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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D2245603 | (X3) Date Survey Completed 02/18/2026 |
| Name of Provider or Supplier Froedtert Community Hospital - Oak Creek | Street Address, City, State 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. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Item 1 Based on surveyor review of personnel records and procedures and interview with the laboratory director, the laboratory did not establish and follow written procedures to assess employee competency for two of two personnel in the technical consultant (TC) role with delegated responsibilities in 2025. Findings include: 1. Review of personnel records showed two staff members with delegated responsibilities. The director had delegated the TC responsibilities to Staff A and Staff B. Further review showed no evidence that the laboratory director evaluated the competency of the TCs in performing their delegated duties in 2025. 2. Review of the laboratory's policies revealed the laboratory did not have a procedure that defined the process for competency evaluation of personnel with delegated responsibilities. 3. Interview with the laboratory director on February 18, 2026, at 12:33 PM confirmed the laboratory did not have a written procedure for competency evaluation of personnel delegated TC responsibilities and the director did not document the evaluation of the TCs in performing their delegated responsibilities in 2025. Item 2 Based on surveyor review of the laboratory's competency assessment records and procedures, and interview with the laboratory director, the laboratory's written policies, procedures, and practice for assessing employee competency did not meet the requirement for assessment of testing personnel competency at this laboratory for two of eight testing personnel records reviewed. Findings include: 1. Review of competency assessment records for two testing personnel revealed the following: 1a. Staff A's records showed Staff B assessed Staff A's competency at an affiliate laboratory in 2025. Further review of records revealed no indication that Staff A had a</p> |

testing personnel competency assessment performed at this location in 2025. 1b. Staff C had initial training documents marked completed with the date April 9, 2024, at this location. Further review of records revealed Staff C performed testing at this location on July 25, 2025. There were no competency records for this location in Staff C's file. 2. Review of the competency assessment process in the laboratory's policy, "Guidelines for POCT Laboratory QA Policy", revealed the procedure did not include the requirement for assessment of testing personnel competency at this laboratory. 3. Interview with the laboratory director on February 18, 2026, at 11:42 AM confirmed the findings in the competency assessment records for the two testing personnel and confirmed the laboratory's written process did not include the requirement for assessment of testing personnel competency at this laboratory.