

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2135321	(X3) Date Survey Completed 06/05/2018
Name of Provider or Supplier Froedtert & The Medical College Cp Mequon	Street Address, City, State 11430 N Port Washington Road, Mequon, 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 review of laboratory procedures, Individualized Quality Control Plan (IQCP), and interview with the technical supervisor, the laboratory has not defined the required parameters for quality control testing and evaluation for the type, frequency of testing, criteria for acceptability, or corrective action for controls which fail to meet criteria for the Piccolo Xpress chemistry analyzer, Sedimat 15 Plus Erythrocyte Sedimentation Rate (ESR) instrument, and the DxH 800 hematology analyzer. Findings include: 1. Review of the IQCP for the Hepatic Function Panel on the Piccolo Xpress chemistry analyzer revealed the plan does not specify the type or the</p>

number of controls to analyze. 2. Review of the 'Piccolo Basic Metabolic Panel' procedure for the Piccolo Xpress chemistry analyzer revealed no definition of the criteria for acceptability of control values or corrective action for controls which fail to meet criteria. 3. Review of the 'Sedimat 15' procedure for the ESR test revealed no definition for the frequency, criteria for acceptability of control values, or corrective action for controls which fail to meet criteria. 4. Review of the 'Hematology Quality Control' procedure for the DxH 800 hematology analyzer revealed no definition of number or frequency for analyzing controls on the DxH 800 hematology analyzer. 5. Interview with technical supervisor on June 5, 2018 at 1:00 PM confirmed the procedures and IQCP do not include all required elements for Quality Control policies in the laboratory.