Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2252088	(X3) Date Survey Completed 06/20/2022
Name of Provider or Supplier Kmr Testing Facility	**Street Address, City, State** 413 E North Ave, Milwaukee, 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: Based on surveyor review of the manufacturer's instructions and interview with testing personnel, testing personnel did not follow the manufacturer's instructions for interpreting the test results for the iHealth SARS CoV-2 antigen test. Findings include: 1. Review of the manufacturer's instructions for the iHealth SARS CoV-2 antigen test showed a graphic with positive test results, one with the control line darker than the test (T) line, one with the control line the same as the test line, and one with the control line lighter than the test line. The instructions state, "The T line can be extremely faint." The instructions also include five photos of positive results including two with a test line lighter than the control line. 2. Interview with testing personnel (staff A) on June 20, 2022 at 11:30 AM confirmed staff A interpreted iHealth SARS CoV-2 antigen test results as negative when the test line was lighter than the control line, and confirmed staff A did not follow the manufacturer's instructions.