Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2245608	04/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Froedtert Community Hospital - Mequon	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
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) reports and laboratory records and interview with the laboratory director, the laboratory director did not ensure an approved corrective action plan was followed when proficiency testing results were found to be unacceptable in two of two events, event three in 2022 and event one in 2023. Findings include: 1. Review of American Proficiency Institute PT reports and laboratory PT records showed the following unacceptable results (80% or less) without evidence of documented corrective action: 2022 event three NT pro-BNP (N-terminal pro b-type natriuretic peptide), 80% score, no documented review Sample CM-15, reported 5348 pg/mL (picograms / milliliter), expected 3515 - 5053 pg/mL BUN (Blood Urea Nitrogen), 80% score, no documented review Sample IB-14 reported 22 mg/dL (milligrams/deciliter), expected 28-34 mg/dL 2023 event one NT pro-BNP, 80% score, no documented review Sample CM-02, reported 9265 pg/mL, expected 7043 - 9155 pg.mL pCO2 (partial pressure of carbon dioxide) 80% score, no documented review Sample IB-04, reported 72 mmHg (millimeters of mercury), expected 57 - 67 mmHg Monocytes %, 80% score Sample XE-03 reported 11.4%, expected 8.8 - 11.2% The laboratory documented no corrective action. Laboratory records showed the following statement, "XE-03 was off by 0.2, the range was 8.8% -11.2%. 11.4% was reported. No corrective action needed." The report showed no evaluation to determine the cause of the unacceptable result. 2. Interview with the

	laboratory director on April 18, 2024 at 11:05 AM confirmed the laboratory had not documented review of the unacceptable results or the corrective actions for each of the unacceptable results in the two events.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on surveyor review of competence assessment documentation from 2022 through 2024 and interview with the laboratory director and hospital administrator, the technical consultant did not document the required competence assessments for two of ten employees reviewed for assessments. Findings include: 1. Review of competence assessment records for ten employees revealed the laboratory was missing documentation for two of the reviewed employees. The laboratory did not have documentation of a second assessment for Staff A during the first year Staff A performed testing and did not have documentation of the annual assessment for Staff B that was due in January 2024. Staff A: initial assessment February 2023, no documented semi-annual assessment, annual assessment January 2024. Staff B: initial assessment January 2023, semi-annual assessment June 2023, no documented annual assessment. 2. Interview with the laboratory director on April 18, 2024, at 10:00 AM confirmed the laboratory did not have the missing documentation for the two employees. Interview with the hospital administrator on April 18, 2024, at 10:00 AM confirmed Staff B had performed patient testing in February and March 2024 after the annual assessment was due.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and patient test results, and interview with the laboratory director, testing personnel did not follow the laboratory's procedure to document the reporting of one of one reviewed critical potassium value resulted on April 12, 2024. Findings include: 1. The laboratory policy for critical value reporting includes the following instructions, "A critical value should be reported to the ordering physician/caregiver immediately upon discovery. The name of the person who is notified, the time of notification, and the person doing the notification, should be documented in Epic preferably using the SmarTest .CRITLAB." 2. Review of the patient test results and medical record for Patient 1 showed a critical potassium value (6.7 milliequivalents per liter) was resulted on April 12, 2024. The chart showed no documentation the testing person notified the provider, the time of the notification or the person doing the notification. 3. Interview with the laboratory director on April 18,

	2024, at 12:45 PM confirmed the identified potassium value was a critical test result and confirmed the testing person did not follow the laboratory's procedures for documentation.