

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0334963	(X3) Date Survey Completed 07/19/2018
Name of Provider or Supplier Dr Jeffrey M P Siminovitch & Associates Inc	Street Address, City, State 36060 Euclid Avenue, Suite 102, Willoughby, OH	
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 record review and interviews with the Service Representative (SR) and Testing Personnel (TP) #4, the laboratory failed to include the appropriate prostatic specific antigen (PSA) and testosterone (TESTO) reference intervals (normal values) in their procedure manual. Findings Include: 1. Review of the laboratory's "Jeffrey MP Siminovitch and Associates, Inc. Policy and Procedure PSA/TESTO" policy and procedure, approved via signature and date by the Laboratory Director on 04/15/2015 and provided on the date of the inspection, found the following normal ranges: Analyte Normal Range PSA 0 - 2.59 ng/ml Anything above 2.59 considered abnormal</p>

Testosterone Male 20 - 49, 400 - 600 ng/dl Anything below 400 or above 600 is considered abnormal. 2. Review of the laboratory's 2016, 2017 and 2018 test records (instrument printouts) and their corresponding final test reports both revealed inconsistent PSA and testosterone reference ranges compared to the laboratory's normal ranges approved by the Laboratory Director, as follows: Analyte Normal Range PSA 0.00 - 4.00 ng/ml Testosterone 280.00 - 800.00 ng/dl 3. The SR and TP#4 stated the test results from the Beckman Coulter Access II analyzer, on which the PSA and testosterone testing are performed, are directly interfaced into the office electronic medical record (EMR) system, the reference ranges were reported correctly and confirmed the reference ranges in the policy and procedure were incorrect. The interviews occurred on 07/19/2018 at 2:58 PM.