

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0921590	<b>(X3) Date Survey Completed</b>  08/17/2023
<b>Name of Provider or Supplier</b>  Women's Care Of Wisconsin	<b>Street Address, City, State</b>  5485 Grande Market Dr, Appleton, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on survey review of chemistry procedures and interview testing personnel, staff A, the laboratory director did not sign and date seventeen of seventeen QuidelOrtho Vitros XT3400 chemistry procedures prior to patient use. Findings include: 1. Review of chemistry procedures showed no documentation the laboratory director reviewed and signed the "Vitros XT3400 Operation and Maintenance" procedure or any of the sixteen analyte procedures. 3. Interview with the staff A on August 17, 2023, at 2:00 PM confirmed the laboratory director did not sign and date new chemistry procedures prior to patient use.</p>
<b>D5409</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and procedures and interview with testing personnel, staff A, the laboratory did not maintain one of one discontinued procedures with the date the testing was discontinued. Findings include: 1. Review of maintenance records for the Alfa Wasserman ACE AXCEL chemistry analyzer showed testing on the analyzer was discontinued on April 18, 2023. 2. Review of the Alfa Wasserman ACE AXCEL chemistry analyzer procedure showed no</p>

documentation of discontinuation of the procedure. 3. Interview with staff A on August 17, 2023, at 2:10 PM confirmed the laboratory did not maintain a copy of the procedure related to the Alfa Wasserman ACE AXCEL chemistry analyzer with date of discontinuance.