

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2256363	(X3) Date Survey Completed 03/30/2022
Name of Provider or Supplier Covid Clinic, Inc	Street Address, City, State 4323 W Wisconsin Ave, Appleton, 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 interview with testing personnel, testing personnel did not follow the manufacturer's procedures for tests performed with the Accula SARS CoV-2 Test System. Findings include: 1. The manufacturer's instructions for the Accula SARS CoV-2 Test state, "Write the patient identification (ID) information and testing date on the Test Cassette label in the area provided." 2. Interview with testing personnel (staff A) on March 30, 2022 at approximately 1:45 PM revealed testing personnel did not write the patient information or testing date on the test cassettes prior to inserting them into the Accula Dock for processing.</p>