

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D2100622	(X3) Date Survey Completed 05/31/2018
Name of Provider or Supplier Boston Heart Diagnostics Corp	Street Address, City, State 200 Crossing Blvd, Framingham, MA	
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	An onsite complaint survey was conducted on May 31, 2018 for compliance with 42 CFR Part 493, of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
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 record review and staff interview the laboratory failed to include pertinent literature reference for the collection and storage of specimens submitted for Fibrinogen in the specialty of hematology. Findings include: 1. Record review on 5/31 /18 of the laboratory's 25496.1235 Fibrinogen procedure revealed: a) Stability and storage requirements: -Room Temperature: data not available -Refrigerated: 3 days -</p>

Frozen -20C: data not available -Frozen -80C: data not available b) References - Med Test DX Fibrinogen Package Insert effective 09/29/2017 2. Record review on 5/31/18 of the Med Test DX Fibrinogen Package Insert effective 09/29/2017 revealed: a) The Specimen collection and stability: "Blood should be collected as recommended by the National Committee for Clinical Laboratory Standards. (National Committee for Clinical Laboratory Standards Procedures for the collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard. 2nd. Ed. Villanova, Pa. NCCLS; 1984. NCCLS Publication H3-A2C.)" 3. Staff interview on with the Vice President of Operations and Laboratory Director (LD) on 5/31/18 at 1:00 PM revealed: -The above committee no longer exists and is now known as Clinical laboratory Standards Institute (CLSI) -The above referenced publication no longer exists -The MedTest DX Fibrinogen package insert effective 09/29/2017 does not include specimen stability criteria. -The manufacturer (MedTest) is working on updating the package insert to show a pertinent literature reference.