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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D2066480 | (X3) Date Survey Completed 08/31/2023 |
| Name of Provider or Supplier Froedtert & Mcw Moorland Reserve Laboratory | Street Address, City, State 4805 S Moorland Rd., New Berlin, 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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| D5775 | <p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a technical consultant, the laboratory had not developed a system that evaluated and defined the relationship between test results using the iSTAT test system and the Roche chemistry analyzers for six of six analytes the laboratory reported from the two test systems. Findings include: 1. Review of the 'Laboratory Test Methodology Report' showed the laboratory performed creatinine, sodium, potassium, blood urea nitrogen, glucose and chloride testing using the iSTAT and the Roche chemistry analyzers. 2. Review of laboratory records showed no evidence of comparisons between the iSTAT test system and the Roche analyzers or other evaluation of the relationship between the results from the two test systems. 3. Interview with a technical consultant (staff A) on August 31, 2023, at 1:30 PM confirmed the laboratory had not developed a system to evaluate the relationship between the test results from the two test systems. This is a repeat deficiency previously cited on September 18, 2017.</p> |