

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>40D0711458</p>	<p>(X3) Date Survey Completed</p> <p>02/20/2025</p>
<p>Name of Provider or Supplier</p> <p>Laboratorio Clinico Y Bacteriologico San Antonio</p>	<p>Street Address, City, State</p> <p>1065 Avenida General Ramey Suite 1 San Antonio, Aguadilla, PR</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico y Bacteriologico San Antonio on February 20, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on February 20, 2025.</p>
<p>D5411</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: A. Based on daily maintenance records review (years 2024-2025), Dimension EXL 200 manufacturer instructions review and interview with the testing personnel on February 20, 2025 at 10:50 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions regarding to the established temperature range for cuvette on four (4) days of the year 2024 and 2025. The records showed that the laboratory processed and reported routine chemistry patient's specimen below the established temperature range. The findings include: 1. The laboratory uses Dimension EXL 200 Chemistry System to perform routine chemistry and endocrinology tests. (Review on February 20, 2025 at 10:15 A.M.). 2. On February 20, 2025 at 10:26 A.M., the Dimension EXL 200 manufacturer's instructions were reviewed. The manufacturer's instructions require a cuvette temperature range of 36.8 C to 37.2C for patient samples processing. 3. On February 20, 2025 at 10:38 A.M., the daily maintenance records review showed that the laboratory did not follow the manufacturer's instructions when the cuvette temperature was below and above the</p>

temperature range established by the manufacturer in the following days: Octobre 1, 2025; January 15, 2025; January 16, 2025; January 17, 2025. 4. The laboratory testing personnel confirmed during the interview on February 20, 2025 at 10:50 A.M., that the laboratory did not follow the manufacturer's instructions regarding to cuvette temperature requirements. B. Based on syphilis serology quality control records, manufacturer's instructions review and laboratory director interview on February 20, 2025 at 1:15 P.M., it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 292 out of 292 patient specimens were tested from January 2024 to December 2024. The findings include: 1. The laboratory uses the ASI reagent kit to perform patient syphilis serology test. Review of the ASI manufacturer's instructions on February 20, 2025 at 12:51 P.M., showed that the laboratory must remove and wash the needle at the end of the day. 2. On February 20, 2025 at 12:51 P.M., the syphilis serology quality control records were reviewed. The records showed that the laboratory did not perform the needle wash as required by the manufacturer, when they processed and reported patient specimens. 3. The laboratory director confirmed on February 20, 2025 at 1:15 P.M., that the laboratory did not follow the manufacturer's instructions related to the needle wash, from January 2024 to December 2024. The laboratory processed and reported 292 out of 292 patient specimens. C. Based on C- Reactive Patient (CRP) patient worksheet record, manufacturer' instructions review, freezer temperature records and laboratory director interview on February 20, 2025 at 12:42 P.M., it was determined that the laboratory failed to follow the manufacturer's instruction related to specimen storage on January 7, 2025 and January 27, 2025. The laboratory processed and reported five (5) patient specimens. The findings include: 1. The laboratory uses the ASI reagent kit to perform CRP test. Review of the ASI manufacturer's instructions on February 20, 2025 at 12:28 P.M., showed that if the samples cannot be tested, the patient samples, must be maintain them in their original tubes at 2-8C and test within 48 hours. Serum samples stored longer than 48 hours should be stored at -20C or below until testing. 2. On February 20, 2025 at 12:30 P.M., the CRP patient worksheet record were reviewed. The records showed that the laboratory collected one (1) patient specimen on January 7, 2025 and was processed on January 10, 2025. Also, the laboratory collected four (4) patient specimens on January 27, 2025 and were processed on January 30, 2025. 3. On February 20, 2025 at 12:36 P.M., the freezer temperature records were reviewed and showed that the freezer temperature was above -20 C in the following days: Days Temperature January 7, 2025 -13C January 10, 2025 -13C January 27, 2025 -12C January 30, 2025 -12C 4. The laboratory director confirmed on February 20, 2025 at 12:42 P.M., that the laboratory did not store the CRP patient specimens at the temperature established by the manufacturer.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
 CFR(s): 493.1252(b)

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
 Based on refrigerator temperature records, direct observation of chemistry and endocrinology reagents temperature ranges established by the manufacturer and interview with the laboratory testing personnel on February 20, 2025 at 11:48 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions for the temperature ranges of the reagents storage on the following days: December 2, 2024; December 6, 2024; December 16, 2024; December 26, 2024; January 7, 2025; January 8, 2025. The laboratory processed and reported 125 patient's samples. The findings include: 1. The refrigerator temperature records was reviewed on February 20 at 11:42 A.M., and showed that the temperature range established by the laboratory was between 2-10 C. 2. On February 20, 2025 at 11:45 A.M., the chemistry and endocrinology reagents stored in the refrigerator were observed and showed that the manufacturer established that the reagents temperature range must be between 2-8 C. The refrigerator temperature record showed that the temperature was out of acceptable reagent temperature range in the following days: Days Temperature Total of patients processed December 2, 2024 10 C 25 December 6, 2024 10 C 17 December 16, 2024 10 C 12 December 26, 2024 10 C 9 January 7, 2025 10 C 35 January 8, 2025 10 C 27 3. On February 20, 2025 at 11:48 A.M., the testing personnel confirmed that the refrigerator temperature was out of the range established by the manufacturer for reagent storage on the following days: December 2, 2024; December 6, 2024; December 16, 2024; December 26, 2024; January 7, 2025; January 8, 2025. The laboratory processed and reported 125 patient's samples.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment 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 daily maintenance, syphilis serology quality control record, CRP patient worksheet record and interview with the laboratory director on February 20, 2025 at 1:20 P.M.; it was determined that the laboratory director did not assure that the laboratory follows the manufacturer's instructions. Refer to D5411, D5413.