

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 52D2078791	<b>(X3) Date Survey Completed</b> 10/08/2021
<b>Name of Provider or Supplier</b> Urgent Care Physicians, Ltd	<b>Street Address, City, State</b> 3329 E Express Ct, Appleton, 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 direct observation, review of manufacturers' instructions and interview with the laboratory director, the laboratory failed to follow the manufacturers' instructions for specimen labeling for four of four observed BD Veritor SARS-CoV-2 patient tests. Findings include: 1. Direct observation on October 8, 2021 at 10:15 AM revealed testing personnel performing car side collections and labeled test devices with only patient initials and with no patient information on the extraction reagent tube. Further observation revealed two test cassettes labeled with the same initials, LH, without another identifier to differentiate the patients' test devices. 2. Review of the "Veritor System for Rapid Detection of SARS-CoV-2" manufacturers' instruction revealed testing personnel are to "Label one test device and one extraction reagent tube for each specimen or control to be tested". 3. Interview with the laboratory director on October 8, 2021 at 10:25 AM confirmed the laboratory did not label the test device and extraction reagent tube to fully identify and differentiate patient specimens per the manufacturers' instruction for four of four observed BD Veritor SARS-CoV-2 patient tests.</p>