

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0968945	(X3) Date Survey Completed 06/22/2022
Name of Provider or Supplier Mycare Medical Of Texas, Pllc	Street Address, City, State 122 North Alamo Road, Alamo, TX	
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 observation, review of manufacturer's instructions, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions for test performance using the Pro Advantage Strep A test for 1 of 1 test procedures monitored the day of the inspection, June 22, 2022. The findings included: 1. Surveyor observation on June 22, 2022 at 10:30 hours in the laboratory found testing personnel #1 (as listed on Form CMS 209) performing a Pro Advantage Strep A test. The test was in the incubation phase and the patient swab was in the vial. 2. Review of the manufacturer's instructions for the Pro Advantage Strep A test stated, "3. Immediately add the throat swab into the tube of pale yellow solution. Rotate the swab vigorously 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab. 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to remove the swab prior to the 10 minute incubation period. No documentation was provided. 4. An interview with the technical consultant on June 22, 2022 at 10:35 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services</p>