Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0693849	07/01/2026
Name of Provider or Supplier	**Street Address, City, State**	
St Thomas Clinical Reference Laboratory	Medical Art Complex Suite #9 Altona, St Thomas, VI	

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
D0000	A recertification survey was conducted July 1, 2026. The laboratory was found to be in compliance with condition level deficiencies. The following standard-level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policies, and interview with the Technical Supervisor (TS) according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to establish and follow written policies and procedures for conditions of specimen transportation for 2 of 2 years (2024 and 2025). Findings Included: 1) Review of the laboratory policy titled 'St. Thomas Clinical Reference Lab QA Lab Systems Manual' failed to define conditions of specimen preservation and transportation (i.e. temperatures), and stated the following on page 8: "Sample Collected by The Patient or Outside the Lab ...Once the sample arrives at the laboratory, the sample will be verified if the specimen complies with the shipment and sample transport requirements (detailed in manual sampling and in the reference laboratories) and the following procedures ..." 2) The laboratory failed to provide the the reference laboratories' shipment and sample transport requirements. 3) The laboratory's QA procedures did not state shipment and sample transportation requirements as the policy stated above. 4) In an interview on 7/1/2026 at 10:59 AM,

	the TS confirmed the laboratory failed to provide specimen preservation and transportation criteria within their policies.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory policy and procedures, test records, verification studies, lot verification studies, and interview with the Technical Supervisor (TS) according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to follow the manufacturer's instructions in establishing a new patient normal mean for 1 of 1 new lot of Dade Innovin reagents used for the Sysmex CA-600 analyzer. Findings Included: 1. Based on direct observation on July 1, 2026 at 11:50 AM, one Sysmex CA-600 analyzer (Serial Number 13545) was in use. 2. Review of the manufacturer's instructions 'Siemens Healthineers Dade Innovin 11528733_en Rev. 13' stated the following instructions on page 4 of 9: "The mean normal Prothrombin Time (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples and, where appropriate, using the coagulation analyzer used for the analysis. Follow appropriate laboratory guidelines for establishing an MNPT, if applicable. Use of CLSI guideline is recommended." 3. Review of the laboratory's policy titled 'St. Thomas Clinical Reference Laboratory Manual for Coagulation Equipment Sysmex CA-600' stated (translated from Spanish to English): "1. Establish a New Normal Patient Mean (Geometric Mean PT Value in Healthy Subjects) 2. Perform a comparison between old and new PT reagent lots (parallel testing) 3. Program the ISI and the Normal Patient Mean in the analyzers ... INR Calculation = Patient PT divided by Mean PT to the power of the ISI. The ISI is assigned to each reagent lot and listed on the thromboplastin reagent package insert .... With every new PT reagent lot (innovin) or every 6 months (whichever comes first), verify the following: 1. Verify the reference INR value using 20 normal patients. Apply 2 standard deviations to establish the reference value. 2. Use these same normal patient results, calculate the Geometric Mean, which becomes the Population Mean for the new PT reagent lot and is used to recalculate the INR. 3. The new INR calculation must be entered into the analyzer. 4. As part of the hematology performance program, patient results are used to verify the analyzer's INR calculation formula ..." 3. Review of the laboratory's 2026 Validation study on the Sysmex CA-600 and review of patient test reports revealed the laboratory's established PT reference interval for normal patients as 9.95 to 11.00. 4. Review of the laboratory's New Lot Study (Dade Innovin Lot Number 564703A), conducted March 2026 after the instrument was installed, titled 'Population mean and reference value of the new PT reagent lot St. Thomas Clinical Reference Lab', revealed the usage of patients with PT values of 9.9 for 5 out of the 20 normal health patients chosen for the Geometric mean calculation purposes. The normal established reference interval, as per the laboratory's validation study and reported on patient test reports was 9.95 on the low end. 5. In an interview on July 1, 2026, at 11:56 AM, the TS confirmed some of the patients used for the new lot Dade Innovin study were lower than the laboratory's established normal reference range.

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 direct observation, manufacturer's instructions, review of the laboratory's temperature records, and interview with the Technical Supervisor (TS) according to the Form Centers for Medicare and Medicaid (CMS) 209, the laboratory failed to define freezer temperature ranges in accordance with manufacturer's instructions for 4 of 4 reagents. Findings Included: 1) During a laboratory tour on July 1, 2026, at 1:33 PM, one Kenmore Freezer (Serial Number BA34739592) was directly observed in use storing the following reagents and test kits: a. 3 Bio-Rad Inteliq Immunoassay Controls, Lot Number 10551T, Manufacturer storage temperature requirements -70 to -20 degrees Celsius. b. 1 Siemens Healthineers Atellica CH ENZ 3 Calibrator, Lot Number 00636, Manufacturer storage temperature requirements -25 to -15 degrees Celsius. 2) Review of the laboratory's temperature log sheet revealed an acceptable freezer temperature range of -20 to -10 degrees Celsius. 3) In an interview on July 1, 2026 at 1:45 PM, the TS confirmed the laboratory's acceptable temperature ranges of the freezer were not defined in accordance with manufacturer's instructions.