Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D1054249	05/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
St Thomas East End Medical Center	4605 Tutu Park Mall, Suite 207, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of product package insert and interview with the executive assistant to the medical director, the laboratory failed to perform quality control (QC) procedures using external QC materials prior to use of HIV 1/2 test kit with lot # 0006654847, expiration date: 4/30/2019.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) 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 review of PT enrollment records, interview with the Executive Assistant to the Medical Director, and telephone conference with a technical representative, the laboratory failed to enroll in the appropriate CBC module for QTR3 2016 and QTR 2 2017. The findings include: a. The laboratory failed QTR3 2016 and QTR 2 2017. Records indicated the laboratory inadvertently enrolled in Module G for cell

	differential that provided PT samples for cell differential that included both automated and manual cell differential challenges. The laboratory has a three-part automated cell differential, and should have been enrolled in Module A. b. The AAB technical representative confirmed that the laboratory was enrolled in CBC module G, rather than Module A. The cell differential failure was due to the enrollment in wrong CBC module.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program. This STANDARD is not met as evidenced by: Based on review of PT records, interview wit the executive assistant to the Medical Director, and telephone conference with the technical representative of AAB PT program, the laboratory director failed to ensure that CBC results for QTR1 2017 were submitted within the established timeframe set by AAB. The technical representative confirmed on the phone that AAB PT program did not receive test results from the laboratory.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records in Human Resources section, interview with the testing personnel and Executive Assistant to the Medical Director, and observation, the laboratory failed to have documentation of educational credentials and training of 1 testing personnel that was hired on May 30, 2017. The findings include: a. Human Resources Documents on testing personnel indicated she was hired as a phlebotomist, and had certificates as certified nurse aide as well as a phlebotomist. b. There was no documentation of her baccalaureate degree from Alfred University in B.S. Global Studies. c. There was no documentation of training on the CBC instrument. She stated she was trained by the previous testing personnel on the Horiba CBC instrument. d. The duties and responsibilities for the testing personnel did not include performing testing on the Horiba CBC instrument.