

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2249356	<b>(X3) Date Survey Completed</b>  03/03/2022
<b>Name of Provider or Supplier</b>  Covid Care Zone Inc	<b>Street Address, City, State</b>  1010 W Layton Ave, Milwaukee, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D1001</b>	<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, the laboratory did not follow the extraction procedure for one of one patient test performed with the Sienna COVID-19 Rapid Antigen Test. Findings include: 1. The manufacturer's instructions for the Sienna COVID-19 Rapid Antigen Test state, "Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab (See Illustration 2). Leave the swab in the extraction buffer for one minute." 2. Interview with testing personnel (staff A) at 12:00 PM on March 3, 2022 revealed they performed a Sienna COVID-19 Rapid antigen Test on one patient (patient 1). Staff A confirmed they removed the swab from the extraction buffer after rotating the swab and did not leave the sample swab in the extraction buffer for one minute.</p>