

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2256367	(X3) Date Survey Completed 03/17/2022
Name of Provider or Supplier Covid Clinic, Inc	Street Address, City, State 95 N Mooreland Rd Unit A1a, Brookfield, 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 review of the manufacturer's instructions and observation of patient testing, testing personnel did not follow the manufacturer's procedures for two of two observed patient tests performed with the Accula SARS CoV-2 Test. Findings include: 1. The manufacturer's instructions for the Accula SARS CoV-2 Test state, "Remove the patient nasal swab from the SARS-CoV-2 Buffer vial and discard it into a biohazardous waste container", and "Write the patient identification (ID) information and testing date on the Test Cassette label in the area provided." A copy of the manufacturer's instructions was not available in the laboratory at the time of the survey. 2. Observation of the performance of two Accula SARS CoV-2 tests performed by testing personnel (Staff A and B) on March 17, 2022 at approximately 10:15 AM revealed personnel returned the sample swab to the swab sleeve after rotating the swab in the SARS-CoV-2 buffer. Testing personnel did not discard the swabs until after they obtained test results. Observation also showed testing personnel did not label the test cassettes prior to inserting them into the Accula Dock for processing.</p>