Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393727	(X3) Date Survey Completed 10/10/2018
Name of Provider or Supplier Wildwood Family Clinic	Street Address, City, State 4901 Cottage Grove Rd, 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	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the AmniSure procedure and interview with the laboratory director, the instructions in the procedure for Quality Control (QC) frequency do not comply with the QC requirements at 493.1256. Findings include: 1. Review of the "AmniSure Rupture of Fetal Membrane (ROM) Test" procedure shows that QC should be run with every new shipment and/or lot number, or if there is suspicion that product performance is compromised. 2. Interview with the laboratory director on October 10, 2018 at 12:30 PM confirmed that the procedure does not meet the requirements to test a negative and positive control material each day of testing as

	required at 493.1256(d)(3)(ii). The laboratory director also confirmed that the laboratory has not developed an Individualized Quality Control Plan that would provide equivalent quality testing. This is a repeat deficiency previously cited on October 25, 2006.