

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D2245603	<b>(X3) Date Survey Completed</b> 12/19/2023
<b>Name of Provider or Supplier</b> Froedtert Community Hospital - Oak Creek	<b>Street Address, City, State</b> 7901 S 6th St, Oak Creek, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5213</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of American Proficiency Institute (API) proficiency testing (PT) records and interview with the laboratory director, the laboratory did not evaluate the accuracy for five of five "Not Graded" PT results for the Pathfast D-dimer assay in 2022 and 2023 Findings include: 1. Review of API PT records showed API entered "Not Graded" for two of five D-dimer results in event 3 in 2022, two of five D-dimer results in event 1 in 2023 and one of five results in event 3 in 2023. Further review showed no documentation the laboratory evaluated the accuracy of the D-Dimer PT for the five "Not Graded" results. 2. Interview with the laboratory director on December 19, 2023, at 10:15 AM confirmed the laboratory did not evaluate the accuracy of "Not Graded" PT results for the Pathfast D-dimer assay in 2022 and 2023.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:

Item 1 Based on surveyor observation of the Abbott I-Stat reagent cartridges and interview with the technical consultant, testing personnel did not label ten of ten I-Stat cartridges with the shortened room temperature expiration date. Findings include: 1. Observation of the Abbott I-Stat cartridges bin on December 19, 2023, at 11:55 AM revealed ten cartridges, Lot# H23291, original expiration date of April 15, 2024, were being stored at room temperature. Further observation showed the cartridges were acceptable for use for two weeks after being placed at room temperature and the stamp on one cartridge stated the new expiration date was January 2, 2023, while the stamp on the rest of the cartridges was illegible. 2. Interview with the technical consultant on December 19, 2023, at 11:58 AM, confirmed testing personnel did not label the I-Stat cartridges with the shortened expiration date after being placed at room temperature. Item 2 Based on surveyor observation of the chemistry quality control (QC) material and interview with the technical consultant, testing personnel did not label four of four opened QC vials with the shortened open expiration date. Findings include: 1. Observation of the BioRad chemistry QC in the laboratory refrigerator on December 19, 2023, at 12:00 PM revealed four vials of quality control, two levels of BioRad D-Dimer QC and two levels of Cardiac Marker QC, in a bin available for use. The vials showed an opened date of 12/19 without a year and showed no revised expiration date. Further observation of the bin showed the D-Dimer QC was acceptable for use for fifteen days after open and no indication how long the Cardiac Marker QC was acceptable for use after being opened. 2. Interview with the technical consultant on December 19, 2023, at 12: 05 PM confirmed the Cardiac Marker QC is acceptable for use for five days after open. Further interview confirmed testing personnel did not label the QC vials with the shortened expiration date after they were opened.

**D6072**

**TESTING PERSONNEL RESPONSIBILITIES**  
 CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Item 1 Based on surveyor review of maintenance records and interview with the laboratory director, testing personnel did not document daily maintenance on the Abbott i-Stat chemistry analyzer for thirty of one hundred eighty-four days from March 1, 2023 through August 31, 2023. Findings include: 1. Review of the maintenance logs for the Abbott i-Stat chemistry analyzer showed no documentation of daily maintenance on the following days in 2023: March: 1, 2, 3, 4, 15, 18, 23, 30 April: 19, 26, 27, 29 May: 15, 23, 24, 28 June: 6, 7, 8, 10, 20, 21, 22, 24 July: 5, 19, 20, 22, 24 August: 1 2. Interview with the laboratory director on December 19, 2023, at 11:35 AM, confirmed testing personnel did not document daily maintenance on the Abbott i-Stat chemistry analyzer for each day of use. Item 2 Based on surveyor review of maintenance records and interview with the laboratory director, testing personnel did not document daily maintenance on the Sysmex XN330 hematology analyzer for seven of one-hundred twenty days from January 2023 through April 2023. Findings include: 1. Review of the maintenance logs for the Sysmex XN330 hematology analyzer showed no documentation of daily maintenance on the following days in 2023: January: 1, 3, 4 March: 2, 3, 23 April: 22 2. Interview with the laboratory director on December 19, 2023, at 11:35 AM, confirmed testing personnel did not

document daily maintenance on the Sysmex XN330 hematology analyzer for each day of use. This is a repeat deficiency from June 8, 2022.