

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2193939	(X3) Date Survey Completed 01/07/2025
Name of Provider or Supplier Froedtert Community Hospital - Pewaukee	Street Address, City, State 209 Pewaukee Road, Pewaukee, 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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of the Abbott I-Stat reagent cartridges and interview with a technical consultant, staff A, testing personnel did not label nineteen of nineteen I-Stat Chem 8+ cartridges with the shortened room temperature expiration date. Findings include: 1. Observation of the Abbott I-Stat Chem 8+ cartridges box on January 7, 2025, at 12::13 PM revealed nineteen cartridges, Lot# H24349A, original expiration date of June 12, 2025, were being stored at room temperature. Further observation of the cartridge box showed a line for the new expiration date after being placed at room temperature and the new expiration date was not labeled on the cartridges or the box. 2. Interview with staff A on January 7, 2025, at 12:15 PM, confirmed the expiration date of the cartridges changed when the cartridges were stored at room temperature and testing personnel did not label the Abbott I-Stat Chem 8+ cartridges with the shortened expiration date after being placed at room temperature.</p>