

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2245608	(X3) Date Survey Completed 04/22/2026
Name of Provider or Supplier Froedtert Community Hospital - Mequon	Street Address, City, State 11421 N Port Washington Rd, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of humidity level records and interviews with the hospital administrator (Staff A) and the laboratory director (Staff B), the laboratory failed to define criteria that were consistent with the manufacturer's instructions for the Sysmex XN-300 hematology analyzer for two of two months reviewed. Findings include: 1. Review of the Primex OneVue reports for the laboratory from December 2025 and April 2026 showed the low humidity limit was set at 0%. 2. Interview with Staff A on April 22, 2026, at 1:10 PM confirmed the Primex system was programmed with a low acceptable humidity level of 0% for the laboratory. Interview with Staff B on April 22, 2026, at 1:15 PM confirmed the manufacturer identified 20% as the low limit of the humidity environmental specification for the Sysmex XN-300 and confirmed the limits defined in the Primex system were not consistent with the manufacturer's instructions.</p>