

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2243534	(X3) Date Survey Completed 01/04/2022
Name of Provider or Supplier Advert Community Health Project Llc	Street Address, City, State 2360 Route 33, Robbinsville, 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:</p> <p>a) Based on surveyor review of the Test Report (TR) and interview with the Owner, the laboratory failed to report Covid 19 testing accurately. The findings state: 1. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement "This test has not been FDA cleared or approved; The test has been authorized by the FDA under an Emergency Use Authorization (EUA)". 2. The laboratory had a false statement on the TR. "Smart Choice Rx Diagnostics SARS-CoV-2 (Covid-19) test used to analyze samples for Sars-CoV-2 (Covid-19) with saliva sputum samples" 3. One out of two Covid test results were emailed to the wrong patient. 4. The Owner confirmed on 1/4/22 at 1:45 pm that Covid 19 tests were not reported accurately. b) Based on surveyor review of the Test Report (TR) and interview with the Owner, the laboratory failed to ensure that the interpretation of Covid 19 tests was on the TR. The finding includes: 1. The TR failed to include interpretation of Covid 19 results as found on the Instructions For Use (IFU). 2. The Manufacturer Package Insert stated "Negative results should be treated as presumptive." Negative test results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. 3. The Owner confirmed on 1/4/22 at 1:45 pm that Covid 19 tests were not reported accurately.</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</p>

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.

This CONDITION is not met as evidenced by:

Based on surveyor review of the Celltrion Dia Trust Covid 19 Antigen Test Kit, the Mesa Biotech Accula Test Kit, and interview with the Owner, the laboratory failed to report SARS-CoV-2 test results. The findings include: 1. The laboratory did not report SARS-CoV-2 test results to the State of New Jersey. 2. The Owner confirmed on 1/4 /22 at 1:45 pm the laboratory failed to report SARS-CoV-2 test results.