

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0394747	(X3) Date Survey Completed 04/05/2022
Name of Provider or Supplier Rivers Bend Health Services	Street Address, City, State 960 S Rapids Road, Manitowoc, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor direct observation, review of the manufacturer's instructions and interview with testing personnel, the laboratory did not time the testing process correctly for one of one individual test performed with the Abbott BinaxNOW (Trademark) COVID-19 Antigen (Ag) Card. Findings include: 1. The manufacturer's instructions for the Abbott BinaxNOW (Trademark) COVID-19 Ag Card state, "Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes." 2. Direct observation of testing personnel (Staff A) at 10:00 AM on April 5th, 2022 (via MS Teams Meeting) performing an Abbott BinaxNOW (Trademark) COVID-19 Ag Card test on one individual. Staff A noted the start of the test processing time as 10:13 AM after adding the Extraction Reagent to the card and prior to collecting the specimen swab from the individual. Staff A collected the specimen swab, inserted the swab into the card, twirled the swab, and closed the card. Staff A did not start timing the process at this time as required by the manufacturer's package insert instructions. Staff A read the test at 10:28 AM, which was 15 minutes after the test card was prepared for testing and not 15 minutes after the specimen swab was collected and added to the test card. 3. Interview with Staff A and Administrator, Staff B, on April 5, 2022 at 10:40 AM confirmed that the laboratory did not follow the manufacturer's instructions and testing personnel did not time the testing process correctly.</p>

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.

This CONDITION is not met as evidenced by:

Based on surveyor review of testing records and the Wisconsin Electronic Disease Surveillance System (WEDSS), the laboratory failed to report all positive SARS-CoV-2 (COVID-19) antigen tests to local, state and federal authorities for six of ten positive results tested between September 30, 2021 and January 29, 2022. Findings include: 1. Surveyor review of COVID-19 testing records provided by Staff B, consisted of ten positive results tested between September 30, 2021 and January 29, 2022. 2. Comparison of laboratory testing records to test results reported to state authorities through WEDSS revealed that five of ten positive results were not reported to state authorities through WEDSS. For one of ten positive results there is a corresponding result in WEDSS but the result is reported as Negative. The State of Wisconsin WEDSS system reports all COVID-19 results to local and federal authorities. 3. Interviews with Staff A and Staff B on April 5, 2022 at 10:40 AM revealed that Staff A used Web-Based Laboratory Reporting (WLR), a service provided by the Wisconsin State Lab of Hygiene (WSLH). WLR is secure portal for entering laboratory results for diseases required by Wisconsin statues and reporting to local, state (WEDSS), and federal authorities. Staff A and Staff B confirmed that they did not ensure COVID-19 test results were reported in WLR nor reported accurately.