Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D2118495	03/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
St Croix Cancer Specialists	3018 Orange Grove, Christiansted, 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 Centers for Medicare & Medicaid Services (CMS) New York CLIA Branch Location federal surveyor conducted an announced CLIA recertification survey at Delgiacco Medical LLC DBA St. Croix Cancer Specialists on March 22, 2023. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiencies was found during the announced routine CLIA recertification survey performed on March 22, 2023.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter D520 quality control (QC), calibration and temperature records and interview with testing personnel (TP) #1, the laboratory failed to retain at least two years of QC, calibration and temperature records for the Beckman Coulter D520 from March 2021 to March 2023. Findings Include: 1. On the day of survey, March 22, 2023, TP #1 could not provide QC or calibration records for the Beckman Coulter D520 performed from March 2021 to September 2022. 2. TP #1 could not provide temperature records from March 19, 2021 to September 23, 2021. 3. TP #1 confirmed the findings above on March 22, 2023 around 11:45 am.
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

	This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) records and interview with testing personnel (TP) #1, the laboratory failed to retain at least two years of QA records for March 2021 to March 2023. Findings Include: 1. On the day of survey, March 22, 2023, TP #1 could not provide QA records from monthly QA reviews performed from March 2021 to December 2022. 2. TP #1 confirmed the finding above on March 22, 2023 around 9:45 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of the laboratory room and refrigerator temperature records and interview with testing personnel (TP) #1, the laboratory failed to define storage conditions (reference ranges) to monitor the Beckman Coulter D520 reagents stored at ambient room temperature and in a refrigerator from March 2021 to March 2023. Finding Include: 1. On the day of survey, March 22, 2023, review of the laboratory refrigerator and ambient room temperature records revealed, the laboratory did not define temperature reference ranges to monitor Beckman Coulter D520 reagents stored at ambient room temperature and refrigerator temperature from March 2021 to March 2023. 2. TP#1 confirmed the laboratory did not have defined the reference ranges for reagents stored at ambient room and refrigerator temperatures on March 22, 2023 around 11: 00 am.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of refrigerator and laboratory room thermometer records and interview with testing personnel (TP) #1, the laboratory failed to establish and perform functions checks on two of two thermometers used to monitor laboratory refrigerator and room temperatures from March 2021 to March 2023. Finding Include: 1. On the day of survey, March 22, 2023, a tour of the laboratory revealed, two Fridge - Freezer thermometers were in use to monitor the

	temperatures for a mini refrigerator storing Beckman Coulter D520 reagents and ambient room temperature from March 2021 to March 2023. 2. TP#1 could not provide an established maintenance protocol that ensures the functionally of the thermometers on a periodic basis. 3. The laboratory was unable to provide documentation of maintenance/ function check performed on the two thermometer in use from March 2021 to March 2023. 4. TP#1 confirmed the findings above on March 22, 2023 around 11: 10 am.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a sampling of laboratory test reports and interview with TP#1, the failed to indicate which one of the two laboratory locations where the complete blood count tests were performed from March 2021 to March 2023. Finding Include: 1. The top of the laboratory test reports state: - St. Thomas & St. Croix Cancer Specialist - St. Thomas Cancer Specialist 9150 Estate Thomas, Suite 230 St. Thomas VI 00802 - St. Croix Cancer Specialist 6048 Estate Castle Coakley Christainsted, VI 00820 2. On the day of survey, March 22, 2023, review of a sampling of test reports (five of five) revealed, the test report did not state which one of the two labs (St. Thomas or St. Croix) the CBC test was performed March 2021 to March 2023. 3. TP# 1 confirmed the findings above on March 22, 2023 around 11:00 am.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records and interview with testing personnel (TP) #1, the technical consultant (TC) failed to document training performed for four of four new testing personnel hired since 2021. Findings Include: 1. On the day of survey, March 22, 2023, TP#1 could not provided training records for four of four new testing personnel not listed on the CMS 209 from the last recertification survey perfom on March 19, 2021. 2. TP#1 confirmed the finding above on March 22, 2023 around 10:00 am.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competency assessment (CA) records and interview with testing personnel (TP) #1, the technical consultant (TC) failed to evaluate the competency of all TP in 2022. Findings Include: 1. On the day of survey, March 22, 2023, review of three of four testing personnel CA records revealed: - TP#2 circled for May 2022, evaluated 17, May 2022 but not completed until May 10, 2023. - TP#3 circled for May 2022, evaluated 23, May 2023 but completed May 23, 2022. - TP#1 circled for May 2022, evaluated 17, May 2023 and completed May 23,2023. - TP#1 circled for September 2022, evaluated 09, September 2023 and completed September 08,2023. - TP#3 circled for September 2022, evaluated 19, September 2023 and completed September 19,2023. 2. TP#1 confirmed the findings above on March 22, 2023 around 10:00 am.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment (CA) records, review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records and interview with TP#1, the technical consultant (TC) failed to document blind testing/ PT performance for two of threeTP in 2022. Finding Include: 1. The laboratory Procedure manual and Quality Assessment Plan states, "Personnel competency assessment will be conducted three times a year on the same schedule as our PT ". 2. On the day of survey, March 22, 2023 review of three TP competency records revealed, all three testing personnel were evaluated and dated for the blind testing/ PT performance for CBC testing on the hematology analyzer. 3. Review of MLE records revealed TP#1 was the only testing personnel attesting to the performance of PT since Event 2 of 2022. 4. TP#1 could not provide documentation showing the performance of blind testing for TP#2 and TP#3. 5. TP#1 confirmed the findings above on March 22,2023 around 10:45 am.