Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0000598	01/26/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Hospital San Antonio	Calle Dr Ramon Emeterio Betances 18 Norte, Mayaguez, 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
D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on P, uerto Rico Proficiency Testing Program records reviewed (2021-2022) and laboratory general supervisor interview on January 26, 2023 at 10:00 A.M., it was determined that the laboratory failed to participate in the routine chemistry second testing event performed in June 2022. The findings include: 1. Proficiency testing records were reviewed from February 2021-December 2022. 2. The laboratory did not participate in the second testing event of routine chemistry (routine chemistry, urinalysis, urine sediment) performed in June 2022, a testing score of 0 % was obtained . (review on 1/26/23 at 10:10 a.m.) 3. The laboratory general supervisor confirmed on January 26, 2023 at 10:20 A.M., that the laboratory failed to participate in the second testing event of routine chemistry specialty in June 2022. 4. The laboratory processed and reported 9,708 routine chemistry patients samples from February 2022 to October 2022.
D2100	ENDOCRINOLOGY CFR(s): 493.843(c)

	Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2021-2022) and laboratory general supervisor interview on January 26, 2023 at 10:15 A.M., it was determined that the laboratory failed to participate in the endocrinology second testing event performed in June 2022. The findings include: 1. Proficiency testing records were reviewed from February 2021-December 2022. 2. The laboratory did not participate in the second testing event of endocrinology performed in June 2022 , a testing score of 0 % was obtained . (review on 1/26/23 at 10:20 a.m.) 3. The laboratory general supervisor confirmed on January 26, 2023 at 10:25 A.M., that the laboratory failed to participate in the second testing event of endocrinology sub-specialty in June 2022. 4. The laboratory processed and reported 209 endocrinology patients samples from February 2022 to October 2022.
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 Bacteriology procedure manual review and laboratory general supervisor interview on January 26, 2023 at 11:20 A.M., it was determined that the laboratory failed to include a written procedure to perform oxidase test in the laboratory. The findings include: 1. On January 26, 2023 at 11:20 AM the written procedure to perform oxidase test was requested. No written procedure was available. 2. On

	January 26, 2023 at 11: 25 AM the laboratory supervisor confirmed that the laboratory did not have a written procedure to perform oxidase test.
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 quality control of culture media record review (2022) , patient worksheet records (2022) and interview with the laboratory supervisor; it was determined that the laboratory performed seven (7) out of seven (7) Methicillin resistant Staphylococcus aureus (MRSA) culture with Spectra-MRSA media that exceeded the expiration date. The findings include: 1. The laboratory perform Methicillin resistant Staphylococcus aureus (MRSA) culture. (review on January 26, 2023 at 10:30 a.m.) 2. On January 26, 2023 at 10:37 AM the quality control record of culture media was reviewed and showed a Spectra-MRSA media Lot # 553298 with expiration date of November 21, 2022. The next new lot was received on November 25, 2022. 3. On January 26, 2023 at 10:50 AM the patient worksheet record was reviewed from November 22, 2022 to November 25, 2022 and showed that the laboratory used the expired culture media to perform and process Methicillin resistant Staphylococcus aureus (MRSA)culture for seven (7) patient's. 4. On January 26, 2023 at 10:58 AM the laboratory supervisor confirmed that the laboratory used a expired culture media to perform and process a Methicillin resistant Staphylococcus aureus (MRSA) culture for seven (7) patient's.
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 review of quality control of oxidase reagent test of Bacteriology specialty and interview with the laboratory supervisor on January 26, 2023 at 11:00 AM it was determined that the laboratory failed to document and identified to which patient's they performed the oxidase test from January 2022 to January 2023. The findings include: 1. On January 26, 2023 at 11:00 AM the quality control of oxidase reagent test was review and showed that the laboratory performed a weekly quality control for oxidase test. 2. On January 26, 2023 at 11:09 AM the oxidase test patient worksheet record was requested. No patient worksheet record was available. 3. The Laboratory general supervisor confirmed on January 26, 2023 at 11:15 AM that the laboratory failed to document and maintain the oxidase patient test records. She stated that they did perform oxidase test.

D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Program testing records review (2021-2022) and laboratory general supervisor interview on January 26, 2023 at 10: 30 a.m., it was determined that the laboratory director failed to ensure that the laboratory was enrolled in an HHS-approved proficiency testing program for the routine chemistry and endocrinology sub specialty . Refer to D2016 and D2100.
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 Bacteriology specialty culture of media records review (year 2022), patients worksheet record review, lack of oxidase test procedure manual and interview with the laboratory supervisor; it was determined that the laboratory director failed to ensure the compliance of quality control in Bacteriology specialty. Refer to D5403, D5417, D5787.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of laboratory personnel and interview with the laboratory supervisor on January 26, 2023 at 9:50 AM, it was found that the laboratory director did not hire a sufficient number of laboratory testing personnel compared to the hospital volume of annual test (241,073- annual test volume). The findings include: 1. On January 26, 2023 at 9:50 AM the laboratory testing personnel records was reviewed. 2. On January 26, 2023 at 9:55 AM the laboratory supervisor confirmed that the laboratory only have a one laboratory personnel per shift with a a one laboratory assistant. The hospital reported 241, 073 of annual test volume.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and

	maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Bacteriology specialty quality control records, lack of oxidase patient's worksheet record and interview with the laboratory supervisor; it was determined that the laboratory testing personnel failed to document and maintain the oxidase patient test record. Refer to D 5787.