

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2245608	(X3) Date Survey Completed 11/09/2022
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the laboratory director, the laboratory did not retain accurate expiration dates for quality control (QC) performed on the Sysmex XN-330 hematology analyzer from May through August 2022 and did not document changes in lot numbers and expiration date during the month of use. Findings include: 1. Review of the "Sysmex Maintenance Log" showed the following QC lot numbers and expiration dates: Month/Lot/Expiration date recorded May/2070/June 21, 2022 June/2070/June 7, 2022 July/2154/July 11, 2022 August/2154/August 15, 2022 Further review showed no documentation of when new lots were opened and in use. 2. Interview with the laboratory director on November 9, 2022, at 12:15 PM confirmed the laboratory did not retain accurate expiration dates for quality control (QC) performed on the Sysmex XN-330 hematology analyzer from May through August 2022 and did not document changes in lot numbers and expiration date during the month of use.</p>