Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2249453	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Covid Solutions Llc	405 S Park St, Madison, 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	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) 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. This STANDARD is not met as evidenced by: Item 1: Based on surveyor direct observation, review of manufacturer's instructions and interview with the site attendant, Staff A, the laboratory failed to follow the manufacturer's instructions for SARS-CoV-2 (COVID-19) rapid antigen testing for testing of patient specimens. Findings include: 1. Direct observation of the patient testing area on January 27, 2022 at 10:40 AM revealed a bin of opened cassettes waiting to be used for patient testing. 2. Review of the Phase Scientific Indicaid COVID-19 manufacturer's instruction revealed "All components in this test kit should remain sealed until ready to use". 3. Interview with Staff A at on January 27, 2022 at 10:40 AM confirmed the laboratory did not follow the manufacturer's instruction by keeping the cassettes sealed prior to patient testing. Item 2: Based on surveyor review of manufacturer's instructions and interview with the site attendant, Staff A, the laboratory failed to follow the manufacturer's instructions for SARS-CoV-2 (COVID-19) rapid antigen testing for testing of specimens. Findings include: 1. Review of the Phase Scientific Indicaid COVID-19 manufacturer's instructions revealed "Read the test line (T) and control line results promptly at 20 minutes, and not earlier to ensure proper test performance. Results after 25 minutes should not be used." 2. Interview with Staff A on January 27, 2022 at 10:40 AM stated patient tests were read at ten minutes, no longer than fifteen minutes per former business association at this site. Further interview confirmed the laboratory failed to follow the manufacturer's instructions for SARS-CoV-2 (COVID-19) rapid antigen testing for testing of specimens.