

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2122420	(X3) Date Survey Completed 10/02/2018
Name of Provider or Supplier Stemina Biomarker Discovery	Street Address, City, State 504 S Rosa Rd Ste 150, Madison, WI	
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 surveyor review of laboratory procedures and interview with the general supervisor, the procedures did not identify the reference ranges for the 32 analytes in the ASD (Autism Spectrum Disorders) panel. Findings include: 1. Review of laboratory procedures showed no identification of reference ranges (normal values) for the 32 individual analytes included in the ASD panel. 2. Interview with the general supervisor on October 2, 2018 at 11:00 AM confirmed the procedures do not include reference ranges for the 32 amines in the ASD panel.</p>

D5465

CONTROL PROCEDURES

CFR(s): 493.1256(d)(8)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the general supervisor, the laboratory does not test control materials in the same manner as patient specimens. Findings include: 1. Review of laboratory records showed controls materials are tested in duplicate while patient samples are tested once. 2. Interview with the general supervisor on October 2, 2018 at 11:00 AM confirmed controls are tested in duplicate while patient samples are only tested once and confirmed the control materials and patient samples are not tested in the same manner.