

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2193618	(X3) Date Survey Completed 01/27/2021
Name of Provider or Supplier Texas Road Pharmacy	Street Address, City, State 1183 Englishtown Road, Old Bridge, NJ	
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 review of the COVID 19 Care Start Test, Patient Results and interview with the Pharmacist (PH), the laboratory failed to follow the Information for Use (IFU) when performing COVID tests from 11/15/2020 to the date of the survey. The findings include: The laboratory did not follow the IFU as below: 1. The Laboratory did not report COVID 19 results to the State of New Jersey. 2. The Laboratory performs approximately 50 COVID 19 tests per day. 3. The PH confirmed at 10:00 am on 1/27//2021 that the laboratory did not follow the IFU.</p>
D1002	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Covid 19 Carestart Test, patient results and interview with the Pharmacist (PH) ,the laboratory failed to report Covid 19 test results to the state of New Jersey (NJ) from 11/15/2020 to the date of the survey. The laboratory did not report as follows: 1. The Laboratory did not report Covid 19 results to the State of</p>

NJ.. 2. The Laboratory performs approximately 50 Covid 19 tests per day. 3. The PH confirmed at 10:00 am on 1/27/2021 that the laboratory did not report Covid test results to NJ.