

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0395327	(X3) Date Survey Completed 09/04/2018
Name of Provider or Supplier Aspirus Wausau Family Medicine	Street Address, City, State 425 Wind Ridge Dr, Wausau, 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 procedures, observation of the centrifuge and interview with the technical consultant, the laboratory procedures do not provide specific instructions for processing urine specimens for microscopic examinations using the equipment available. Findings include: 1. Review of the "Urinalysis: Microscopy" procedure showed urine is transferred to a tube and centrifuged for five minutes at 400 RCF (relative centrifugal force). 2. Observation of the centrifuge used for urinalysis processing on September 4, 2018 at 3:30 PM showed the centrifuge uses RPM (revolutions per minute) units to adjust speed. No correlation to RCF is evident. 3.</p>

Interview with the technical consultant on September 4, 2018 at 3:30 PM confirmed the laboratory had not evaluated the correlation between RPM and RCF for the centrifuge used for urine processing. Further interview confirmed laboratory procedures did not provide specific instructions for processing urine specimens using the equipment available in the laboratory. This is a repeat deficiency previously cited on August 31, 2016.