

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2245603	<b>(X3) Date Survey Completed</b>  06/20/2022
<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>D3000</b>	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor observation of test systems, review of testing records and records in the WEDSS (Wisconsin Electronic Disease Surveillance System) database, and interview with the laboratory director, the laboratory did not report SARS CoV-2 test results for 155 patient tests performed between March 24 and June 17, 2022 using the Lucira Check It test system. Findings include: 1. Observation of the laboratory on June 8, 2022 at 9:00 AM revealed the laboratory performs SARS CoV-2 tests using the Lucira Check It test system which uses a molecular amplification technology for the detection of SARS-CoV-2 viral RNA. 2. A search of the WEDSS database on June 13, 2022 for two randomly identified patients (Patient 1 and 2) revealed no record of the SARS CoV-2 tests performed on these two patients in April 2022. 3. Email from the laboratory director on June 17, 2022 at 12:23 PM confirmed the laboratory started testing for SARS CoV-2 on March 24, 2022 and performed 155 SARS CoV-2 tests between March 24 and June 17, 2022. Email from the laboratory director on June 20, 2022 at 5:32 PM confirmed the laboratory did not report SARS CoV-2 test results to the Wisconsin health department.</p>