

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0388938	<b>(X3) Date Survey Completed</b>  03/08/2021
<b>Name of Provider or Supplier</b>  Watertown Family Practice Associates Sc	<b>Street Address, City, State</b>  127 Hospital Dr, Watertown, 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 review of testing records and interview with testing personnel, the laboratory failed to report negative SARS CoV-2 test results for 75 of 75 days when the laboratory performed testing from November 4, 2020 through February 26, 2021. Findings include: 1. Review of laboratory test logs for SARS CoV-2 testing performed on the cobas Liat and the Abbott ID NOW test systems from November 4, 2020 through February 26, 2021 showed the laboratory tested patient samples on 18 days in November and 20 days in December 2020, and 18 days in January and 19 days in February 2021. 2. Review of SARS CoV-2 test results in the WEDSS (Wisconsin Electronic Disease Surveillance System) from this laboratory showed the laboratory entered positive test reports from January 22 and 25, and February 10, 11, and 16. No negative test results from this laboratory were in the system. 3. Interview with testing personnel (staff A) on March 8, 2021 at 1:30 PM revealed the laboratory only entered patient information and results for patients with positive test results. Staff A confirmed the laboratory reported no negative test results to state or local public health entities.</p>

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records, observation of reagent storage, and interview with testing personnel, the laboratory did not define criteria consistent with the manufacturer's instructions for the frozen storage of the TriLevel Immunoassay control. Findings include: 1. Review of laboratory records show the laboratory defined acceptable temperature range for the laboratory freezer is negative five to negative fifteen degrees Celsius (C). 2. Observation of the reagents in the laboratory freezer on March 8, 2021 at 2:00 PM revealed a box of TriLevel Immunoassay controls. The box showed the manufacturer's acceptable storage temperature range was less than negative twenty degrees C. 3. Interview with testing personnel (staff F) on March 8, 2021 at 2:15 PM confirmed the laboratory's defined range for acceptable storage of the control was not consistent with the manufacturer's instructions. Further interview confirmed the controls were not stored at less than negative twenty degrees C.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with testing personnel, the technical consultant did not evaluate and document the performance of five of five providers semiannually during the first year of testing. The five providers performed twelve wet mount examinations from January 20, 2020 through March 4, 2021. Findings include: 1. Review of laboratory testing records showed five providers performed wet mount microscopic examinations between January 20, 2020 and March 4, 2021. The identified providers performed testing on the following days: Staff A: May 7, 2020 and March 4, 2021 Staff B: March 5, 2020 Staff C: January 30, 2020 (two tests) and February 26, 2020 Staff D: November 17, 2020 and February 4, 2021 Staff E: January 20, 2020, March 4, 2020, November 18, 2020, and January 25, 2021 2. Interview with testing personnel (staff F) on March 8, 2021 at 2:15 PM confirmed the technical consultant did not evaluate or document competency of the five providers semiannually during the first year the five providers performed wet mount microscopic examinations.