

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0710717	(X3) Date Survey Completed 05/17/2018
Name of Provider or Supplier Baltimore City Hlth Dept Eastern Sexual Hlth Clini	Street Address, City, State 1200 E Fayette St 1st Floor, Baltimore, MD	
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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not have step by step written instruction for tracking patients in the electronic medical record. Findings: 1. The laboratory started the BDC Insight patient tracking program in 2017. 2. The laboratory did not have step by step written procedures for testing personnel to follow for entering patient results, reviewing patient information, and test results. 3. The testing person stated that the information technology person is in the process of writing procedures for review by the laboratory director.</p>