 2023 at 12:15 P.M. , it was determined that the laboratory general supervisor failed to establish the quality control procedures for the sperm count test. Refer to D5403 and D5543.