

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2054714	(X3) Date Survey Completed 01/25/2021
Name of Provider or Supplier Medexpress Urgent Care - Willingboro	Street Address, City, State 4318 Route 130 North, Willingboro, 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 Abbott ID Now and BD Veritor Test, Patient Results and interview with the Site Manager (SM), the laboratory failed to follow the Information for Use (IFU) when performing COVID tests from January 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 all COVID 19 results to the State of New Jersey. 2. The Laboratory performs approximately 80 COVID 19 tests per day. 3. The SM confirmed at 10:30 am on 1/25/2021 that the laboratory did not follow the IFU.</p>