

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2258004	(X3) Date Survey Completed 06/28/2024
Name of Provider or Supplier Froedtert Hospital - Bluemound Campus	Street Address, City, State 601 N 99th St, Milwaukee, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of verification studies and laboratory procedures and interview with a general supervisor (Staff A), the laboratory did not have an approved test procedure for one of one Immunohistochemical (IHC) test performed in the laboratory. Findings include: 1. Review of verification studies completed for MART-1 (MelanA or Melanoma antigen) IHC test showed a technical supervisor (Staff B) evaluated and approved the MART-1 IHC test for use in the laboratory. 2. Review of laboratory procedures showed no evidence of an approved procedure for the MART-1 IHC test. 3. Interview with Staff A on June 28, 2024, at 10:10 AM confirmed the laboratory did not develop and the laboratory director did not approve a standard operating procedure for the performance of MART-1 IHC test.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of supply logs, observation of supplies in the laboratory,</p>

and communication with a general supervisor (Staff A), the laboratory used expired coverslip film in the laboratory six of the last eight months. Findings include: 1. Review of the laboratory's supply logs showed the laboratory received coverslip film in October 2023 with an expiration date of December 2023. Further review showed the laboratory did not document receipt of any additional coverslip film since October 2023. 2. Observation of the coverslip film in the laboratory on June 28, 2024, at 11:00 AM revealed the laboratory had Tanner Tape coverslip film lot 224264 available for use. The box showed the film expiration date was December 2023. 3. Communication with the general supervisor via email on July 1, 2024, at 7:06 AM confirmed the laboratory used the coverslip film from November 2023 until the date of the survey.